Co-Development of a Novel Treatment Adherence Intervention for Young People with Inflammatory Bowel Disease (IBD)

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Doctor of Philosophy

Aston University

January 2023

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Abstract

Rates of treatment non-adherence could be as high as 93% amongst young people with Inflammatory Bowel Disease (IBD). However non-adherence to prescribed treatment plans can have significant clinical consequences for young people with IBD. Subsequently, additional support is needed to help young people maintain their IBD treatment adherence behaviours. Paediatric IBD treatment plans contain multiple complex self-management behaviours, including medication taking and following lifestyle advice. Currently, published interventions solely aim to improve adherence to oral medication among young people with IBD. This thesis details the co-development of a novel online, evidence-based theory-driven user-centred behaviour change intervention to improve treatment adherence in young people (aged 13-18) with IBD.

Findings from a systematic review evaluating the effectiveness of treatment interventions as well as outcomes of a framework analysis of young people with IBD's adherence experiences and support needs, were synthesised and mapped onto psychological constructs. The Behaviour Change Wheel approach informed the intervention's development, and supported the identification of relevant behaviour change theories and techniques. An online Patient and Public Involvement and Engagement group of young people (aged 13-17) with IBD co-developed the intervention's components and delivery methods; resulting in novel youth-led intervention functions. To strengthen the intervention's acceptability, feedback from young people with IBD and their parents were incorporated into the intervention prototype.

The co-developed intervention, A Self-led Self-management Intervention to Support Teenagers with IBD (ASSIST-IBD), contains ten interactive modules informed by psychological theory and constructs. ASSIST-IBD aims to empower young people to follow their IBD treatment plan and autonomously perform self-management behaviours. Within each intervention module, young people are supported to develop user-centred action plans to improve their treatment adherence behaviours. This research highlights how co-developing interventions can enrich the intervention development process and result in an acceptable and relevant intervention for young people with IBD.

Keywords: Young people; Inflammatory bowel diseases; Treatment adherence; Digital intervention; Co-production; Self-Management; Arts-based research methods; Behavioural science; Adolescent health; Parents

Acknowledgments

I would like to thank everyone who has supported me during the completion of this PhD thesis. While there is not room to thank everyone individually, there are a few people who have been incremental in my PhD journey.

First, I would like to thank every individual who volunteered their time to participate in this research project. This research would not exist without your willingness to share your views and experiences with myself.

Thank you to my PhD supervisors Dr Gemma Heath, Dr Lou Atkinson, and Dr Rachel Shaw for their guidance. Your wisdom and support mean so much to me and I have thoroughly enjoyed working with you over the past few years. You have not only challenged me to grow as a researcher, but also shared invaluable advice that will be of benefit throughout my academic career. I also give thanks to Prof Helen Pattison, who taught me so much yet whose untimely passing meant their involvement in this research was unfortunately brief.

Thank you to Dr Rafeeq Muhammed for providing your invaluable expertise and time throughout this project.

Thank you to Crohn's and Colitis UK and Aston University for funding this body of research.

Finally, I would like to thank my family who have provided me with endless support and encouragement. I would be lost without you all. With a special thank you to my parents for always being a source of comfort and reassurance during the challenging times. Thank you for all that you have done for me and all that you still do. To my fiancé, who encouraged me to follow my dreams of gaining my PhD. You have provided me with unwavering love and kindness over the last few years and I could not have undergone this journey without you. To Gramps, for inspiring me with anecdotes of your fantastic life and career. And finally, to Nanna, who is sadly not here to see the completion of this thesis, but whose support I feel every day. After years of asking me when I would cease being a university student, I am glad to finally be able to tell you, Nanna, that the submission of this thesis marks the end of me being a student and the start of my postdoctoral career.

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Publications and Presentations Derived from this Thesis

Publication

Screti, C., Heath, G., Shaw, R., & Atkinson, L. (2022). 1825 Co-development of a behavioural intervention to support treatment adherence in young people with inflammatory bowel disease. *BMJ Paediatrics Open*; 6(1), A1-A41. http://dx.doi.org/10.1136/bmjpo-2022-RCPCH.12

Publication in preparation

Screti, C., Heath, G., Shaw, R., & Atkinson, L. (In preparation) The success of interventions on treatment adherence in young people with Inflammatory Bowel Disease (IBD). A Systematic Review.

Oral presentations

Screti, C. (2022, December 8th). *Co-development of a behavioural intervention to support treatment adherence in young people with Inflammatory Bowel Disease*. PowerPoint presentation at the Psychology Research Seminar Series, Aston University, UK.

Screti, C., (2022, July 7th). *Development of a new user-centred intervention to improve treatment adherence in young people with Inflammatory Bowel Disease (IBD).* PowerPoint presentation at the Aston Institute of Health and Neurodevelopment (IHN) Research Showcase, Aston University, UK.

Screti, C. (2021, December 8th). *The experiences of a PhD research student: Improving treatment adherence in young people with Inflammatory Bowel Disease (IBD).* PowerPoint presentation at the Midlands Health Psychology Network's Career event, Online.

Screti, C. (2020, November 5th). *Treatment Adherence in Young People with Inflammatory Bowel Disease.* PowerPoint presentation at the Psychology Research Seminar Series, Aston University, UK.

Poster presentations

Screti, C. (2022, November 9th). *Co-development of a behavioural intervention to support treatment adherence in young people with Inflammatory Bowel Disease.* Poster presentation at the Royal College of Paediatrics and Child Health (RCPCH) “RE-coming of Age” Adolescent Health Conference, Birmingham, UK. Poster Presentation Prize Winner (day 1).

Screti, C. (2020, October 17th). *Improving treatment adherence in young people with Inflammatory Bowel Disease (IBD).* Virtual Poster presentation at Crohn’s and Colitis UK’s Virtual IBD Patient & Public Involvement in Research Day, Online.

List of abbreviations

Anti-TNF	Anti-Tumour Necrosis Factor
APEASE criteria	Affordability, Practicability, Effectiveness or cost effectiveness, Acceptability, Side-effects / safety and Equity criteria
ASSIST-IBD	A Self-led Self-management Intervention to Support Teenagers with IBD
BCT	Behaviour Change Technique
BCTTv1	Behaviour Change Technique Taxonomy v1
BCW	Behaviour Change Wheel
CCTV group	Crohn’s and Colitis Teen Voice group
COM-B	Capability, Opportunity, Motivation and Behaviour
EEN	Exclusive Enteral Nutrition
Extended CS-SRM	Extended Common Sense-Self Regulation Model
FC level	Faecal Calprotectin level
HrQoL	Health related Quality of Life
IBD	Inflammatory Bowel Disease
IV	Intravenous
MAM	Medication Adherence Measure
MARS	Medication Adherence Report Scale
MEMS	Medication Event Monitoring System
MMAS-8	Morisky Medication Adherence Scale
MMAT	Mixed Methods Appraisal Tool
NCF	Necessity and Concerns Framework
PICOS	Population, Intervention, Comparison, Outcome, Study design
PPA	Perceptions and Practicalities Approach
PE	Public Engagement
PPI	Patient and Public Involvement

PPIE	Patient and Public Involvement and Engagement
PSST	Problem Solving Skills Training
QoL	Quality of Life
RCT	Randomised Control Trial
SCT	Social Cognitive Theory
TPB	Theory of Planned Behaviour
TRAQ	Treatment Regimen Adherence Questionnaire
VAS	Visual Analogue Scale

Chapter one: Introduction

1.1. What is Inflammatory Bowel Disease?

In the UK, 300,000 people are believed to be diagnosed with Inflammatory Bowel Disease (IBD) (Crohn's & Colitis UK, 2019). It is further approximated 25 per 100,000 young people aged 10-16, in the UK, live with IBD (Pasvol et al., 2020). Furthermore, incidences of IBD are growing amongst young people worldwide (Kuenzig et al., 2022). IBD is a term used to describe two conditions, Crohn's Disease and Ulcerative Colitis, both of which cause painful ulcers and inflammation of the digestive system. While the two conditions have similar symptoms and treatment regimes, they differ in terms of the location of inflammation. An individual diagnosed with Crohn's Disease may experience inflammation in any part of their gastrointestinal tract, whereas the inflammation found in patients with Ulcerative Colitis is limited to the colon only (Sandhu, 2007). Additionally at diagnosis, uncertainty over the patient's inflammation may lead to the diagnosis of IBD-Unclassified (Aloi et al., 2016). Frequently reported symptoms of IBD include abdominal pain, diarrhoea, and weight loss (Sawczenko & Sandhu, 2003). While the common age of receiving a diagnosis of IBD is between 10-40 years, disease activity in children and adolescents tends to be more severe than in adulthood, with young people more prone to severe relapses and extensive areas of inflammation (Barabino et al., 2002; Goodhand et al., 2011; Kelsen & Baldassano, 2008; Sawczenko et al., 2001; Turner et al., 2011).

IBD is a challenging condition to live with, characterised by periods of relapse and remittance (Hommel et al., 2013). To manage the condition, individuals are prescribed treatments that include medication and changes to lifestyle behaviours (Hanghoj & Boisen, 2014). Self-management is dependent on the severity of the condition, as well as the type of medication and required lifestyle modifications (Gumidyala et al., 2017). During adolescence, the need to manage a health condition alongside the challenges of typical adolescent development, can be difficult. Research suggests adolescents benefit from practical and emotional support from their family (Hommel et al., 2013; Nicholas et al., 2007). Being able to openly discuss the challenges of living with IBD with family members, can lead to a decrease in feelings of social isolation and an increase in feelings of control, resulting in stronger family relationships and a greater awareness of personal coping skills (Nicholas et al., 2007). However, Holmes et al. (2021) noted that even when young people receive optimum emotional and practical support, the unpredictable nature of IBD symptoms can still leave young people feeling socially isolated.

Living with IBD as a young person can threaten normal psychosocial development (van den Brink et al., 2016). As IBD can impact on an individual's growth, body image, and education, it is not surprising that such IBD related matters are a source of worry and upset for adolescents (Goodhand et al., 2011; Nicholas et al., 2007). It is, however, plausible that the distress and vulnerability reported by young people living with IBD, is a result of their condition accentuating and complicating typical adolescent developmental issues, such as personal appearance or peer relationships (Nicholas et al., 2007; Staples & Bravender, 2002). Therefore, there is a greater importance for the treatment and management of IBD in younger patients to reflect these age-related concerns (Goodhand et al., 2011; Nicholas et al., 2007; Staples & Bravender, 2002; Turner et al., 2011).

In a literature review, Ross et al. (2011) concluded there was consistent evidence that young people with IBD have a poorer quality of life (Qol), and greater incidences of anxiety and depression than healthy young people. While remission is often viewed as a time of symptom and worry remittance, Keeton et al. (2015) identified young people still had significant IBD concerns, causing them to experience anxiety and low mood during periods of remission. Living with IBD symptoms is associated with poorer health related QoL (HrQoL) and a higher occurrence of depression and anxiety in young people (Ahmed et al., 2022; Kilroy et al., 2011; Randall et al., 2020; Srinath et al., 2014). IBD symptoms can often cause social embarrassment and prevent young people from discussing their needs with family members and friends, which may result in symptoms of depression and anxiety (Engstrom, 1999). Young people report anxiety over IBD medication side effects, having a lack of control over their body; and their bodily appearance (Reigada et al., 2011). Furthermore, experiencing significant symptoms of depression increases young people with IBD's body image dissatisfaction (Cushman et al., 2021).

A greater disease severity is associated with a higher prevalence of anxiety, depression as well as poorer QoL in young people with IBD (Chouliaras et al., 2017; Otley et al., 2006; Zhang et al., 2016). Age may also impact young people with IBD's emotional wellbeing, as HrQoL is poorer in older teenagers than in children, likely due to the burden of living with a chronic condition during adolescence (Ross et al., 2011). Despite a high prevalence of psychiatric comorbidity, very few young people with IBD receive the psychological support they need (Engelmann et al., 2015). When self-reported QoL measures were compared with parental proxy scores, young people reported fewer limitations to their QoL than their parents (Mueller et al., 2016). This misperception may be due to parents' own QoL, which is often negatively impacted when compared with parents of healthy children (Jelenova et al., 2015).

This highlights the importance of capturing both young people's and their parent's QoL in order to identify appropriate support measures for families of young people with IBD.

Parenting a child with a chronic health condition, such as IBD, can be challenging as parents are required to balance their normal parental roles with the added responsibilities of managing their child's health (Greenley & Cunningham, 2008). Parents report experiencing IBD-specific stressors including worry that their child will develop further health complications, managing their child's illness through periods of remission and flare up, concerns about their child's social and emotional wellbeing and worrying how their child's education and future will be affected (Akobeng et al., 1999; Cunningham & Banez, 2006). In addition, some parents believe their child's IBD impacts on their own careers and the family lifestyle (Akobeng et al., 1999). Parental stress is greater in parents of children with a more active Crohn's Disease, due to their child's need for extra parental support (Gray et al., 2013). Therefore, it is not surprising that parents of children with IBD, often experience depression (Burke et al., 1994). As increased parental distress has been linked to poorer disease outcomes for young people with IBD, there is a clear need to consider the role of parents in the management needs of young people with IBD (Diederen et al., 2018).

1.2. Treatment plans for young people with Inflammatory Bowel Disease

Upon diagnosis or flare up, medical interventions for IBD aim to place the disease into remission, followed by maintenance medication to prevent a future relapse (LeLeiko et al., 2013; Sandhu, 2007). Medication routines vary, with some patients required to take multiple medications, while others are prescribed one medication, known as a monotherapy routine. Due to the location of inflammation, there are differences in possible treatments for the two main types of IBD (Carroll et al., 2019). The medical treatment for those diagnosed with Ulcerative Colitis may include the use of 5-aminosalicylates acids (e.g., mesalamine), corticosteroids, or biological injectable Anti-Tumour Necrosis Factor (Anti-TNF) drugs (e.g., humira), depending on the severity and extent of inflammation (National Institute for Health and Care Excellence [NG130], 2019). Similarly, individuals diagnosed with Crohn's Disease may be prescribed treatments such as, immunosuppressants (e.g., azathioprine or 6-mercaptopurine), biological injectable Anti-TNF drugs (e.g., humira) and biological intravenous (IV) Anti-TNF therapies (e.g., infliximab), dependent on the extent of active disease (National Institute for Health and Care Excellence [NG129], 2019). The immunosuppressants azathioprine and 6-mercaptopurine are oral medications which reduce inflammation within the digestive system by manipulating the abnormal immune system response and require patients to take multiple tablets each day (Carroll et al., 2019).

Biological injectable Anti-TNF drugs on the other hand can be self-injected every 1-8 weeks depending on the dose (Carroll et al., 2019). Biological IV Anti-TNF therapies can be used independently or as part of a combination therapy routine (e.g., infliximab and azathioprine) to manage IBD symptoms and improve remission rates; thus, requiring patients to adhere to multiple medications (Carroll et al., 2019). In addition to medication treatment routines, Exclusive Enteral Nutrition (EEN) is an effective non-pharmacological treatment used to induce remission in children with IBD. This requires young people to exclusively consume liquid supplements for a specified length of time (Carroll et al., 2019; Ruemmele et al., 2014). Usually administered for 6-12 weeks, EEN is the sole source of nutrition provided for young people during this timeframe. While EEN is usually taken orally, some children are required to be tube fed to ensure they are consuming enough of the treatment (Carroll et al., 2019).

As well as adhering to their prescribed medication, IBD patients may be suggested to follow lifestyle advice relating to diet, physical activity, and sleep. Due to the nature of IBD, many patients struggle to absorb the correct amount of nutrients from their food, requiring patients to be conscious of their food intake and adjust their diet appropriately (Turner et al., 2011). Typically, patients with IBD are advised to eat a varied diet, containing fruit and vegetables, cereals, grains, and proteins; with foods high in fats and sugar eaten in moderation (Lamb et al., 2019; Miele et al., 2018). Some foods may cause an exacerbation of IBD symptoms; however, this differs between individuals. With the support of their consultant, patients are therefore recommended to monitor how their food intake impacts their symptoms and make informed decisions on their diet based on this (Crohn’s & Colitis UK, 2019). However, older adolescents and those less satisfied with their physical appearance are more prone to ignore dietary advice (Vlahou et al., 2008).

Engaging in moderate exercise may improve IBD inflammation suppression and disease management as well as feelings of fatigue (Legeret et al., 2019). However, young people with IBD have higher self-reported levels of sedentary behaviour as well as lower levels of physical activity frequency and general fitness than healthy young people (Bourdier et al., 2019; Penagini et al., 2022; Sledzinska et al., 2022). Lower levels of physical activity in young people with IBD are associated with a poorer HrQoL and more body image concerns (Plevinsky et al., 2018). Disease activity is a determinant for physical activity in young people with IBD, due to the worsening of IBD symptoms preventing engagement in physical activity (Mahlmann et al., 2017; Penagini et al., 2022; Plevinsky et al., 2018). Symptoms of tiredness and fatigue can hinder young people’s sports participation, with 45% of young people perceiving their IBD diagnosis impacted their ability to partake in such activity (Beery et al., 2019). However, during periods of IBD remission, lower levels of physical activity have been objectively observed in older adolescents with active disease (Lund et al., 2022; Plevinsky et al., 2018).

Poor sleep is a significant predictor of IBD symptoms and poorer health outcomes in young people with IBD (Rozich et al., 2020; Manhart et al., 2016). A greater IBD disease activity is associated with poorer levels of objective sleep (e.g., awakening during the night) and subjective sleep (self-reported sleep) when compared with young people with well controlled IBD or healthy controls (Mahlmann et al., 2017). Comparing young people with IBD's self-reported measures of sleep behaviours to parental proxy measures have shown parents both overpredict and underpredict the amount of poor-quality sleep experienced by young people (Jarasvaraparn et al., 2019; Pirinen et al., 2010). This indicates complexity in the sleep behaviours of young people with IBD. Manhart et al. (2016) proposed the relationship between IBD and sleep is bi-directional, with a greater presence of IBD symptoms causing poor sleep, yet poorer sleep increasing the severity of IBD symptoms. This cyclical relationship highlights the benefits of assessing sleep behaviours within young people's treatment plans, not least because IBD symptoms such as fatigue are a known cause of medication non-adherence.

1.3. What is Adherence?

Historically, it was thought treatment failure was indicative of the poor efficacy of the medication in question, however stricter drug efficacy testing procedures encouraged the medical world to investigate patient adherence behaviours (Rogers et al., 2001). Adherence is defined as "the extent to which the patient's behaviour matches agreed recommendations from the prescriber" (Horne et al., 2005, p. 12). Individuals are normally classed as non-adherent if they do not adhere to ≥80% of their prescribed treatment; however, more recent research has used a stricter measure of non-adherence, defined by taking ≤90% of their treatment (Hommel et al., 2015). Non-adherent medication taking behaviour presents in many different forms, including missing occasional doses, lowering, or increasing the prescribed dose or failing to administer all the prescribed doses (Horne & Weinman, 2002). It is estimated up to half of all medications for long-term conditions are not taken as prescribed, costing the National Health Service (NHS) approximately £300 million per year (National Institute for Health and Care Excellence, 2009; National Institute for Health and Care Excellence, 2015; World Health Organisation, 2003).

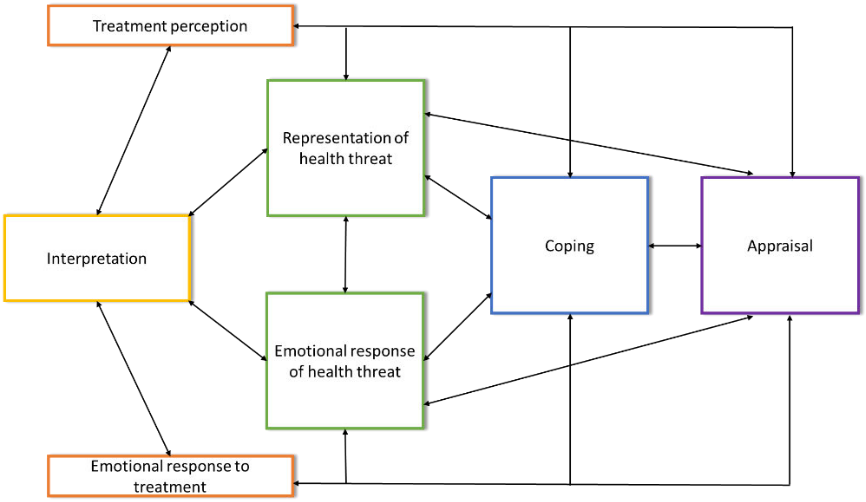
Non-adherence is considered to be both volitional, where an individual chooses whether to follow their treatment regime or not, and non-volitional, where an individual encounters one or more barriers, preventing them from adhering to their treatment (Horne et al., 2009). Non-volitional or unintentional, non-adherence is often related to poor memory recall, for example forgetting how and/or when to take medication (Horne & Clatworthy, 2010). However, volitional, or intentional non-adherence can be explained through the individual's beliefs over the necessity of their treatment, as well as their concerns over following their treatment plan (Horne & Weinman, 1999). For example, a belief that a treatment is unnecessary, coupled with a concern about the effects of taking the medication, is likely to result in volitional non-adherent behaviours (Horne & Weinman, 1999).

Theoretical models of adherence can be used to further understand non-adherence behaviours. The Perceptions and Practicalities Approach (PPA) describes non-adherence as a variable behaviour which is the result of both intentional and unintentional causes (Clifford et al., 2003). The PPA details two main components which influence adherence, motivation and resources (Horne, 2001). The model demonstrates how a person's thoughts or feelings can impact their motivation to adhere to treatment which in turn results in the formation of perceptual barriers, leading to non-adherent behaviours. The PPA also suggests when a person experiences practical barriers, due to a limited number of resources and capabilities required for adherence, this results in unintentional non-adherence (Horne, 2001). The Necessity and Concerns Framework (NCF) can assist in the understanding of factors resulting in intentional or unintentional non-adherence (Horne & Clatworthy, 2010). The NCF suggests that intentional non-adherence is related to an individual's beliefs about the necessity of their treatment, as well as concerns about adverse side effects of treatment (Horne & Weinman, 1999). Unintentional non-adherence is thought to be related to poor memory recall, for example forgetting how and/or when to take the medication (Horne & Clatworthy, 2010).

Leventhal et al.'s (2016) Extended Common Sense-Self Regulation Model (Extended CS-SRM) (See Figure.1) can also provide an explanation and understanding of the processes underpinning the development and maintenance of behaviours required in managing illness threats. Building on the work of the Common Sense-Self Regulation Model (Leventhal et al., 1980), the Extended CS-SRM details how and when presented with an illness threat, an individual begins to interpret the threat to subsequently form illness beliefs. These illness beliefs, or perceptions are informed by an individual's knowledge, social environment, and previous illness experiences (Leventhal et al., 1980; Leventhal et al., 2016). The Extended CS-SRM details how both cognitive illness perceptions (referring to the illness threat's identity; cause; consequence; timeline and cure/control) and emotional response to the illness threat are formed in parallel (Leventhal et al., 2016). Upon forming these representations individuals complete the final stages of the model; coping and appraisal (Leventhal et al., 2016). The illness perceptions formed in the first stage of the Extended CS-

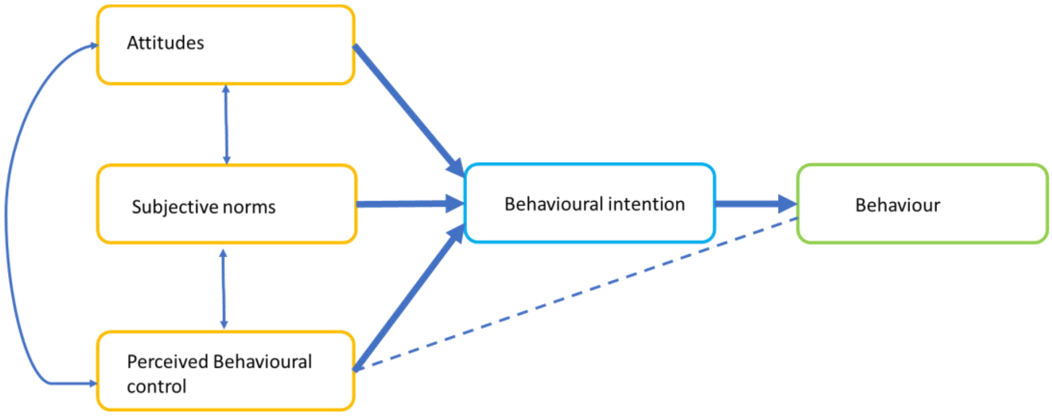
SRM can influence treatment adherence behaviours and are predictive of adherence behaviours in adolescents with chronic conditions including diabetes and cystic fibrosis (Bucks et al., 2009; McGrady et al., 2014). In addition to illness perceptions, the Extended CS-SRM acknowledges the development of treatment perceptions, (relating to the perceived necessity for treatment and the concerns of taking medication). In a large systematic review of adherence in adults with IBD, medication beliefs were identified as a primary reason for non-adherent behaviours (Jackson et al., 2010). A more recent study comparing adult IBD patients' adherence to maintenance medications in the UK and Australia, found beliefs in necessity to take the medication as well as an individual's concerns over potential adverse medication side effects, were strong predictors of adherence behaviours (Selinger et al., 2013). Due to the complexities of such factors, and the potential for different IBD medications to induce different medication beliefs, Selinger et al. (2013) warned about the unlikeliness to improve maintenance medication adherence using 'over simplified' solutions. Thus, theoretical models such as the Extended CS-SRM (Leventhal et al., 2016) can be used to specify where to target intervention strategies within treatment adherence behaviour interventions.

Figure 1. Extended Common Sense-Self Regulation Model (Leventhal et al., 2016)



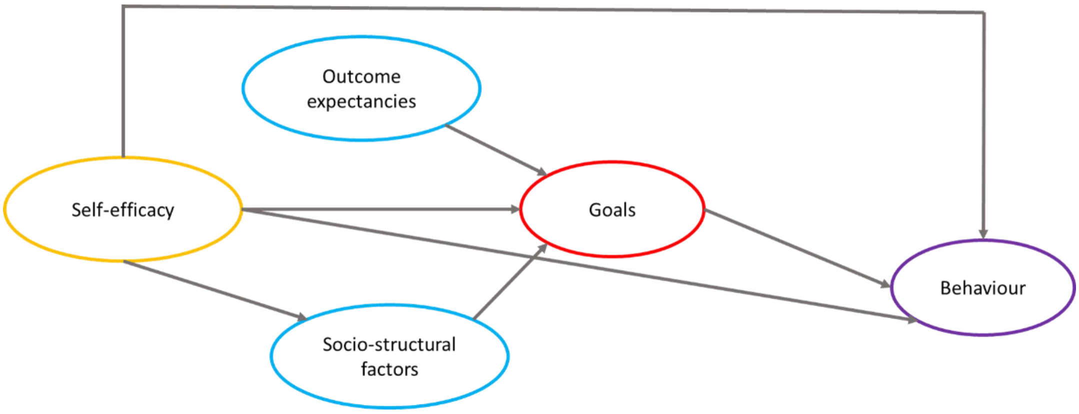
Social cognition models can also be applied to adherence behaviours, two models often used to describe health behaviours are the Theory of Planned Behaviour (TPB) (Ajzen, 1991) and the Social Cognitive Theory (SCT) (Bandura, 1986). The TPB details how an individual's intentions to carry out a specific behaviour are influenced by their attitude, subjective norms, and perceived behavioural control (Ajzen, 1999) (Figure.2).

Figure 2. Theory of Planned Behaviour (Ajzen, 1991)



The TPB suggests an individual is more likely to intend to be adherent if they hold a positive evaluation of medication taking; believe it is socially preferable to perform the behaviour; and feel in control over performing medication behaviours (Ajzen, 1991). In contrast, SCT explains behaviour in terms of goals and actions; which are both related to an individual's beliefs around self-efficacy and action-outcomes (Bandura, 1986) (Figure.3). Perceived self-efficacy is related to an individual's belief in their capability to perform a specific behaviour (Bandura, 1977), and can be used to understand any health behaviour, including physical activity and nutrition (Rodgers et al., 2002; Szczepanska et al., 2013). As outlined by Bandura (1977), self-efficacy is fostered in four ways; previous personal success (e.g., previous feelings of similar achievements), vicarious experiences (e.g., seeing others similar to yourself performing the behaviour), verbal persuasion (e.g., encouragement from others to perform the behaviour), and emotional arousal (e.g., bodily sensations of panic or anxiety).

Figure 3. Social Cognitive Theory (Bandura, 1986)



Within a large systematic review, components of both the TPB (e.g., perceived control beliefs), and the SCT (e.g., self-efficacy), have been shown to predict medication adherence to a wide range of chronic health conditions (Holmes et al., 2014). Due to similarities between perceived control beliefs and self-efficacy, it is unsurprising that these constructs were identified as a strong predictor of adherence behaviours, leading Holmes et al. (2014) to underscore the importance of targeting self-efficacy within behaviour change interventions. The TPB components are predictive of medication adherence in adults with chronic health conditions (Chisholm et al., 2007; Lin et al., 2016). Furthermore, medication self-efficacy predicted mesalamine adherence in adult patients with Ulcerative Colitis (Cook et al., 2010). Self-efficacy can be beneficial in producing cost-effective models to support self-management behaviours in patients with chronic health conditions (Bandura, 2004). Therefore, theories are needed within the design and discussion of behaviour change interventions as they provide a crucial insight into human behaviour.

1.4. Adherence in adolescents with IBD

While adolescents are known to be the least adherent group of paediatric patients, often performing risky health behaviours (DiMatteo, 2004; Staples & Bravender, 2002), it is likely that factors underpinning adherence rates in young people with IBD are complex and not fully understood (Goodhand et al., 2011). This is demonstrated in systematic reviews indicating reported rates of medication non-adherence in adolescents with IBD vary from 2%-93% (Spekhorst et al., 2016), with the frequency of non-adherence believed to range from 3%-57% (Hommel et al., 2008). Within both reviews, the considerable variance in medication behaviours were attributed to differing measures of adherence behaviours, suggesting adherence is not a stable construct (Hommel et al., 2008; Spekhorst et al., 2016).

Living with IBD during adolescence can complicate normal adolescent challenges such as physical, psychological, and social changes (van den Brink et al., 2016). Having a long-term condition, such as IBD, can often leave young people feeling that they lack control over their health, therefore choosing to not follow their treatment regime may allow young people to gain a sense of control over their bodies (Nicholas et al., 2007; Taddeo et al., 2008). Similarly, sometimes young people may choose to deny the existence of their health condition, resulting in non-adherence behaviour; this lack of acceptance highlights the challenges of adolescence, where an individual is trying to develop their sense of self-identity, as well as avoiding feeling different from their peers (Taddeo et al., 2008). Young people often fear discussing their IBD with others will alter their friendships and result in stigmatisation, which often influences their adherence behaviours (Carter et al., 2020; Weiss et al., 2006). Needing to administer treatment whilst socialising with their friends, can highlight difference, making young people more likely to avoid adhering to their medication routine in these circumstances (Nicholas et al., 2007).

IBD treatment plans are formulated to minimise inflammation and maintain a feeling of wellness during periods of symptom remittance, meaning young people are still prescribed medications when they feel well (Sandhu, 2007). As adolescents are predisposed to live in the present, rather than thinking about the long-term unseen consequences of their non-adherent behaviours, young people with IBD may be more inclined to not adhere to their treatment if non-adherence does not cause any immediate repercussions (Taddeo et al., 2008). These changes in cognition could also be explained using the two principal factors discussed by Horne et al. (1999); necessity beliefs and concerns. Due to the asymptomatic nature of IBD, adolescents may not believe they need to take their medication during periods of symptom remittance. In addition, adolescents may not be concerned about the long-term consequence of non-adherence due to their tendency to live in the present. Similarly, it has been suggested that during times of stress, adolescents regress in their thought processes, relying on simpler problem-solving methods, rather than hypothesizing possible cause and effect (Taddeo et al., 2008). For example, during stressful situations such as school exams, young people may be more inclined to not-adhere to their treatment if doing so will cause debilitating side-effects. These factors are a likely contributor to volitional non-adherent behaviours in adolescents with IBD.

Adolescents with IBD are further presented with the challenge of preparing for and beginning the transition from paediatric to adult healthcare. As part of this process, young people are required to increasingly become responsible for the management of their health (Hait et al., 2006). This often requires the acquisition of behaviours which have previously been the responsibility of a young person’s caregiver, such as discussing changes to their health in medical appointments, independently taking their medication, booking medical appointments, and organising prescription refills (Hait et al., 2006; Hommel et al., 2011).

Research in young people with IBD has indicated certain disease demographics are associated with increased adherence behaviours. Adolescents, who have been diagnosed with IBD for longer for example, report higher levels of non-adherence compared with recently diagnosed patients (Reed-Knight et al., 2011). Reed-Knight et al. (2011) suggested this relationship could be due to feelings of hopelessness in participants who have managed their condition for longer. As well as disease specific demographics, more general demographic factors, such as age, are associated with medication adherence, with older adolescents (aged 15-17) being less likely to adhere than younger adolescents (LeLeiko, 2007). This may be due to younger patients welcoming the help of their caregivers to manage their IBD, where older adolescents may be faced with the challenge of managing their condition more independently (LeLeiko, 2007). The link between demographic factors and adherence is not consistent throughout the literature, suggesting barriers to adherence may be independent of demographic information such as disease duration, age, and gender (Greenley et al., 2010).

Adherence rates may be associated with the frequency and complexity of a young person's medication routine, as patients with a more complex, multiple medication treatment routine are less likely to be adherent than those prescribed a monotherapy treatment routine (Greenley et al., 2010; Hommel & Baldassano, 2010). The number of adverse effects, experienced by adolescents, because of adhering to their medication was associated with participants being more likely to demonstrate future non-adherence and a higher use of alternative therapies, such as herbal medication (Heuschkel et al., 2002). Despite the low reported rates of adherence, it has been shown that families still place a greater importance on their prescribed medication, due to the perceived benefits of the medication in maintaining control over the condition. For example, when exploring the different adherence rates to prescribed medication or physician recommended over-the-counter medicines (such as multi-vitamins or calcium supplements) families demonstrated higher rates of adherence to prescribed medication than to over-the-counter medicine (Reed-Knight et al., 2011).

Around 25% of adolescents with IBD experience at least one perceived adherence barrier to their treatment plan per year (Greenley et al., 2010). Commonly reported barriers include forgetting, lack of time, treatment routine interfering with social activities, child fatigue, families' views on the effectiveness of the prescribed medications and embarrassment of administering medication in front of friends (Gray et al., 2012; Greenley et al., 2010; Hommel & Baldassano, 2010; Ingerski et al., 2010; Modi et al., 2006). The most common of these barriers is that of "just forgetting", with one study reporting this barrier by 85% of young people with IBD (Gray et al., 2012). The perception of experiencing one or more barriers to treatment adherence has been found to be a significant predictor of non-adherent behaviour in adolescents with IBD and their families (Greenley et al., 2010). As well as symptom reduction and relapse prevention, reducing perceived barriers to medication adherence may positively impact on young people's psychological wellbeing (Varni et al., 2018).

Another possible barrier is a lack of knowledge about IBD management. Common gaps in IBD knowledge in 16-20-year-olds include the effects of risk-taking behaviours on their IBD (such as illicit drug use) and how often their prescription needs refilling (Gumidyala et al., 2017). Not knowing what might aggravate the condition or how often they need to refill their prescription, may lead to non-adherent behaviour, particularly if young people then attribute a symptom fare up to medication failure. It has been suggested that paediatric clinicians should ensure young people are fully informed about the importance of their medication, including the benefits of adhering to their maintenance therapy, as well as offering suggestions to help adolescents with their adherence, for example using a pill box or medication reminder (Lu & Markowitz, 2011).

Adherence rates differ depending on whether young people and families are asked about their volitional or non-volitional adherence behaviours. When questioned about their non-volitional non-adherence, 70% of parents and young people reported forgetting at least one medication dose (Schurman, et al., 2011). However, in the same sample, only one third of young people and parents reported displaying volitional non-adherent behaviour, such behaviour was attributed to multiple factors including a lack of satisfaction with their medication, feeling better, or wanting to feel more in control (Schurman, et al., 2011). Volitional non-adherence was also related to participants experiencing more severe disease activity and having a poorer QoL, suggesting a misconception over the benefits of altering their medication routine (Schurman et al., 2011). Acts of volitional non-adherence may be less frequent; however, they highlight the need for evidence-based interventions to help improve young people's treatment adherence, disease activity, and emotional wellbeing.

The method used to measure adherence can vary between studies with researchers choosing to measure adherence objectively using pill counts, electronic monitors, and medical records, or subjectively via the use of self-report measures. In young people with cystic fibrosis, Modi et al. (2006) concluded different adherence measures identified different levels of adherence in the same population. Subjective measures of adherence are associated with rates of greater adherence in young people with IBD than objective adherence measures (Hommel et al., 2009; Wu et al., 2013). Hommel et al. (2009) identified rates of adherence differed by up to 50%, depending on the measure of adherence used, with subjective measures suggesting adherence rates were almost twice as high as objective measures. In addition to the measurements used, rates of adherence may vary greatly depending on the definition of adherence used by the research team (Spekhorst et al., 2016).

Attendance to clinic is often viewed as an objective measure of adherence. However, in a retrospective review looking at the relationship between frequency of clinic visits and medication adherence, the frequency of clinic attendance was not associated with treatment adherence (Kitney et al., 2009; Kluthe et al., 2018). Indicating the need to support young people's treatment adherence outside of clinical appointments.

Due to the lack of standardised self-report adherence measures for patients with IBD, some questions on the typically used 8-item Morisky Medication Adherence Scale (MMAS-8) are not suitable for non-daily medication frequencies and may bias a study's outcome (Severs et al., 2016). Other researchers have adapted the Medication Adherence Measure (MAM), a validated structured interview tool, which looks to confirm the presence of certain adherence barriers in paediatric patients, as a measure of IBD medication adherence (Hommel et al., 2008; Hommel et al., 2009; Hommel & Baldassano, 2010; Ingerski et al., 2009). However, the MAM does not collect information on the context of the experienced barrier, for example, in Ingerski et al.'s (2009) study, forgetfulness was commonly identified within MAM scores, however no further information was available as to when or why young people were prone to forget their medication.

The inclusion of patient-parent dyads has frequently been used to identify young people's adherent behaviours within the context of family life (Hommel et al., 2008; Hommel & Baldassano, 2010; Reed-Knight et al., 2011; Schurman et al., 2011), Within some articles young people and parents have completed measures of adherence cohesively (Hommel et al., 2008; Hommel & Baldassano, 2011), however doing so may limit young people's willingness to divulge non-adherent behaviours to their parents. When completing patient and parent proxy measures of adherence separately, young people reported poorer adherence behaviours than parent-proxy scores, indicating that parents may not be fully aware of their child's adherence behaviours (Reed-Knight et al., 2011). Additionally, young people in Schurman et al.'s (2011) research, identified a greater variety of IBD non-adherence barriers than their parents and furthermore placed greater importance on the simplicity of a medication routine for adherence than within parent-proxy scores. Thus, demonstrating the importance of listening to young people's adherence challenges and developing interventions to directly meet young people's needs.

1.5. Interventions to improve treatment adherence in adolescents with IBD

Compared with the volume of research exploring determinants of adherence in young people with IBD, interventions are limited. However, it has been shown that without intervention, adolescents' perceived barriers to medication adherence do not change over time, thus impacting medication adherence trajectories (Plevinsky et al., 2019).

Within interventions aiming to improve medication adherence in young people with IBD, the provision of educational materials alone has been shown insufficient to improve adolescent adherence (Carlsen et al., 2017; Vaz et al., 2019). However, the use of an individually tailored behavioural intervention has improved young people’s adherence to oral medications (Maddux et al., 2017). The inclusion of parents/carers, within interventions, has also been successful in improving young people’s oral medication adherence (Greenley et al., 2015; Hommel et al., 2012; Maddux et al., 2017). However, little is known about the behavioural theories influencing the development or application of existing interventions.

It is important to note the several methodological issues within current treatment adherence interventions for young people with IBD. The main issue is a lack of diversity. Currently, there is a clear gap in interventions aiming to improve treatment plan adherence relating to recommendations other than medication, for example adherence to dietary advice (Carlsen et al., 2017; Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017; Vaz et al., 2019). Furthermore, interventions only target young people’s adherence to commonly prescribed oral medications such as immunosuppressants (e.g., azathioprine). The actions of taking oral medications differ considerably to administering injectable medications or receiving an IV infusion in hospital. Such differences may illicit different adherence barriers and medication beliefs. Equally, few existing interventions look to understand non-volitional adherence, such as forgetting, rather interventions address young people’s conscious medication taking decisions. Therefore, the tendency for interventions to solely evaluate young people’s oral medication adherence limits a comprehensive understanding of young people’s adherence behaviours. Similarly, in the wider IBD adherence literature, there is a deeper understanding of young people’s oral medication adherence behaviours in comparison to other aspects of IBD treatment plans (Greenley et al., 2010; Hommel et al., 2008; Hommel et al., 2009; Hommel & Baldassano, 2010; Nicholas et al., 2007; Reed-Knight et al., 2011; Schurman et al., 2011). Further research is needed to understand adherence barriers and facilitators to the entirety of young people with IBD’s treatment plan. Through this understanding, more inclusive interventions can be developed to support young people’s adherence behaviours.

Most interventions recruited a larger number of participants identifying their ethnicity as White, indicating a limited representation of cultural diversity within our understanding of IBD (Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2012; Maddux et al., 2017; Vaz et al., 2019). The lack of diversity, is likely to correlate with the high prevalence of participants diagnosed with Crohn’s Disease, as there is a greater incidence of Ulcerative Colitis in young people of an Asian ethnicity (Sawczenko et al., 2001). Additionally, when measures of disease severity were taken, most participants presented with inactive or mild disease (Carlsen et al., 2017; Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017), suggesting current interventions do not capture the adherence behaviours of young people with the most severe areas of inflammation and debilitating symptoms.

Furthermore, each intervention only included patient populations from a single gastroenterological department, limiting generalisation of the results to other geographical locations or hospital sites (Carlsen et al., 2017; Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017; Vaz et al., 2019). In a recent exploration of UK IBD incidences, geographical differences were noted in the prevalence of Crohn's Disease and Ulcerative Colitis, providing further support for the inclusion of more geographical locations within adherence research (Pasvol et al., 2020).

Within the literature, there is currently a lack of standardised self-report adherence measures for young people with IBD, resulting in interventions utilising study-specific adherence measures (Carlsen et al., 2017; Hommel et al., 2012). Most interventions selected objective measures of adherence such as pill counts (Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017; Vaz et al., 2019), which have been associated with lower levels of adherence in comparison to subjective measures (Hommel et al., 2009; Wu et al., 2013). This limits a cohesive understanding of young people's adherence experiences and behaviours. Further research is therefore needed to develop a standardised measure of adherence for this population.

Equally, all interventions only used quantitative measures of adherence (Carlsen et al., 2017; Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017; Vaz et al., 2019). This is a further issue across the wider IBD adherence literature and limits the ability for young people's voices to be heard within research projects. To overcome this, qualitative research methods can provide a rich in-depth exploration of the lives of young people living with IBD, providing context to known adherence barriers. For example, in a large qualitative exploratory study into young people's experiences of living with IBD, Nicholas et al. (2007) reported young people's undesirable view of medication, particularly how experiencing medication side effects were perceived as worse than experiencing IBD symptoms. Additional qualitative research is needed to inform the development of effective behavioural interventions and evaluate the success of such interventions.

Future research should be mindful of these methodological limitations and aim to explore the gaps in the literature. Further intervention development, informed by a theoretical understanding of behaviour, is vital for advancing the understanding of how best to support adolescents with IBD to engage in effective self-management. Effective interventions will lead to better outcomes for young people and a reduction in healthcare costs

1.6. Designing future interventions

Adherence to IBD treatment plans is complex and requires young people to maintain their adherence during periods of IBD symptom remission (Sandhu, 2007). IBD treatment plans may contain a variety of adherence behaviours, inclusive of changes to lifestyle behaviours (e.g., diet and physical activity), as well as medication taking (Carroll et al., 2019; Lamb et al., 2019; Legeret et al., 2019). There are many known factors associated with treatment adherence in young people with IBD, such as forgetfulness, the simplicity of a treatment routine, embarrassment over taking medication in public, and IBD knowledge (Gray et al., 2012; Greenley et al., 2010; Hommel & Baldassano, 2010; Guimdyala et al., 2017).

Currently few behaviour change adherence interventions exist for young people with IBD. Reported interventions predominantly focus on volitional medication non-adherence and are absent of both accidental non-adherence behaviours (e.g., forgetting) as well as non-medication adherence behaviours such as adhering to lifestyle advice (Carlsen et al., 2017; Greenley et al., 2015; Hommel et al., 2012; Maddux et al., 2017). This limited array of intervention support options, may not fully address the barriers young people face to adhere to their entire treatment plan.

To date little is known about the behavioural theories used within the design and application of current interventions. However, within an intervention's development, theories of adherence can be utilised to target relevant behavioural constructs and develop appropriate intervention strategies of behaviour change. Previously, medication beliefs have been identified as a significant determinant of adherence behaviours in IBD patients (Jackson et al., 2010; Selinger et al., 2013). The Extended CS-SRM (Leventhal et al., 2016), demonstrates the relevance of targeting young people's treatment beliefs within adherence interventions, specifically views on the necessity to adhere to treatment plans as well as concerns over doing so. Additionally, social cognition models should also be considered within the design of adherence behaviour interventions. For example, self-efficacy, a key component of SCT (Bandura, 1977; Bandura, 1986), has been shown to be a strong predictor of adherence behaviours in adults with Ulcerative Colitis (Cook et al., 2010). Therefore, the inclusion of theories of adherence behaviours and social cognition models, can provide a concrete understanding of an intervention's active behaviour change components and outcome measures.

To address the significant gap in the current literature, the research detailed within this thesis will provide a clear documentation of the use of adherence theories and social cognition models to develop a novel evidence-based theory-driven treatment adherence intervention for young people with IBD. Additionally, the intervention will be inclusive of all IBD treatment plan behaviours, to further meet the deficit of behaviours targeted within IBD adherence interventions in the current literature, Furthermore, views and experiences of young people with IBD will be collected and directly inform the development of the current intervention, ensuring it meets the needs of the target population. The systematic Behaviour Change Wheel approach (Michie et al., 2011) will guide the interventions design and support the selection of relevant intervention functions and behaviour change techniques. Young people with IBD will further be included in the development of the intervention components and aesthetic design, with the aim of increasing the acceptability of the intervention for the target population.

1.7. Thesis Aims and Objectives

It is clear that living with IBD is a challenge for young people. The need to adhere to treatment plans necessitates a series of complex behaviours including adherence to a daily treatment routine (e.g., medication taking, dietary modification), symptom monitoring and attendance at healthcare appointments; all of which can be hindered by volitional and non-volitional barriers. During adolescence, the acquisition of adherence behaviours is vital for the transition from paediatric to adult healthcare services. However, it has been shown that without an intervention, adolescents' perceived adherence barriers do not change over time, thus impacting their wellbeing trajectories (Plevinsky et al., 2019). The aim of this thesis is to describe the development of an evidence-based, theory-driven and user-centred behavioural intervention to improve treatment adherence in young people with IBD. In doing so, the following objectives will be met to:

1) Assess the effectiveness of existing interventions designed to improve treatment adherence in young people with IBD
2) Explore adherence barriers and facilitators, and adherence support needs in young people (aged 13-18) with IBD
3) Use findings from the formative research, together with the Behaviour Change Wheel, to design a novel behaviour change intervention to improve treatment adherence in young people (aged 13-18) with IBD
4) Refine the intervention with input from young people (aged 13-18) with IBD, through the implementation of co-development techniques
5) Explore the views of parents of young people (aged 13-18) with IBD on the practicalities of the developed intervention for young people with IBD.

1.8. Research Design

The thesis is informed by the philosophical framework of critical realism, which is well suited to health sciences (Alderson, 2021; Bhaskar, 1979). In contrast to positivist health research, which concerns itself with empirically verifiable/falsifiable knowledge, critical realism acknowledges that an external reality exists but that knowledge about that objective world is socially produced and thus, subjective. Critical realists argue that we cannot just observe the world and produce knowledge about universal laws as positivists claim, without acknowledging that our beliefs, values, and understanding are socially produced and changeable (Alderson, 2021; Koopmans & Schiller, 2022; Ormston et al., 2014). Research undertaken from a critical realist approach looks to explore unpredictable decision-making mechanisms and how they operate in a real world of multifaceted open systems (Alderson, 2021).

Looking beyond surface level observable illness symptoms or factors can provide an understanding of a patient's reality and thus, critical realism can help formulate a more successful understanding of healthcare systems (Koopmans & Schiller, 2022). Critical realism thus adds to positivist and interpretivist paradigms within the formation of a three-tier examination of reality; the first level, or "empirical" level, aims to understand and analyse reality, often detailing events as we experience them and allowing for common-sense making (Alderson, 2021; Fletcher, 2017). The second level, the "actual" level, looks to define the world as existing independently to our thoughts, whereby events happen irrespective of the human experience (Alderson, 2021; Fletcher, 2017). The third level or "real" level details the unseen behaviour causal mechanisms or influences (Alderson, 2021). Bhaskar (1979) detailed the significance of causal mechanisms, as humans do not purely exist within the empirical level of reality and therefore, to understand human actions and ideas, researchers must gain an understanding of the mechanisms generating them.

When contemplating people's health behaviours, social scientists can aim to look beyond the evidence for empirical and actual levels of reality and focus on causal mechanisms which determine an individuals' health outcomes (Alderson, 2021). Critical realism can subsequently support the identification of knowledge and practical suggestions to progress healthcare systems by exploring intricate health problems (Sturgiss & Clark, 2020). Furthermore, critical realism encourages medical professionals to locate underlying causes of naturally occurring events (McEvoy & Richards, 2003). Therefore, taking a critical realistic stance can be beneficial to gain a greater picture of people's health experiences and behaviours.

From this critical realist position, qualitative and arts-based research methodologies were selected to support understanding of context, mechanisms and outcomes relating to treatment adherence in young people with IBD. While quantitative research methods focus on factors or relationships within large populations, qualitative methods look to explore and understand individual participant's experiences (Yardley, 2000). Therefore, qualitative research methods allow for a rich exploration of psychological concerns in health and illness (Lyons, 2011). To understand the needs of young people with IBD, the use of qualitative methods, informed by critical realism, enabled the gathering of in-depth information on participants' experiences, and the causal mechanisms generating adherence behaviours.

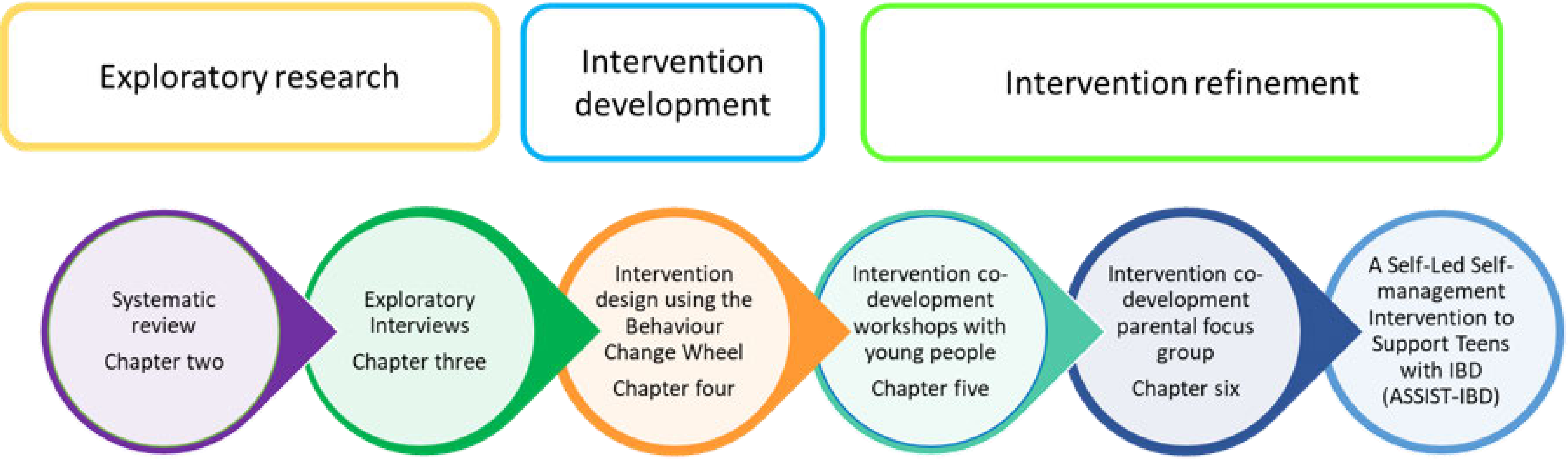
Arts-based methods further supported a so called "outside the box" thought process of how to respond to a researcher's question (Bagnoli, 2009; Mason, 2006). When combined with qualitative research, the visual nature of arts-based methods encourages participants to explore wider dimensions of their experiences that would not be shared within the standard interview format (Bagnoli, 2009). By opening up the range of opportunities for expression, arts-based mediums further supported discussion of sensitive topics (Tumanyan & Huuki, 2020). This was particularly needed for young people discussing issues related to living with IBD that have previously been constructed as stigmatized and embarrassing.

Within the design of adolescent health interventions, it is important researchers remain focused on the needs of the target population (Strommer et al., 2021). Thus, following the expansion of Public and Patient Involvement and Engagement research (PPIE), there has been a recent shift in co-producing new health services with young people (Boote et al., 2016; Smith et al., 2022). Arts-based methods can benefit the co-design process, as they allow young people to create visual representations of their thoughts in a fun and engaging manor (Bowen et al., 2013; Bray et al., 2022; Thabrew, et al., 2018). Subsequently, conducting arts-based methodologies within PPIE research is likely to improve the intervention design process.

1.9. Thesis layout

Each Chapter within the thesis follows a sequential programme of research undertaken to inform and develop a novel evidence-based, theory-driven user-centred treatment adherence intervention for young people (aged 13-18) with IBD (Figure.4). Initially, the thesis reports two knowledge elicitation activities which informed the intervention's development.

Figure 4. Thesis layout



First, a systematic review, presented in Chapter two. This review collates and evaluates the success of behaviour change interventions aimed at improving treatment adherence in young people with IBD. The systematic review also extracts information on behaviour change theory that underpins the included interventions, as well as behaviour change techniques utilised within the interventions. Second, to understand underlying causes of non-adherence and what young people with IBD would want or need from an intervention to help address these causes, Chapter three details an analysis of qualitative interviews with young people (aged 13-18) with IBD, parents of young people (aged 13-18) with IBD, and IBD health professionals.

Chapter four then discusses how findings from this exploratory research (Chapters two and three) informed the development of an intervention. Here the Behaviour Change Wheel (Michie et al., 2011) approach to design the theoretical components of the intervention are described and applied. Chapter five reports on a series of co-development workshops undertaken with young people with IBD, who co-transformed the intervention from its theoretical design into a practical intervention plan, including how it looks and how it is delivered. This Chapter also presents young people's assessment of the acceptability of the intervention for the target population. Chapter six reports a qualitative analysis of the views of parents of young people with IBD on the practicality of the intervention for young people. Finally, Chapter seven collates and evaluates the research as a whole, discussing implications for practice and further research.

Chapter two: The success of interventions designed to improve treatment adherence in young people with Inflammatory Bowel Disease (IBD). A Systematic Review

2..1. Introduction

Approximately, 25 per 100,000 UK adolescents, aged 10-16, are diagnosed with Inflammatory Bowel Disease (IBD) (Pasvol et al., 2020). Living with IBD can be challenging for young people, due to the psychological impact and physical manifestations of their condition, for example, short stature, stomach cramps, diarrhoea, and fatigue (Goodhand et al., 2011; Nicholas et al., 2007; van den Brink et al., 2016). Treatment plans include self-management behaviours to control a young person's IBD, such as medication taking, as well as adhering to lifestyle behaviour changes, such as eating a balanced diet (Hanghoj & Boisen, 2014).

Medical treatments for IBD aim to encourage the remission of debilitating symptoms and inflammation, as well as to prevent future relapses (LeLeiko et al., 2013; Sandhu, 2007). Possible medications prescribed to IBD patients include immunosuppressants (e.g., azathioprine and 6-mercaptopurine), 5-aminosalicylates acids (e.g., mesalamine), biological Anti-Tumour Necrosis Factor injections (e.g., humira), and biological Anti-Tumour Necrosis Factor intravenous (IV) infusions (e.g., infliximab), which can be prescribed independently or as a combination therapy routine (Carroll et al., 2019). Furthermore, Exclusive Enteral Nutrition (EEN), is an effective non-pharmacological treatment to induce remission in young people with IBD, which requires young people to exclusively consume liquid supplements for a specified length of time (Carroll et al., 2019; Ruemmele et al., 2014). Lifestyle advice surrounding diet, physical activity, and sleep, may also be included in a young person's IBD treatment plan, as modifying such factors are beneficial for a young person's health (Lamb et al., 2019; Manhart et al., 2016; Turner et al., 2011; van Langenberg & Gibson, 2014). Treatment plans are formulated and modified to suit an individual's illness severity; thus, young people may experience frequent changes to their treatment plan requiring adaptation of self-management behaviours (Gumidyala et al., 2017). When combined with the known difficulties of adolescence (e.g., cognitive development, development of identity and development of peer relationships), it is understandable that young people report poor treatment adherence (DiMatteo, 2004; Staples & Bravender, 2002).

Rates of medication non-adherence in adolescents with IBD, may be as high as 93% (Spekhorst et al., 2016). There is great variance in reported medication adherence barriers including forgetfulness, lack of IBD related knowledge, and embarrassment over following treatment plans in public (Goodhand et al., 2011; Gray et al., 2012; Gumidyala et al., 2017;

Hommel & Baldassano, 2010). It is further possible that through exercising choice over their treatment adherence, young people are provided with a sense of autonomy over their bodies, which can reduce feelings of powerless induced by living with a long-term condition (Nicholas et al., 2007; Taddeo et al., 2008). Demographic factors, such as age and illness duration, are also associated with medication adherence in adolescents with IBD (LeLeiko, 2007; Reed-Knight et al., 2011).

Rather than being a fixed construct, treatment adherence is a variable behaviour which can be both intentional and unintentional. The Perceptions and Practicalities Approach (Clifford et al., 2003; Horne, 2001) details how the perception of adherence barriers (e.g., beliefs about the condition) can lead to intentional non-adherence; whereas practical barriers (e.g., limited resources and capabilities; forgetting) can lead to unintentional non-adherence. Furthermore, an individual’s treatment preferences, including beliefs about the necessity of a medication compared to their concerns about administering the medication can impact their adherence behaviours, as outlined in the Extended Common Sense-Self Regulation Model (Leventhal et al., 2016). Medication beliefs have been identified as a significant cause of non-adherence in adults with IBD (Jackson et al., 2010).

Health theories and models, such as the Theory of Planned Behaviour (Ajzen, 1991), the Social Cognitive Theory (Bandura, 1986) and the Capability, Opportunity, Motivation and Behaviour (COM-B) model (Michie et al., 2011), can further assist in the understanding of adherence behaviours, and the mechanisms required to effectively facilitate behaviour change. Despite this, there is often a lack of theory-based interventions within health research (Jackson et al., 2014; Lippke & Ziegelmann., 2008; Michie et al., 2011). Use of Behaviour Change Techniques (BCTs), should also be explicitly specified to ensure the fidelity in the intervention’s delivery and for an intervention’s replicability (Michie et al., 2013; Michie et al., 2015).

Despite an emerging understanding of the barriers young people with IBD face in adhering to their treatment plan, little is known about effective interventions. Specifically, it is unclear which behaviour change theories have informed effective interventions, and which BCTs are utilised within such interventions. In a literature review of effective strategies to enhance adherence in paediatric and adult IBD patients, Greenley et al. (2013) concluded promising paediatric intervention strategies could include education, behavioural management (such as the use of rewards), dose simplification, and promoting adaptive family functioning. However, such conclusions were made from only three identified articles and were absent of how behaviour change theory had informed or could be used to understand the outcomes of identified interventions (Greenley et al., 2013). Therefore, the current systematic review, detailed within this Chapter, looks to provide an updated understanding of effective treatment adherence interventions for young people with IBD. Furthermore, the reported systematic review makes a novel and much needed contribution to the literature by aiming to synthesise which behaviour change theory and/or theory components inform effective intervention's design and delivery and provide a clear summary of the implementation of BCTs within such interventions.

This Chapter reports a systematic review of published interventions designed to improve treatment adherence in young people with IBD. Alongside findings of a qualitative analysis of young people, parents and healthcare professionals' views and experiences on young people's treatment adherence behaviours (Chapter three), the outcomes of this systematic review will inform the development of a novel behavioural intervention to support young people with IBD to adhere to their treatment plan.

2.1.1. Research aims and objectives

Aim

To evaluate the effectiveness of interventions designed to improve treatment adherence in young people with IBD, and to identify such intervention's use of theory, mode of delivery, and BCTs.

Objectives

This review has four objectives

(1) to evaluate the success of treatment adherence interventions for young people with IBD
(2) to identify behaviour change theories underpinning the design of reported interventions
(3) to identify the mode of delivery used within reported interventions
(4) to identify BCTs utilised within interventions to promote treatment adherence in young people

2.2. Method

2.2.1. Protocol and registration

A protocol for this review was developed and registered with Prospero international prospective register of systematic reviews related to healthcare and social sciences (registration number: CRD42020158961). The protocol can be accessed via the Prospero website (https://www.crd.york.ac.uk/prospero).

2.2.2. Inclusion Criteria

Inclusion criteria for the review were specified as follows:

Population: Young people (aged 13-18 years) who have been clinically diagnosed with IBD. Interventions which involved parents/carers alongside young people (aged 13-18 years) with IBD were also included.

Intervention: Behavioural interventions, in any setting worldwide, aiming to improve young people's treatment adherence.

Comparison: Articles with or without a comparison group were included.

Outcome: Treatment adherence (including medication adherence, adherence to lifestyle factors such as diet and exercise).

Study design: Any study design (including quantitative, qualitative, and mixed methods).

Exclusion Criteria:

Articles not available in English were excluded as the authors could not make an informed judgement on the article's relevance for the review.

2.2.3. Information sources

The following databases were searched for relevant articles published between 1980 and May 2022; Web of Science, Medline, and Scopus. The reference lists of all included studies and relevant reviews were searched. A citation search of included studies was also performed. Relevant grey literature was searched using Google Scholar; ProQuest Dissertations and Theses database; Conference Proceedings; Citation Indices for Science, and for Social Science and Humanities, available through Web of Science.

2.2.4. Search terms

The search strategy included a combination of free text terms and index terms. Synonyms were combined using the word OR; concepts were combined using the word AND (Boolean logic). The search terms were developed using the PICOS tool (Richardson et al., 1995); Population (adolescents with IBD), Intervention (behavioural change intervention), Comparison (any or none), Outcome (impact on treatment adherence), Study design (any). See Appendix.1 for a full list of search terms used.

2.2.5. Data selection

The title and abstracts for all articles identified from the search were downloaded using data management software (Endnote) and duplicates removed. Articles were then screened against the inclusion/exclusion criteria. Where the article's title and abstract met the inclusion criteria, full text copies were obtained and screened in more detail. If an article's title and abstract did not provide sufficient information to conclude if the article met the reviews inclusion criteria, full text copies were obtained and screened in order to make an informed decision about the article's inclusion. A second researcher (LA/GH) also assessed the selected articles to ensure they met the inclusion criteria.

2.2.6. Data collection process

A data extraction form was created and used to extract information from the included articles. Information were extracted on population demographics, study methodology, use of behaviour change theory, use of BCTs and outcome in terms of change in treatment adherence (Appendix.2). The coding of behaviour change theory was conducted by two researchers (CS & LA) using the Theory Coding Scheme (Michie & Prestwich, 2010). BCTs were coded by two researchers (CS & LA) using the Behaviour Change Technique Taxonomy v1 (BCTTv1) (Michie et al., 2013). Inter-rater reliability was recorded for the coding of BCTs. There was an almost perfect agreement between the researchers, κ = 0.906 (95% CI, 0.837 to 0.975), $p < .001$.

2.2.7. Quality Assessment

Included articles were quality appraised using the Mixed Methods Appraisal Tool (MMAT) (Pluye et al., 2009). The MMAT permits to simultaneously appraise and describe the methodological quality for three methodological domains: mixed, qualitative, and quantitative (subdivided into three sub-domains: randomized controlled, nonrandomized, and descriptive). As it had been anticipated the current review would be inclusive of a range of research methods, the MMAT was assessed as being an appropriate tool when devising the review protocol. Despite the final sample of interventions exclusively using quantitative research methodologies, the MMAT was still viewed as a suitable tool to assess the quality of identified interventions. Two researchers (CS and either LA/GH) independently assessed the included studies for quality. Any discrepancies were resolved through discussion.

2.2.8. Data Analysis and Synthesis

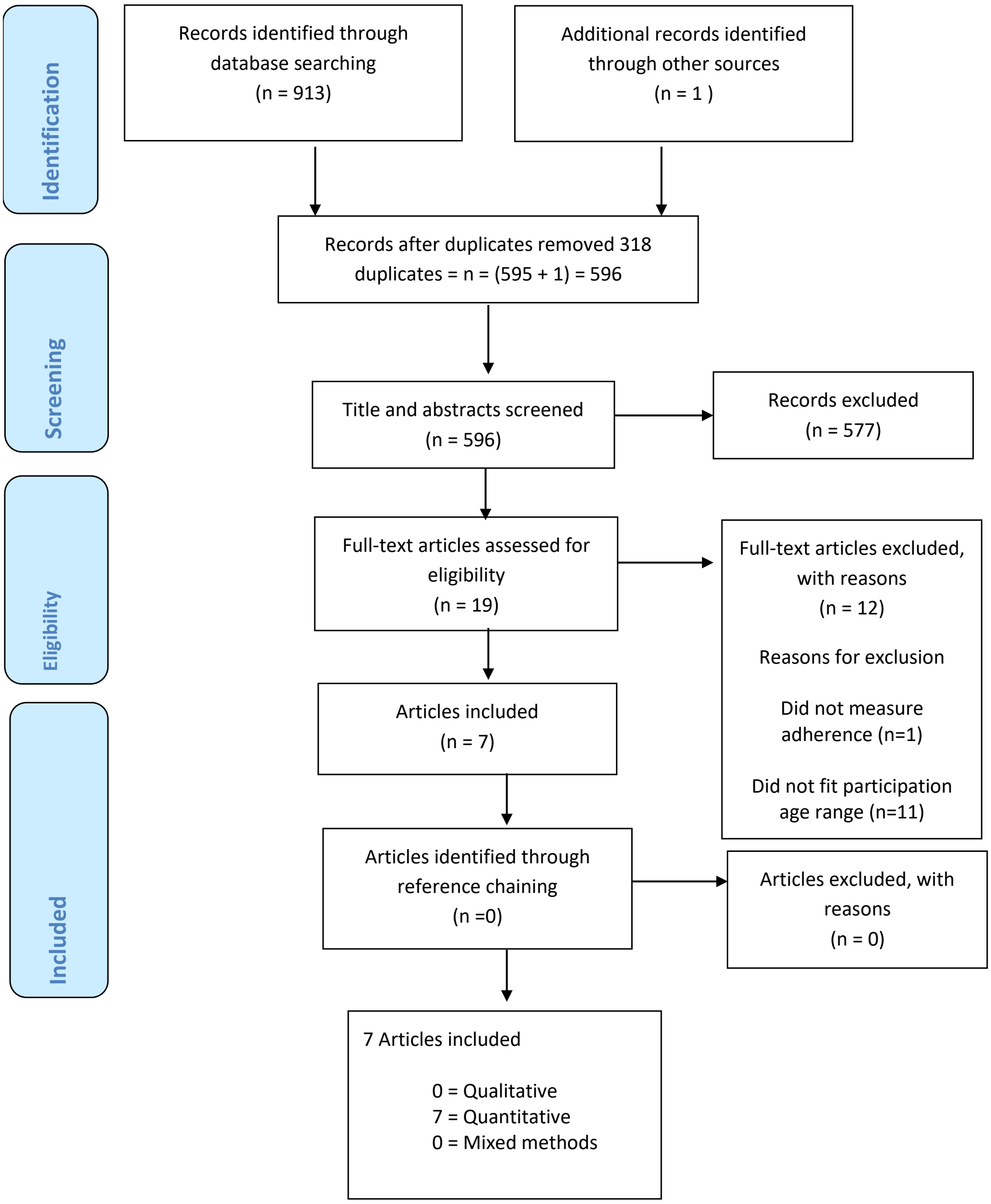
A narrative synthesis approach was utilised to “tell the story” of the review’s findings (Popay et al., 2006). The synthesis was guided by the items on the data extraction form to provide a textual summary of intervention characteristics, mode of delivery, outcomes, use of theory and BCTs. Within each summary, I explore similarities and differences amongst the identified interventions in order to understand the landscape of previous treatment interventions for young people with IBD. Throughout the analysis process I followed guidance published by Popay et al. (2006) in order to maintain rigour in my narrative synthesis. Steps included generating a textual summary of data, tubulising data, and exploring relationships in the data to consider factors that might explain any differences in intervention components and effects. Due to the sample size, as well as the heterogeneity in methods used within the final sample, performing a meta-analysis was unfeasible.

2.3. Results

2.3.1. Searches

Following removal of duplicates, a total of 596 articles were identified. Title and abstract screening resulted in the exclusion of 577 studies and the retention of 19 articles. Full text articles of the remaining studies were then screened, where a further 12 articles were excluded; 11 due to the age range of the participants, and a further article for not measuring adherence (Appendix.2). This resulted in a final sample of seven articles reporting seven interventions (Figure.5 for PRISMA flowchart).

Figure 5. PRISMA Flowchart



2.3.2. Study characteristics

Included interventions aimed to improve young people’s adherence to oral medications; see Table 1 for a full overview of the included studies. Five interventions were randomised control trials (RCTs), and all seven interventions used quantitative research methods. Four intervention programmes were delivered within a hospital setting (Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017; Vaz et al., 2019). One study took place online; however, participants were required to attend hospital appointments for regular blood tests (Carlsen et al., 2017). Two interventions were delivered over the telephone (Greenley et al., 2015; Hommel et al., 2015). All but one intervention (Carlsen et al., 2017), took place in the USA. Of the five studies that used a control group, three control groups received usual care (Carlsen et al., 2017; Hommel et al., 2012; Vaz et al., 2019) and two participated in the intervention as a wait-list control (Greenley et al., 2015; Hommel et al., 2011). The wait-list control studies did not compare the outcome measures of the intervention group with the control group; rather they included the intervention outcomes for both groups within their findings.

Table 1. A full overview of the included studies

Author, (year) Country, study design, Adherence measure	**Type of intervention, Sample numbers and withdrawal rates**	**Intervention content**	**Data Collection**	**Primary outcomes**	**Secondary outcomes**
Carlsen et al. (2017) Denmark. RCT. Oral Medication Adherence	**Individual intervention** 27 young people took part in the intervention and 26 young people were allocated to the control group. Twelve young people withdrew from the intervention and eight young people withdrew from the control group.	**Intervention group:** Two-year online intervention, where participants were asked to input self-reported measures of medication adherence, QoL, contact with hospitals, and days off school into an online programme. Participants also provided faecal and blood samples and received feedback on these results. **Control Group:** Received Usual Care	Participants completed subjective self-reported disease severity every month. Every three months, participants self-reported their medication adherence, using the MARS and an adherence VAS. Participants also participants self-reported their QoL, contact with hospitals, and days off school Participants provided a faecal sample and blood sample every three months.	**MARS and Adherence VAS*** Post-intervention, there was no significant difference in rates of medication adherence between those who undertook the intervention and the control group (p>0.05).	**Disease Severity*** There was no difference between groups in symptom scores. **Contacts to hospital*** The intervention group had significantly less outpatient visits (N=8) than controls (N=185; p<0.001). While there was a tendency for lower hospital admissions in the intervention group, this was not significant (p>0.05). **School absences*** The intervention group had significantly fewer days off school (mean=1.6) than

					the control group (mean=16.5; p<0.05) **QoL** In general, there were no significant differences between self-reported QoL in the intervention group and control group, apart from the subscale emotional functioning which was significantly lower in the intervention group (p<0.05).
Greenley et al. (2015) USA. RCT. Oral Medication Adherence	**Family intervention** 41 families took part in the intervention; 21 were allocated to intervention group one and the remining 20 families were allocated to intervention group two. 24 families were allocated to the control group.	**Intervention** 18-week intervention with two intervention conditions. **Intervention Group one** Received two educational sessions, which covered the following information: **<u>Session 1- 60-90 minutes</u>** Introduction/education on five core steps to problem solving. Families received personalised feedback on adherence barriers and chose a specific barrier they wished to work on during the intervention. Families were guided to use PSST to overcome the identified barrier. **<u>Session 2 – 45 minutes</u>**	Objective measures of the amount of successfully administered medication doses was recorded at baseline and post intervention. A MEMS track cap was used to record medication adherence behaviours.	**MEMS track cap** **Entire Sample (N=65).** There was a 3% non-statistically significant increase in adherence from baseline to post-intervention. This increase in adherence rates had a small effect size (d=0.22). **Imperfect adherers** Those with perfect adherence (>80% doses taken) were removed from the sample, leaving a subset of participants referred to as imperfect adherers (N=41). There was a significant 6% increase in adherence rates from baseline to post-intervention, (p<0.010), which had a moderate effect size (d=0.41). When imperfect adherers were categorised by age,	**QoL** Full sample (N=65). There was a significant 4% increase in QoL (p<0.05), which had a moderate effect size (d=0.49). **Intervention group two:** For those who participated in the extra two PSST session, there was a marginal non-significant increase in QoL

		The family's success in implementing plans formed in previous sessions was reviewed. Families identified an additional barrier and used PSST to overcome the identified barrier. **Intervention group two** Received the two sessions outlined above as well as a further two educational sessions, which covered the following information: **Session 3- 45 minutes** The family's success in implementing plans formed in previous sessions was reviewed. Families identified an additional barrier and used PSST to overcome the identified barrier. **Session 4 - 45 minutes** The family's success in implementing plans formed in previous sessions was reviewed. Families identified an additional barrier and used PSST to overcome the identified barrier. **Control group** Wait list control		older imperfect adherers (aged 16-18) saw a significant 10% increase in their adherence (p<0.05). Younger imperfect adherers (aged 13-15) also saw an increase in their adherence (4%), but this was non-significant. **Intervention group two** For those who participated in the extra two PSST sessions (N=20), there was a non-significant increase in medication adherence, which had a small effect size (d=0.05).	(p>0.05), with a moderate effect size (d=0.40).
Hommel et al. (2011). USA. RCT.	**Family intervention** 14 families took part in the intervention. The study reported one family withdrew from the intervention.	**Intervention group** Seven-week intervention with four weekly face-to-face group educational sessions Session 1: Educational and organisation intervention Session 2: Behaviour modification	Objective measures of the amount of successfully administered medication doses of immunosuppressants & mesalamine, were recorded at baseline and post intervention.	**Pill count.** Paired samples t-tests were conducted on the data once all participants had received the intervention. The analysis revealed a non-significant difference between the intervention and control group in adherence rates for immunosuppressants (4% increase,	None.

Oral Medication Adherence		Session 3: Problem solving skills and monitoring adherence Session 4: Family function **Control group** Wait list control	Pill counts were used to record medication adherence behaviours.	p>0.05, d=0.07) and mesalamine (25% increase, p>0.05, d=0.57).	
Hommel et al. (2012). USA. RCT. Oral Medication Adherence	**Family group intervention** Intervention group N=20. Control group N=20 20 families took part in the intervention and 20 families were allocated to the control group. Four families withdrew from the research.	**Intervention group** Six-week face-to-face intervention with four weekly educational group sessions. In sessions 1-3 young people and parents met separately. In session 4, young people and parents met together. Session 1: Educational and organizational intervention Session 2: Behavioural modification Session 3: Problem solving skills and monitoring adherence Session 4: Family functioning **Control group** Usual care	Objective and subjective measures of the amount of successfully administered medication doses was recorded at baseline and post-intervention. Objective measures Pill counts and a MEMS track cap was used to record medication adherence behaviours. Subjective measures The TRAQ was used to record medication adherence behaviours.	**Pill count*** There was a small non-statistically significant increase (4%) in adherence for those taking immunosuppressants, which was marginally higher than the control group (2%). Results for those taking mesalamine, identified a greater increase in adherence for the intervention group (17%) compared to the control group (6%). However, this increase non-significant (p>0.05) **MEMS track cap*** Data from the overall sample resulted in very small changes in adherence for both the intervention group (7%) and the control group (3%), the difference between these two groups were non-significant (p>0.05). **TRAQ** Parental-reported levels of adherence for immunosuppressants, saw a small non-statistically significant increase in adherence for both the intervention group (8%) and control group, (6%). Whereas parental reported adherence rates for mesalamine, identified a non-statistically significant increase in adherence for the intervention group (17%) compared to the control group (2%; p>0.05). Patient reported rates for adherence for immunosuppressants	None.

				also identified a slightly higher rate of adherence for the control group (10%) compared to the intervention group (6%). The difference between these groups were non-significant (p>0.05). For mesalamine, patient reported adherence rates identified a 25% increase for the intervention group compared to 1% of the control group. This difference was significant (p<0.05). F-tests concluded there were a significant increase in mesalamine adherence for the condition (F = 22.24, p< 0.01; d=0.79) and Condition × Time interaction (F =13.32, p< 0.05; d=0.69).	
Hommel et al. (2015) USA. Single arm clinical trial. Oral Medication Adherence	**Family intervention** Nine families took part in the intervention. No families withdrew from the research.	Six-week intervention with four weekly educational sessions conducted over the phone **Session 1:** Educational and organisation intervention **Session 2:** Behaviour modification **Session 3:** Problem solving skills and monitoring adherence **Session 4:** Family functioning	Objective measures of the amount of successfully administered medication doses of immunosuppressants & mesalamine, were recorded at baseline and post-intervention. Pill counts were used to record medication adherence behaviours.	**Pill counts.** There was a non-significant increase in adherence rates for immunosuppressants and mesalamine from baseline to post-intervention. Analysis of the median adherence rates, identified a decrease in adherence rates for immunosuppressants (Baseline=61%, Post-intervention = 53%), which had a small effect size (d=-0.17). However, analysis of median adherence rates did show an increase in adherence for mesalamine (Baseline: 62%, Post-intervention 91%), which had a large effect size (d=0.63).	None.
Maddux et al. (2017). USA. Longitudinal, single-site	**Family intervention** Twelve families took part in the intervention. No families withdrew from the intervention.	Seven-week intervention, with four tailored weekly educational sessions (60-90 minutes long). **Session 1:** Educational and organisational **Session 2:** Behaviour Modification	Objective measures of the amount of successfully administered medication doses were recorded at baseline and post-intervention and at a	**Pill box & MEMS*** There was a significant increase in adherence rates from baseline to post-intervention (p<0.01). There was also a significant increase in adherence rates from baseline to the one month follow up (p<0.05).	None.

noncurrent multiple baseline design across subjects. Oral Medication Adherence		Session 3: Problem solving skills and adherence monitoring Session 4: Family functioning	one month follow up. Pill counts and a MEMS track cap were used to record medication adherence behaviours.	Odd ratio identified adherence rates at baseline as 2.58 out of 3.58 doses taken. Post-intervention, this increased to 5.09 out of every 6 doses. At the one month follow up, participants adherence dropped to 3.42 out of every 4.42 doses, however this was still higher than at baseline.	
Vaz et al. (2019). USA[34]. RCT. Oral Medication Adherence	**Individual intervention** Five families took part in the intervention and four families were allocated to the control condition. Two families withdrew from the intervention and a further two families withdrew from the control condition.	**Intervention group** Received a single 30-minute educational session **Control group** Usual care	Objective measures of the amount of successfully administered medication doses were recorded at baseline and post-intervention. Pill dispensers were used to record medication adherence behaviours.	**Pill dispensers** Post-intervention, there was a no difference in adherence for the intervention group, whereas there was a decrease in adherence for the control condition. While this decrease in adherence had a medium effect size (d=0.85), this was not statistically significant.	**IBD Knowledge*** The intervention group scored higher on the IBD knowledge subscales, however none of these differences were statistically significant. **Transition readiness questionnaire*** While there were differences between the intervention control groups scores in the questionnaire's subscales, none of these were statistically significant

***Study did not report effect sizes**

2.3.3 Participant characteristics

Included studies had a total sample of 202 young people diagnosed with IBD, see Table 2 for an overview of the pooled participant's baseline characteristics. Of these, 128 young people were assigned to receive an intervention, with the remaining 74 assigned to a control condition. Study sample sizes varied, ranging from nine to 65 participants, with an average sample size of 29 young people per intervention.

The average baseline age of participants was 14.75 years. Only one study reported the age of the participants in each intervention condition (Carlsen et al., 2017), revealing intervention participants to be slightly older (M=15.1 years) than those in the control condition (M=14.7 years). Participants mainly identified as female (59.4%). There was poor reporting of ethnicity across the interventions, however where reported, samples were predominately White.

All the included studies recorded their participants' IBD diagnosis. The most frequently recorded type of IBD was Crohn's Disease (65.31%), with the remaining participants reported as being diagnosed with Ulcerative Colitis (32.14%) or IBD-Unclassified (2.55%). Six of the seven interventions, (all bar Greenley et al., 2015), measured participant illness severity using self-report data. Most participants with Crohn's Disease reported mild illness severity (57.97%). Around a third of participants with Ulcerative Colitis reported inactive illness severity, and a further third reported moderate illness severity. All interventions required participants to be prescribed at least one oral IBD medication, however only four studies reported participants' prescribed medication (Carlsen et al., 2017; Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2012). Most frequently prescribed medications were immunosuppressants, such as 6-mercaptopurine or azathioprine (46.91%), followed by 5-aminosalicylic acids, such as mesalamine, (42.27%). A further 5.15% of participants were prescribed both immunosuppressants and 5-aminosalicylic acids. A small number of participants were prescribed corticosteroids (2.58%) or antibiotics (1.55%).

Table 2. Overview of the pooled participant's baseline characteristics

		Carlsen et al. (2017)	*Greenley et al. (2015)*	*Hommel et al. (2011)*	*Hommel et al. (2012)*	*Hommel et al. (2015)*	*Maddux et al. (2017)*	*Vaz et al. (2019)*
Total number of participants (N)	Intervention	N= 27	Group 1: N=21 Group 2: N=20	N=14	N=20	N=9	N=12	N=5
	Control	N=26	N=24	N/A	N=2	N/A	N/A	N=4
Mean age, years (s.d)	Intervention	15.1 (1.82)	14.54 (1.84)	14.89 (2.01)	15.4 (1.5)	13.71 (1.35)	14.9 (2.16)	14.9
Gender split (M/F)	Intervention	(10/15)	(36/29)	(4/10)	(20/20)	(6/3)	(4/8)	(4/3)
	Control	(12/13)						
Ethnicity	White/Caucasian	n/a	N= 57	Unknown	N=36*	N=8	N=8	78%
IBD Diagnosis	Crohn's Disease	N=21	N=47	N=11	N=30	N=7	N=6	N=6
	Ulcerative Colitis	N=32	N=16	N=3	N=7	N=2	N=6	N=3
	IBD-Unclassified		N=2		N=3			
Time since diagnosis	Intervention	2.76 years (1.79)	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
IBD severity								
Chron's Disease	Inactive	N=7	Unknown**	N=4	N=8	N=4	N=4	Unknown
	Mild	N=11		N=7	N=17	N=3	N=8	
	Moderate	N=2						
	Moderate to severe				N=5			
	Severe	N=1						
Ulcerative Colitis	Inactive	N=23	Unknown	N=2	N=4	N=1	N=4	Unknown
	Mild	N-9			N=4		N=2	
	Moderate			N=1	N=2	N=1	N=6	
	Moderate to severe							
	Severe							
Type of IBD Medication	Immunosuppressants (e.g. 6-mercaptopurine/ azathioprine)	N= 24	N=43	Unknown	N=24		Unknown	Unknown
	5-aminosalicylates acids (e.g. Mesalamine)	N=32	N=29		N=21			
	Immunosuppressants and 5-aminosalicyltaes acids				N=6	N=4***		
	Other		N=8					

***Hommel et al. (2012) sample specified that participants were not Hispanic **Greenley et al. (2015) combined the total disease severity scores of their participants indicating Inactive N=46, Mild N=16, Moderate N=3 ***Hommel et al. (2015) omitted to report the prescribed medication of their entire sample.**

Five interventions included parents in the intervention (Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017). Greenley et al. (2015) provided no information about the total number or demographic characteristics of parents involved in the intervention, therefore, the following analysis was conducted on the four remaining interventions. See Table 3 for an overview of parental demographic information. A total of 75 parents were recruited into the four interventions, with sample sizes ranging from nine to 65. Overall, the reporting of demographic information for parents was poor. Only three interventions reported the average age of parents as well as the median household income (Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011). Of those reported, parents had a combined average age of 46.05 years and income ranging from $75,000-$125,000. None of the studies reported parental gender or ethnicity. All interventions partially reported the relationship status of parents, with 89.33% identifying as married.

Table 3. Overview of parental demographic information

	Carlsen et al. (2017)	**Greenley et al. (2015)**	**Hommel et al. (2011)**	**Hommel et al. (2012)**	**Hommel et al. (2015)**	**Maddux et al. (2017)**	**Vaz et al. (2019)**
Were parents included in the intervention?	No	Yes	Yes	Yes	Yes	Yes	No
No. of participants		Unknown	Unknown	N=40	N=9	N=12	
Mean age (SD)		Unknown	Unknown	46.2 (4.9) years	46.08 (5.86 years)	Unknown	
Gender split (M/F)		Unknown	Unknown	Unknown	Unknown	Unknown	
Ethnicity		Unknown	Unknown	Unknown	Unknown	Unknown	
Married		Unknown	Unknown	N=35	N-9	N=9	
Household income		Unknown	Unknown	$100,001-125,000*	$100,001-125,000*	Unknown	

*** Household income given as a median vale**

2.3.4. Withdrawal rates

Overall, 40 young people withdrew from the included interventions, three quarters of whom were receiving an intervention. The average withdrawal rate was 5.71 participants per intervention. Two studies reported having a withdrawal rate of zero (Hommel et al., 2012;

Maddux et al., 2017). No intervention reported the demographic characteristics of those who withdrew from the study.

2.3.5. Quality assessment

All interventions demonstrated use of a clear research question alongside appropriate data collection methods. Both non-randomized studies (Hommel et al., 2015; Maddux et al., 2017) included participants who were representative of the target population, as well as appropriate outcome measures, and reported complete outcome data. However, only one study accounted for confounders in the design and analysis (Maddux et al., 2017). Neither non-randomized study clearly reported if the intervention was administered as intended. The remaining interventions were RCTs (Carlsen et al., 2017; Greenley et al., 2015; Hommel et al., 2012; Hommel et al., 201; Vaz et al., 2019). All RCTs demonstrated appropriate sample randomization, with the intervention and control groups comparable at baseline, and reported participants adhered to the assigned intervention. Two RCTs randomized participants to either an intervention or a wait-list control (Greenley et al., 2015; Hommel et al., 2011) however, neither reported complete outcome data for the control group. The remaining four RCTs all reported complete outcome data. None of the RCTs blinded the outcome assessors to the intervention.

2.3.6. Impact on medication adherence

Two studies conducted interventions at an individual level (Carlsen et al., 2017; Vaz et al., 2019). Both of these utilised a control group who received ‘usual care’, however, neither provided clarity of the contents of ‘usual care’. Carlsen et al. (2017) reported a two-year online intervention, where young people were asked to self-monitor adherence behaviours and biomarkers were used to provide young people with virtual feedback using a traffic light system (red indicated a concerning result and green indicated no cause for concern). This intervention did not produce a significant difference in post-intervention adherence between the intervention and control group (Carlsen et al., 2017). Equally, a single 30-minute IBD medication educational session did not improve post-intervention measures of medication adherence (Vaz et al., 2019). See Table 1 for a full overview of outcome measures.

Five interventions included one or more family members (Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017). Most of these used a similar four-session family education approach covering the following topics:

educational and organisation interventions, behaviour modification, problem solving skills, family functioning (Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017). This did not significantly impact young people's medication adherence when conducted face-to-face (Hommel et al., 2011) or over the telephone (Hommel et al., 2015). However, by tailoring the content of these four education sessions to family's individual needs and thus allowing families to identify their own adherence barriers and set tailored goals, Maddux et al. (2017) found significant improvements in adherence from baseline to post-intervention measures ($p<0.01$) and at a one month follow up ($p<0.05$). Similarly, a family group intervention, consisting of four separate educational sessions for young people and their family members, demonstrated a significant increase in adherence to mesalamine post-intervention, compared with the control group ($p<0.05$) (Hommel et al., 2012). Greenley et al. (2016) delivered a four-session Problem Solving Skills Training (PSST) intervention over the telephone, to guide families to overcome their adherence barriers. This intervention improved young people's medication adherence ($p<0.010$, $d=0.41$), but only for those who were ≤80% adherent at baseline. Further categorisation by age, identified an increase in adherence for older adolescents only ($p<0.05$).

Adherence measurement strategies used within the interventions

Five interventions only used objective adherence measurement strategies (Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2011; Maddux et al., 2017; Vaz et al., 2019). Of these, three interventions solely used pill counts to measure adherence. However, neither a single educational session nor a four-session intervention (delivered face-to-face or over the telephone) significantly improved medication adherence when measured using pill counts (Hommel et al., 2015; Hommel et al., 2011; Vaz et al., 2019). Greenley et al.'s (2015) intervention used Medication Event Monitoring System (MEMS) track caps to measure adherence, a devise which fits onto a medication bottle capturing when and how often each dose is taken. Following a two-session family intervention, non-adherers at baseline had a significant increase in adherence post-intervention ($p<0.01$, $d=0.41$); however, when categorised by age, only older adolescents had a significant increase in their adherence ($p<0.05$) (Greenley et al., 2015). Maddux et al. (2017) utilised a combination of pill counts and MEMS track cap measures to determine the success of their family intervention. Through tailoring interventions to each family's adherence needs, as well as reviewing families' weekly progress, young people's medication adherence was significantly improved at post intervention measures ($p<0.01$), as well as at a one-month follow-up ($p<0.05$) (Maddux et al., 2017).

Only Hommel et al. (2012) used a combination of objective and subjective adherence measures. Despite finding no significant results using objective measures (pill counts and MEMS track caps), Hommel et al.'s (2012) four-session family group intervention reported significant improvements in self-reported adherence to mesalamine ($p<0.05$) when measured using a study specific Treatment Regimen Adherence Questionnaire (TRAQ). However, this was not observed in parent-proxy self-reported adherence (Hommel et al., 2012).

A further intervention solely used subjective measures of adherence. Self-reporting adherence behaviours every month for two years, as well as receiving feedback on disease severity biomarkers did not significantly improve young people's medication adherence measured using The Medication Adherence Report Scale (MARS) and an adherence Visual Analogue Scale (VAS) (Carlsen et al., 2017).

2.3.7. Impact of interventions on other outcomes

IBD Knowledge & Quality of Life

One intervention explicitly aimed to improve young people's IBD knowledge within the intervention (Vaz et al., 2019); however, this single session educational intervention did not statistically improve young people's IBD knowledge. Greenley et al.'s (2015) use of PSST to improve medication adherence resulted in a significant increase ($p<0.05$, $d=0.49$) in young people's self-reported Quality of Life (QoL). After using a digital platform to monitor and receive feedback on health outcomes for two years, there were no significant differences between the intervention and control group's overall QoL. However, the emotional functioning subscale was significantly lower in the intervention group ($p<0.05$), indicating the control group had a greater emotional functioning QoL than those assigned to the intervention (Carlsen et al., 2017).

Disease severity, hospitalisations, school absences and transition readiness

Self-monitoring adherence behaviours, as well as receiving feedback on these, every three months online for two years, did not significantly impact young peoples' self-reported symptom scores or biological markers (Carlsen et al., 2017). Despite this there was a significant reduction in the number of outpatient appointments ($p<0.001$), but not hospital admissions (Carlsen et al., 2017). Those receiving the intervention also reported significantly fewer school absences than the control group ($p<0.05$) (Carlsen et al., 2017).

2.3.8. Use of BCT’s

Eleven BCTs were identified as being used within the seven included interventions. BCTs were coded a total of 37 times with an average of five BCTs per intervention (ranging from 2-7 BCT’s per study). BCT coding was not possible for control groups, as no authors provided descriptions of control conditions or ‘usual care’. See Table 4 for an overview of BCTs identified in each intervention.

BCT’s associated with a successful medication adherence outcome.

Three BCTs were solely associated with successful medication adherence intervention outcomes; *1.4. Action planning, 2.2. Feedback on behaviour* and *12.5. Adding objects to the environment*. The BCT 1*.4. Action planning* was identified in Greenley et al.’s (2015) family intervention which significantly improved medication adherence in older adolescents (≤80% at baseline). Greenley et al. (2015) and Maddux et al. (2017) demonstrated the use of the BCT *2.2. Feedback on Behaviour*. Both interventions successfully improved young people’s medication adherence. Only Maddux et al. (2017) used the BCT *12.5. Adding objects to the environment* which significantly increased medication adherence for the intervention group, including at post-intervention follow up.

Table 4. Overview of BCT's within included interventions

	Carlsen et al. 2017	Greenley et al. 2015		Hommel et al. 2011	Hommel et al. 2012	Hommel et al. 2015	Maddux et al. 2017	Vaz et al. 2019
Behavioural Change Techniques Identified		Intervention group 1	Intervention group 2					
Section1. Goals and planning								
1.1. Goal-setting (behaviour)		X	X	X	X	X	X	
1.2. Problem-solving				X	X	X	X	
1.3. Goal-setting (outcome)								
1.4. Action planning		X	X					
1.5. Review behaviour goal(s)								
1.6. Discrepancy between current behaviour and goal								
1.7. Review outcome goal(s)								
1.8. Behavioural contract				X	X	X	X	
1.9. Commitment								
Section 2. Feedback and monitoring								
2.1. Monitoring of behaviour by others without feedback								
2.2. Feedback on behaviour		X	X				X	
2.3. Self-monitoring of behaviour				X	X	X	X	
2.4. Self-monitoring of outcome(s) of behaviour								
2.5. Monitoring of outcome(s) of behaviour without feedback								

2.6. Biofeedback								
2.7. Feedback on outcome(s) of behaviour								
Section 3. Social support **								
Section 4. Shaping knowledge								
4.1. Instruction on how to perform the behaviour	X							
4.2. Information about the antecedents								
4.3. Re-attribution								
4.4. Behavioural experiments								
Section 5. Natural consequences								
5.1. Information about health consequences	X			X	X	X	X	X
5.2. Salience of consequences								
5.3. Information about social and environmental consequences								
5.4. Monitoring of emotional consequences								
5.5. Anticipated regret								
5.6. Information about emotional consequences								
Section 6. Comparison of behaviour **								
Section 7. Associations								
7.1. Prompts/cues				X	X	X		X
7.2. Cue signalling reward								
7.3. Reduce prompts/cues								
7.4. Remove access to the reward								
7.5. Remove aversive stimulus								
7.6. Satisfaction								

7.7. Exposure								
7.8. Associative learning								
Section 8. Repetition and substitution **								
Section 9. Comparison of outcomes **								
Section 10. Reward and threat**								
Section 11. Regulation **								
Section 12. Antecedents								
12.1. Restructuring the physical environment				X		X		
12.2. Restructuring the social environment								
12.3. Avoidance / reducing exposure to cues for the behaviour								
12.4. Distraction								
12.5. Adding objects to the environment							X	
12.6. Body changes								
Section 13. Identity **								
Section 14. Scheduled consequences **								
Section 15. Self-belief **								
Section 16. Convert learning **								

* BCT’s could only be identified in the intervention conditions for all seven interventions, **No BCT’s were identified in this section

BCT's associated with a successful and unsuccessful medication adherence outcome

Six BCTs were identified across interventions which reported successful and unsuccessful medication adherence outcomes; *1.1. Goal setting (behaviour), 1.2. Problem solving, 1.8. Behavioural contract, 2.3. Self-monitoring of behaviour, 5.1. Information about health consequences* and *7.1. Prompts/cues*.

Although five interventions included the BCT *1.1. Goal setting (behaviour)*, only three interventions were able to demonstrate a significant increase in medication adherence (Greenley et al., 2015; Hommel et al., 2012; Maddux et al., 2017). However, within these three interventions there was variance in how they were successful. Maddux et al.'s (2017) four session intervention, where families were provided tailored advice to improve their adherence demonstrated a significant improvement in adherence for all participants, whereas Greenley et al.'s (2015) four session family intervention only improved adherence for older adolescents with ≤80% adherence at baseline. Equally, a four-session family group intervention was only associated with a successful outcome for those prescribed mesalamine (Hommel et al., 2012). However, this BCT was not associated with a successful outcome when used in family education interventions conducted face-to-face (Hommel et al., 2011) or over the telephone (Hommel et al, 2015).

Four family interventions, all comprising of four intervention sessions utilised the BCTs *1.2. Problem solving; 1.8. Behavioural contract* and *2.3. Self-monitoring of behaviour* (Hommel et al, 2015, Hommel et al., 2012, Hommel et al., 2011, Maddux et al., 2017). Two of these reported significant improvements in medication adherence to either the entire intervention group (Maddux et al., 2017), or participants prescribed mesalamine (Hommel et al., 2012). However, when similar educational interventions were conducted over the phone (Hommel et al., 2015) or face-to-face (Hommel et al., 2011), this was associated with unsuccessful medication adherence outcomes.

Six of the included interventions utilised the BCT *5.1. Information about health consequences* (Carlsen et al., 2017; Hommel et al, 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017; Vaz et al., 2019). However, only two four session family interventions significantly increased levels of medication adherence either for the entire intervention group (Maddux et al., 2017), or for a subsection of participants (Hommel et al., 2012). Despite using a similar four session intervention; neither Hommel et al. (2015) nor Hommel et al. (2011) saw a significant increase in adherence. Equally, the inclusion of the BCT *5.1.Information about health consequences* was not associated with improvements in medication adherence for a single session educational intervention (Vaz et al., 2019) or a two year online individual intervention (Carlsen et al., 2017), suggesting that while not always successful, this BCT may be more beneficial in family interventions.

Despite being identified in four interventions, the BCT *7.1. Prompts/cues* was only associated with a successful outcome for participants prescribed mesalamine in Hommel et al.'s (2012) family-based intervention. When this BCT was used in similar family interventions delivered face-to-face (Hommel et al., 2011) or over the telephone (Hommel et al., 2015), as well as a single session educational intervention (Vaz et al., 2019), this was not associated with a successful medication adherence outcome.

BCT's associated with unsuccessful medication adherence outcomes

Two BCTs were solely associated with unsuccessful medication adherence intervention outcomes; *4.1. Instruction on how to perform the behaviour* and *12.1. Restructuring the physical environment*. The BCT *4.1.Instruction on how to perform the behaviour*, was used in a two-year individual online intervention; however, this did not significantly impact on young people's medication adherence (Carlsen et al., 2017). Similarly, two interventions included the BCT *12.1. Restructuring the physical environment*, neither of which reported successful medication adherence outcomes (Hommel et al., 2015; Hommel et al., 2011).

2.3.9. Use of Behaviour change theory

None of the included studies explicitly reported use of behaviour change theory within the intervention's formulation or delivery. The interventions were reviewed to not only identify behaviour change theories/models as a whole, but also to identify theory-relevant constructs and predictors. Only one intervention (Greenley et al., 2015) mentioned the behaviour change theory construct of self-efficacy (Bandura, 1977; Bandura, 1986). This was referred to in the context that "cognition/self-efficacy" could be chosen as a potential barrier to medication adherence for young people, however no further explanation was provided.

2.4. Discussion

To the author's knowledge, this is the first systematic review to investigate the effectiveness of treatment adherence interventions for young people with IBD, as well as the exploration of behaviour change theory and BCTs used within such interventions. The current systematic review included seven interventions aiming to improve the medication adherence of young people with IBD. However, just over half of the interventions reported no significant improvements to the primary outcome. Overall, nine BCTs were identified within effective interventions, however theories of behaviour change (or adherence) were not found to be underpinning any of the included interventions. A quality assessment of the included interventions suggested the quality of the papers was good overall, except for two interventions omitting to report their control group data (Greenley et al., 2015; Hommel et al., 2011).

This review intended to explore the success of interventions aiming to improve young people's adherence to factors related to living well with IBD treatment plans, including the full range of medications and lifestyle behaviours. However, none of the included interventions addressed anything other than oral medication adherence. Yet, it is possible that non-oral medications differ in their adherence barriers and intervention needs. Previous research has discussed the difficulties young people face in adhering to diet and physical activity advice (Lamb et al., 2019; Turner et al., 2011; van Langenberg & Gibson, 2014). Due to the challenges young people face in adhering to these lifestyle factors, it is important that such factors are not overlooked in future interventions.

The two main oral medications included within the seven interventions were immunosuppressants (e.g., 6-mercaptopurine and azathioprine) and 5-aminosalicylic acids (e.g., mesalamine). These drugs not only differ in their physiological function, but also in their administration. Mesalamine is commonly used to treat patients with Ulcerative Colitis and typically administered once a day; whereas immunosuppressants (mercaptopurine and azathioprine) are often taken multiple times a day and are prescribed equally for Crohn's Disease and Ulcerative Colitis. The current systematic review identified that while the results did not always reach statistical significance, interventions reported better intervention outcomes for mesalamine than immunosuppressants. We know that more frequent or complex medication routines lead to less adherent behaviours (Greenley et al., 2010; Hommel & Baldassano, 2010). It could be then, that the greater increase in adherence observed for those taking mesalamine relates to mesalamine's simpler administration requirements, rather than the intervention content. Furthermore, as mesalamine, is mainly prescribed to patients diagnosed with Ulcerative Colitis, the effects noted for mesalamine may be influenced by the smaller sample of participants who were prescribed this medication. Due to the complexity and wide range of drugs available for patients with IBD, future interventions should aim to explore the intervention's impact on medication specific adherence.

Parenting a child with IBD is associated with increased worry and depression, which is further associated with poorer disease outcomes for young people with IBD (Burke et al., 1994; Cunningham & Banez, 2006; Diederen et al., 2018). Generally, interventions which included family members were more effective in improving medication adherence than those which only included young people. This was apparent when interventions were conducted over the phone (Greenley et al., 2015), face-to-face (Hommel et al., 2012; Maddux et al., 2017) and as part of a group design (Hommel et al., 2012) as well as through using subjective (Hommel et al., 2012) or objective (Greenley et al., 2015; Maddux et al., 2017) measures. Despite this, parents' role in family interventions, particularly their role in identifying and overcoming adherence barriers, was poorly reported. This lack of clarity limits our understanding of *how* parents support young people's adherence behaviours. While parental support is crucial in the facilitation and maintenance of adherence in younger adolescents (Gray et al., 2013; Greenley & Cunningham, 2008; LeLeiko,, 2007), as they get older, young people are expected to, and start to, develop skills to self-manage their IBD in preparation for adulthood and adult healthcare services. Here, parents are required to incrementally relinquish their management responsibilities to their child (Goodhand et al., 2011; Stollen et al., 2017). Subsequently as parental support is withdrawn, so adherence worsens (LeLeiko, 2007). Only one intervention examined differences in post-intervention outcomes in relation to participants' age. Greenley et al. (2015) identified a significant increase in older adolescents' medication adherence for mesalamine only. This may be due to younger participants receiving more support from their parents. It is plausible that the effectiveness of family interventions is related to the intervention impacting parental support as well as parental wellbeing; however, this was not captured within the included interventions. Further research is needed to measure the impact of family interventions on parental behaviours and wellbeing, as well as those of young people (Diederen et al., 2018).

Previous research has suggested that illness duration is also a factor for medication adherence behaviours, with a greater length of time since diagnosis linked to higher levels of non-adherence behaviour, possibly related to feelings of hopelessness or burnout associated with the chronicity of their condition (Platak et al., 2013; Reed-Knight et al., 2011). Such experiences could have been a factor in an intervention's success, however, only one intervention reported the length of time since their participants IBD diagnosis (Carlsen et al., 2017). Similarly, the relatively short length of time since diagnosis observed in Carlsen et al.'s (2017) intervention, may, in part, explain the lack of significant outcomes. Reporting participants' demographic information in detail is crucial for understanding the outcomes of such interventions going forward.

Most interventions used objective measures of medication adherence. However, subjective measures of adherence, such as self-report measures, are typically associated with higher rates of adherence in young people with IBD, when compared to objective measures

(Hommel et al., 2009; Wu et al., 2013). Such differences between the adherence measures were identified within Hommel et al.'s (2012) intervention, whereby subjective measures of adherence identified a significant increase in medication adherence, but this was not replicated in the intervention's objective adherence measures. Therefore, future interventions should include objective and subjective measures of adherence, thus capturing any variance in adherence behaviours.

While withdrawal rates were relatively low across the seven interventions (suggesting the interventions were both well received and feasible), there was nonetheless, under reporting of the demographic information for participants who withdrew from the interventions. As highlighted previously, demographic factors may play a vital role in the success of interventions (LeLeiko, 2007; Reed-Knight et al., 2011). Therefore, the provision of demographic information regarding participants who withdraw from interventions is important for the understanding of the feasibility of the intervention for different groups.

In general, even though the MMAT assessed the quality of the articles as good, the reporting of the content and delivery of the interventions was poor, often with researchers summarising the intervention's content into a brief table within the Appendix. This was often complicated by the absence of a detailed published intervention protocol. Not fully reporting the active components of these interventions led to a significant lack of information from which future interventions can replicate or develop further informed interventions. This has been previously identified as a limitation within the reporting of behaviour change interventions, in response to which, guidance has been developed to assist in the effective reporting of interventions (Hoffmann et al., 2014; Michie et al., 2011). In addition, some interventions required participants to identify their own adherence barriers and actively develop plans or set goals to help reduce these barriers (Greenley et al., 2015; Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017). Within the reporting of these interventions, there was no discussion regarding the barriers highlighted by young people and the plan or goal they were guided to formulate. Omitting this information again, makes it unclear whether the intervention was successful for reducing all adherence barriers or just a select few. Future behaviour change interventions should utilise tools to ensure the consideration of the most appropriate intervention options to obtain the required behaviour change (Michie et al., 2011). For example, the COM-B model suggests the barrier of forgetting to administer medications may require a different intervention strategy than the barrier of not wanting to take medication in social settings (Jackson et al., 2014). Clear reporting of the different intervention strategies utilised and the impact such strategies have on adherence is vital for the future development of evidence-based interventions. When evaluating an intervention, it is reductionist to focus solely on an intervention's effectiveness.

Rather, evaluations should look to assess *how* the intervention's mechanisms of change facilitated the desired outcome; in addition, researchers should evaluate the intervention in a broader context, for example by identifying secondary impacts of the intervention (Skivington et al., 2021).

A small selection of BCTs, as classified by Michie et al. (2013), were identified across the included interventions, however none of the included articles referred to the BCTTv1. Commonly utilised BCTs related to Goals and Planning, as well as Feedback and Monitoring. It is likely that there was a greater number of BCT's used within interventions than was reported. Three BCTs were associated with a successful intervention outcome (*1.4. Action planning; 2.2. Feedback on behaviour* and *12.5. Adding objects to the environment*), however these were only utilised by a small number of interventions. Two of these BCTs were identified within Greenley et al.'s (2015) intervention, which was only successful for a subsection of its participants. Thus, definitive conclusions cannot be drawn as to whether these BCTs are directly related to a successful intervention outcome. Two BCTs were associated with only unsuccessful interventions (*4.1. Instruction on how to perform the behaviour, 12.1. Restructuring the physical environment*), however, as these were each only identified in one intervention, a conclusion that the BCTs are not associated with improved medication adherence in young people with IBD, cannot be drawn with certainty. In addition, most of the identified BCTs were utilised in both successful and unsuccessful interventions, highlighting a need for further research.

One aim of the current review was to explore the use of behaviour change theory in the development of treatment adherence interventions for young people with IBD. However, none of the included articles explicitly mentioned how such interventions were informed by behaviour change theory. This highlights a major limitation in the design and reporting of such interventions and indeed, health interventions more broadly (Lippke & Ziegelmann., 2008). Future interventions may benefit from using an established intervention development framework, such as the Behaviour Change Wheel (Michie et al., 2011) or Intervention Mapping (Bartholomew et al., 1998), to provide a systematic approach to the development of an intervention and allow for greater transparency in the reporting of the intervention development process. The use of behaviour change theories/models should be considered when developing behaviour change interventions, as the utilization of such theories/models can provide a further understanding of the mechanisms underpinning how and why the intervention has succeeded or not, as well as what extent the intervention has succeeded.

2.4.1. Strengths and Limitations

A key strength of this review is that it has highlighted major gaps in the literature concerning interventions to increase adherence in young people with IBD. Further research is required to build on findings of this review to design and report more effective adherence interventions for this population. Another strength is the identification and collection of information in a systematic, rigorous, and robust manor, using structured coding frameworks, such as the Theory Coding Scheme (Michie & Prestwich, 2010). The current study was limited however, in its ability to perform in-depth analysis on the included interventions' content and subsequently was unable to identify the use of behaviour change theory within the interventions. Additionally, the research was unable to perform a meta-analysis due to the small size, and heterogeneity in methods used within the final sample.

Only a small number of studies were retrieved during the search process. This may be due to the review's strict inclusion/exclusion criteria. However, it is more likely to demonstrate a lack of behavioural interventions aiming to increase treatment adherence in young people with IBD. In the seven interventions included in this systematic review, there was a variety of measures used to determine impact on medication adherence. Although most of these measures were appropriate, there needs to be greater consistency in the type of measures used to assess the benefits of medication adherence interventions for patients with IBD.

2.4.2. Implications for research and practice

This review highlights several implications for research and practice, including the need for:

- A better demographic understanding of those who participate, and more specifically, those who benefit from interventions (e.g., participant age, gender, IBD diagnosis, medication routine, ethnicity). Without this, researchers cannot design good quality interventions to be used by healthcare professionals in clinical practice.
- A better description of behaviour change theory and BCTs. None of the interventions explicitly demonstrated use of behaviour change theory within the formation, application, or analysis of the intervention. Future interventions should explicitly report their use of behaviour change theory and BCTs within such interventions, to enable a wider understanding of why and intervention was successful or not, as well as the extent to which the intervention was successful.
- A wider geographical scope of intervention development and delivery. Despite an extensive search of the literature, nearly all the interventions were conducted in the

USA, primarily by the same research team and appear to have used the same patient populations and intervention content (Hommel et al., 2015; Hommel et al., 2012; Hommel et al., 2011; Maddux et al., 2017). This limits the applicability of these intervention outcomes to other populations of young people with IBD. Furthermore, it is essential that future research is conducted in more geographical locations to ensure adequate interventions are developed for the geographical needs of patients.

2.5. Conclusions

In the context of improving treatment adherence for young people with IBD, interventions that include the whole family and/or offer tailored advice to reduce personal adherence barriers have greater beneficial outcomes, than individual or educational interventions. Interventions involving a combination of education and goal setting strategies are also more likely to be successful in improving young people's adherence than those which include education or self-monitoring alone.

However, poor reporting of the intervention's content, participant demographic information and statistical results, mean that the evidence is too weak to make concrete recommendations regarding the effectiveness of intervention components. More research is needed to understand the benefits of theory-driven behavioural change interventions to improve treatment adherence in young people with IBD.

Chapter three: Supporting young people to live well with Inflammatory Bowel Disease (IBD): A Framework analysis.

3.1. Introduction

As discussed in Chapter one, negotiating adolescence while living with Inflammatory Bowel Disease (IBD) can be highly demanding for young people. While treatment non-adherence may provide young people with a short-term respite from the burden of managing their health, it can have significant clinical consequences. Interventions are therefore needed to support treatment adherence in young people during what is often experienced as a turbulent phase of life.

This Chapter presents a thematic framework analysis of qualitative data exploring the challenges young people with IBD face in adhering to their treatment plan, as well as what support young people want and need from an intervention. Data are presented from interviews with young people with IBD, parents, and healthcare professionals. Alongside findings of a systematic review of the topic (Chapter two), analyses from this qualitative study will inform the development of a new intervention to support treatment adherence in young people with IBD (Chapter four).

3.1.1. Chapter aims and objectives

Aim

The aim of this Chapter is twofold. First, to explore the challenges young people and families face in adhering to an IBD treatment plan. Second, to understand what support young people with IBD want and need from an intervention to address those challenges.

3.2. Method

3.2.1. Design

A qualitative approach was selected to support flexibility in investigating how participants make sense of their own and others' experiences, allowing for in-depth exploration of emergent issues (Ormston et al., 2014). Qualitative methods are especially beneficial for conducting research with adolescents as they can provide a rich understanding of how young people experience the world (Rich & Ginsburg, 1999). The study design was informed by the philosophical framework of critical realism (Chapter one). Critical realism is well suited to health sciences as it separates the premises of epistemology (e.g., thoughts) from the ontological view of an independent world of being and therefore, understands that human knowledge only represents a small section of a greater reality (Alderson, 2021; Ormston et al., 2014). Taking a critical realist approach can encourage identification of the underlying processes responsible for natural and social phenomena, rather than looking at surface level details (McEvoy & Richards, 2003). Complex health problems require research approaches to explore the intricacy of such issues to expand knowledge and make feasible suggestions to improve healthcare (Sturgiss & Clark, 2020). The impact of ill health on people's "empirical" and "actual" levels of reality are clear, however critical realism can be beneficial to investigate how causal mechanisms can determine people's "real" reality (Alderson, 2021). Therefore, taking a critical realist stance can enable researchers to gain a greater picture of people's health experiences and behaviours, and is appropriate for this research project. Semi-structured interviews were used as a tool to collect data from participants which is described further below in the section on data collection.

3.2.2. Sample & Recruitment

Purposive sampling was used to identify young people (aged 13-18) diagnosed with IBD, parents/carers of young people (aged 13-18) with IBD and healthcare professionals who work with young people with IBD. Recruitment was facilitated by a Consultant in Paediatric Gastroenterology at a Specialist Children's Hospital. The Consultant provided eligible participants with a pre-prepared study information pack, containing an invitation to take part in the research and participant information sheet (Appendix.3-6). Young people, parents and healthcare professionals who were interested in participating in the study were invited to contact a member of the research team, who would answer any questions before gaining participant consent/assent and arranging a suitable time for interview.

While the study was planned to recruit all participants from the Specialist Children's Hospital, NHS recruitment was halted mid-project due to the Covid-19 pandemic. As such, following discussion with the wider research team, the approach to data collection was revised. Opportunistic and snowball sampling were used to recruit young people and parents through advertising on the social media pages of two leading IBD charities, Crohn's and Colitis UK and CICRA. Respondents were asked to contact a member of the research team, who would answer questions and provide a pre-prepared study information pack via email. This pack included a letter of invitation, and participant information sheet similar to those used for

Hospital recruitment (Appendix.7-9). Young people and parents who were interested in participating in the study were again invited to provide their consent/assent before arranging a suitable time for interview (Appendix.10-13).

3.2.3. Data collection

In-depth semi-structured interviews were used to collect qualitative data from young people, parents, and healthcare professionals over the telephone or online using Microsoft Teams and Zoom. Due to social distancing restrictions imposed as part of the Covid-19 pandemic response, no in-person interviews were conducted. Research conducted throughout the pandemic has found that online interviews can be cost-effective, convenient and reduce participation accessibility barriers (Meherali & Louie-Poon, 2021). The use of digital platforms such as Teams or Zoom, are preferable to telephone interviews, because they facilitate researchers to observe participant's non-verbal communications, akin to an in-person interview (Gray et al., 2020). Online methods may elicit richer data, in comparison to in-person interviews, particularly when discussing sensitive topics, as participants can feel more relaxed being interviewed within a familiar location, without the physical presence of a researcher (Gray et al., 2020; Thunberg & Arnell, 2022). However, technical issues or a lack of visual information can threaten the quality of data collected using digital methods (Gray et al., 2020; Oliffe et al., 2021; Thunberg & Arnell, 2022) and thus must be managed accordingly.

Participants in the present study were encouraged to select a quiet location for their interview where they would not be disturbed and felt comfortable. It was anticipated that selecting a comfortable and familiar location would reduce feelings of uneasiness, particularly amongst young people, in a situation that they may never have before experienced and where power indifferences may have occurred (Schelbe et al., 2015). With the knowledge that pre-interview rapport building conversations can be more limited online (Jowett et al., 2011; Shapka et al., 2016), interviews consciously began with a discussion of the participant's or participants child's likes or dislikes, with the researcher providing personal disclosures on shared interests (e.g., enjoying similar past-times). Throughout the interviews, additional efforts were then made to reduce any power imbalance between myself (an adult researcher) and the young person. I was aware that ignoring this power imbalance could have impacted young people's unwillingness to ask questions or seek clarification during interviews (Duncan et al., 2009). To accommodate young people's cognitive and language abilities, accessible, clear language was used within the interviews as well as the participant information sheets (Kirk, 2007).

Interviews explored young people's, parent's and healthcare professional's views and experiences of the challenges young people face in managing their IBD and adhering to their treatment plan, as well as how an intervention could improve young people's adherence to their prescribed treatment (Appendix.14-16). Topics included family's medication and illness beliefs as well as practical, social, and emotional challenges of adhering to prescribed IBD treatment plans. Healthcare professionals were further asked about their knowledge of how previous interventions have benefited young people's adherence.

To facilitate data collection, I used an arts-based approach, inviting young people and parents to complete a creative mapping task allowing families to identify and rate possible adherence intervention strategies within a PDF document, shared with participants at the start of their interview (Appendix.17). Arts-based research methods can beneficially support qualitative interviews by adding a new dynamic to the research and assisting participants to communicate their views in a different way (Fargas-Malet et al., 2010). Additionally, arts-based methods can further help reduce the power imbalance between adult researchers and young people, as they allow participants adequate time to think about their response rather than feeling pressured to answer the question "correctly" (Punch, 2002). The creative task was designed to explore what participants perceived to be the most significant barrier young people faced to adhere to their treatment plan, as well as what support options would facilitate or hinder overcoming this barrier. When selecting barriers, participants could either recall something from their own experiences or choose a barrier that they believed others would encounter. Proposed adherence barrier solutions were categorised along a spectrum of 'very helpful', 'slightly helpful', or 'unhelpful' (Appendix.17). The use of support mapping techniques within qualitative research can assist participants to answer the research questions in more detail and maintain participant engagement within interviews (Fargas-Malet et al., 2010; Greyson et al., 2017; Punch, 2002).

Each interview lasted approximately 60 minutes, depending on how much the participant had to say. Following completion of the interview, participants were debriefed on how their information would be kept confidential within the reporting of the research, as well as on their right to withdraw data if they wished to. Each participant was further asked to complete a short demographic questionnaire (Appendix.10-13), which allowed for the findings to be interpreted in context. As a token of thanks, parents and young people were compensated for their participation with a £15 online shopping voucher.

3.2.4. Data Analysis

Interviews were audio-recorded and transcribed verbatim. Transcripts were anonymised and analysed using a thematic framework analysis method (Ritchie & Spencer, 1994). Framework Analysis is a flexible, qualitative approach that permits in-depth exploration of the views and experiences of participants through the active generation and interpretation of themes by the researcher. It supports identification, analysis, and reporting of patterns within the data, and is suited to health research due to the methodological ability to compare experiences both within, as well as across cases (Gale et al., 2013). Data analysis was carried out in accordance with the five stages of the framework method, outlined by Ritchie & Spencer (1994). The process of analysis was carried out as follows.

Step 1: Familiarisation. During this initial stage, I became familiar with the interview transcripts through repeated reading and note making. This process was continued until I felt I had a good understanding of the diversity of experiences and characteristics within the data. Throughout this process I recorded potential codes based on thematic or conceptual notions identified within the data. Codes were related to ideas such as young people’s experiences of adhering to treatment plans in different situations, illness and treatment beliefs and beneficial sources of adherence support. Towards the end of this step, I further revised and combined potential codes to create a collection of initial codes for each participant group (young people, parents, and healthcare professionals). This involved referring back to the original transcripts to ensure the initial meaning of each potential code was preserved.

Step 2: Identifying a thematic framework. To capture the variety of participant experiences, I created a thematic framework for each group of participants (young people, parents, and healthcare professionals). The development of each framework followed the same process. Initially, I began connecting ideas within the initial codes in order to revise and refine codes. This involved going back and forth between the interview transcripts and initial codes, to ensure my analysis remained grounded within the data. As part of this iterative process, I began organising codes into groups and subgroups, to form an initial framework, again this involved referring back to the interview transcripts until I felt each framework was an appropriate representation of the codes identified within the data. Within each framework, groups and subgroups of codes were given a descriptive name. Finally, codes were also individually named and given a brief description to differentiate between each code within the framework.

Step 3: Indexing and sorting. For each group, I applied the final coding framework to all relevant transcripts. Within the transcripts, each sentence was examined in fine detail to determine which element of the framework was applicable. If data was identified which did not fit into the coding framework, the framework was revised to add the new code and previously coded transcripts were revisited. In line with Spencer et al.'s (2014) suggestion, some data items were labelled with multiple codes, to both preserve the meaning of the indexed items and promote further insight or analysis of indexed data.

Step 4: Charting. Using a spreadsheet, I developed a framework matrix for each participant group. Each framework matrix was sorted into themes, whereby each subtheme was allocated a column (Appendix.18). Doing so allowed me to return to the original material with ease when assessing thematic meanings and relevance. Within this stage, I summarised each code to reduce the amount of data, whilst maintaining the intention of each participant's indexed quotes (Gale et al., 2013).

Step 5: Mapping and Interpretation. As suggested by Gale et al. (2013), I maintained a reflective journal to record my analytical thoughts and ideas throughout the mapping and interpretation of the data. Themes and subthemes were analysed to understand the mechanisms underpinning the themes, as well as, how the range of participant views and experiences were impacted by such mechanisms. Connections and differences within themes for each group were identified and mapped onto previously existing knowledge and behaviour change theory.

A subset of transcripts were independently coded by another member of my supervisory team (GH/LA/RS), this promoted reflectivity and discussion within the research team, as differences in coding were discussed in order to clarify any conflicting interpretations (O'Connor & Joffe, 2020). This process aided the analytical process, as it incorporated different interpretations within the data analysis. Furthermore, my reflective journal was used throughout the data collection and analysis process, allowing key ideas or concepts to be recorded as they developed.

3.2.5. Ethics

Due to the Covid-19 pandemic, this project experienced considerable research complications, resulting in the need to obtain two sets of ethical reviews. Initially, a favourable review was obtained through the NHS Research Ethics Committee, London Bloomsbury board (IRAS #126868) to recruit participants from the gastroenterology department within a Specialist Children's Hospital. However, recruiting participants via this site was hindered during the Covid-19 pandemic. A favourable ethical opinion was then obtained from the School of Life and Health Sciences Research Ethics Committee at Aston University (ref: Project #1648) to recruit participants through UK-based charities, Crohn's and Colitis UK and CICRA.

All participants provided informed consent. Young people aged below 16 years of age provided informed assent with parental consent (Appendix.10-13).

3.2.6. Reflections on the data collection process

Throughout this project I was conscious of how I presented myself to participants. As my initial contact with families and healthcare professionals was over email, I paid attention to the language used within each correspondence to ensure it was friendly and welcoming. At the start of each interview, I introduced myself to participants as a PhD health psychology researcher, who was interested in understanding more about family's experiences of living with IBD and adhering to IBD treatment plans. When discussing the project, I used plain English and stressed the importance of understanding participants experiences, to help other young people who may be struggling with their adherence. I also informed participants the PhD project was part funded by Crohn's and Colitis UK, as most families were a member of the organisation this strengthened families' views on the importance of the research project. I also outlined that even though a Specialist Children's Hospital's paediatric gastroenterology department were partners in this project, I myself was not part of the gastroenterology team, as I wanted to ensure families understood that while I had developed a good understanding of IBD, I was not a medical professional. This aimed to reduce the power imbalance between myself and participants', as it emphasised the value of participants expertise within this research.

3.2.7. Reflexivity

As an individual who also suffered with ill health during childhood, there was a resounding familiarity with the topics discussed within the interviews. After being diagnosed with Myalgic Encephalopathy (M.E.) aged seven, I experienced severe cognitive and physical fatigue which heavily impacted my mobility and school attendance. When participants discussed their concerns about missing social and school activities, I was reminded of my own experiences and how living with a chronic health condition distanced myself from my friends.

When young people discussed the importance of their parent's ongoing support, I also understood the value of this, as when you are unwell as a child, your parents are often your main source of comfort and reassurance. However, as I am not a parent, I was unable to relate to parents' experiences of supporting their child. I therefore discussed such matters with my supervisor, who was able to share their analytical interpretations of the data from a parental perspective, which provided additional context to my analysis. Furthermore, I understood participants' frustrations over living with an invisible illness, and societies' lack of awareness over the complexities of not looking as unwell as you feel. It is likely that my health experiences and the empathic response induced within the interviews impacted on my data collection methods and analysis. However, my reflective journal supported me to question my analytical thoughts and discuss such matters with my supervisory team to ensure my analysis remained focused on my participants experiences.

Due to being a relatively young adult myself, I could relate to the pressures of adolescence discussed by participants, such as the complexities of navigating peer pressure, academic stressors, as well as developing your own identity. However, as someone who rarely uses social media and had limited internet access during their adolescence, my participants' extensive use of social media felt alien to me. Young people were joining social media support groups to validate their experiences and seek health advice while avoiding such discussions in their friendship groups. At points when young people discussed their trust in social media group members' suggestions, it was challenging to refrain from highlighting the possibility for group members suggesting false information. Rather it was important to look beyond my concerns and aim to understand how social media groups met young people's adherence support needs.

3.3. Findings

3.3.1. Participants

A total of 33 interviews were conducted, with young people with IBD, parents of young people with IBD and healthcare professionals who work with young people with IBD.

Twelve young people aged between 13-17 years were recruited and interviewed (Table 5). This included eleven young people with a diagnosis of Crohn's Disease and one young person diagnosed with Ulcerative Colitis. The sample consisted of roughly equal numbers of males (N=7) and females (N=5). Most young people had received their IBD diagnosis within the last three years, with an average age at diagnosis of 14.75 years. The sample were primarily prescribed azathioprine, an oral medication, and/or humira, an injectable biologic medication. The sample also included one participant who lived with a stoma, an opening in the stomach to allow the contents of the bowel to be emptied into an external pouch. Three quarters of young people identified as White British.

Thirteen parents of young people with IBD were recruited and interviewed, this included nine participants whose children had also took part in the research project; however, all parents and young people were interviewed separately. More mothers (N=11) participated in the research than fathers (N=2), with an average age of 53.17 years (Table 5). Most parents identified themselves and their children as White British. Participants reported their children were currently between the ages of 13-17 years and had received their IBD diagnosis between the ages of 3-15 years. Most parent participants' children were male (N=7), diagnosed with Crohn's Disease (N=9), and prescribed azathioprine and/or humira. Two participant's children lived with a stoma.

Table 5. Participant characteristics

		Young person (N=12)	*Parent (N=13)*
Child Characteristics	**Age (Mean, SD)**	14.75 (1.42)	14.38 (1.44)
	Gender (N=)		
	Male	7	7
	Female	5	5
	Non-binary		1
	Ethnicity (N=)		
	White British	9	11
	White Irish	1	
	Indian	1	1
	Pakistani	1	1
	Age at Diagnosis (Mean, SD)	12.08 (2.66)	10.77 (3.26)
	IBD Diagnosis (N=)		
	Crohn’s Disease	11	9
	Ulcerative Colitis	1	3
	IBD-Unclassified		1
	Medication (N=)		
	Azathioprine	5	5
	Humira	5	6
	Infliximab	2	1
	Methotrexate	2	
	Ustekinumab	1	
Parent Characteristics	**Age (Mean, SD)**		49.08 (5.6)
	Gender (N=)		
	Male		2
	Female		11
	Ethnicity (N=)		
	White British		11
	White Irish		
	Indian		1
	Pakistani		1

Of the 13 parents and 12 young people who took part in this research, nine parent and child pairs took part, with a further three young people whose parents did not take part, and four parents whose children did not take part. Jordan, a 17-year-old diagnosed with Crohn’s Disease, is the child of Tina. Erika, a 15-yearold diagnosed with Crohn’s Disease, is the child of Clare. Damien is a 16-year-old diagnosed with Crohn’s Disease, and the child of Hannah. Aiden, a 15-year-old diagnosed with Crohn’s Disease, is the child of Philippa. Maria, a 14-year-old diagnosed with Ulcerative Colitis is the child of Hasim. Amy, a 14-year-old diagnosed with Crohn’s Disease is the child of Fiona. Felix, a 13-year-old diagnosed with Crohn’s Disease, is the child of Sadie. Oliver is also 13 78 years old, diagnosed with Crohn’s Disease, and the child of Beverley. Vihaan, a 14-year-old diagnosed with Crohn’s Disease is the child of Priya. The three young people who took part in the research, but whose parents did not, included Laura, a 16-year-old, Leila, a 17-year-old, and Robert, a 13-year-old, all diagnosed with Crohn's Disease. The additional four parents who took part, but whose children did not, included Julie, the parent of a 13-year-old diagnosed with Crohn's Disease. Steve, also the parent of a 13-year-old diagnosed with Crohn's Disease. Maxine, the parent of a 13-year-old diagnosed with Ulcerative Colitis.

Eight healthcare professionals from a Specialist Children's Hospital were interviewed. This included a range of job roles including: Paediatric Gastroenterologists (N=3), Specialist Nurses (N=2), Dieticians (N=2), and a Psychologist. Most healthcare professionals had worked with young people with IBD for a significant period, with an average of 11.31 years qualified in their current role, with a range of 3-33 years. To provide additional context to the participants views and experiences discussed within the analysis, Table 6 contains relevant information for healthcare professionals.

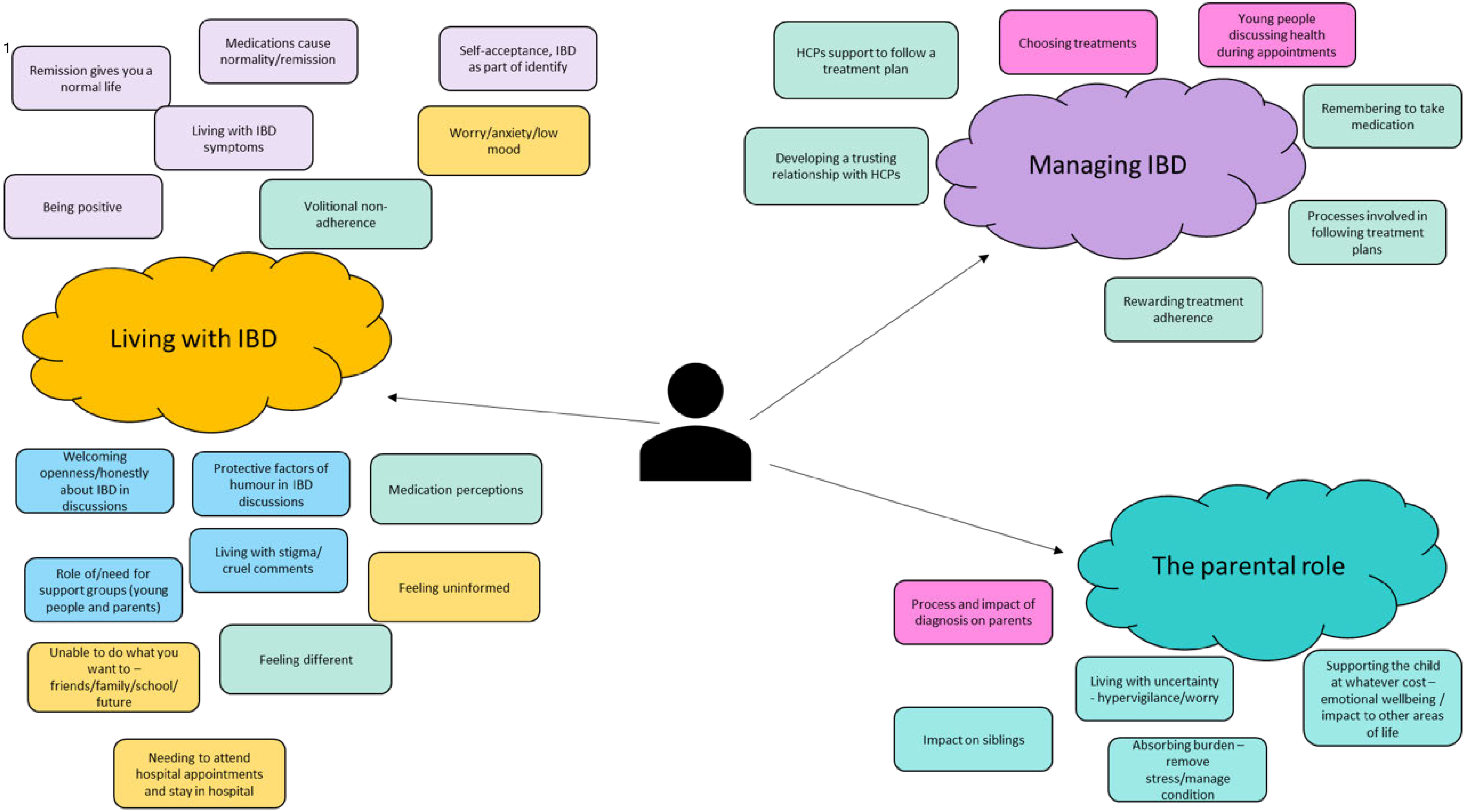
Table 6. Healthcare professional's job roles

Pseudonym	*Job role*
Healthcare professional 1	Advance Nurse Practitioner
Healthcare professional 2	Clinical Nurse Specialist IBD
Healthcare professional 3	Consultant Gastroenterologist
Healthcare professional 4	Paediatric Gastroenterology Registrar
Healthcare professional 5	Specialist Paediatric Dietitian
Healthcare professional 6	Specialist Paediatric Gastroenterology Dietitian
Healthcare professional 7	Consultant Clinical Psychologist
Healthcare professional 8	Consultant Paediatric Gastroenterologist

3.3.2. Analysis findings

Analysis generated three themes across the whole dataset which explored barriers and facilitators faced by young people to follow their treatment plan: Living with IBD; Managing IBD and Parental role. A visual representation of the topics relevant to each theme was developed to convey the complexity of treatment plan adherence (Figure.6).

Figure 6. Thematic map of data codes[1]



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[1] This figure details how the data codes within the thematic framework, were combined to create the themes discussed within this chapter.

Living with IBD

"It's a pain in the arse, literally" (Damien, young person).

This theme explores what it is like for young people to live with IBD. It contains four related ideas: that living with IBD means living a limited life; that in managing their IBD symptoms, young people are always striving for a sense of 'normality'; that young people with IBD feel different to their friends; and that living with IBD means living with stigmatisation.

Living a limited life

Physical and cognitive fatigue as well as having "constant pain all the time" (Oliver, young person) featured heavily in young people's accounts of life with IBD. As such, their accounts were peppered with examples of feeling unable to participate in 'normal' activities. To manage their symptoms, young people developed coping strategies including taking regular breaks and distraction. Despite experiencing pain or fatigue however, young people often chose to hide these feelings from their friends and family, to "make yourself look like you have more energy than you actually do" (Felix, young person). Often young people did not want to be treated differently.

The most prominently discussed IBD symptom by young people was a sense of urgency and lack of control over their bowels.

> "[I was] having accidents like every other day, I could never make it to the toilet in time…it was honestly terrible" (Erika, young person).

Understandably, these symptoms limited the social activities young people felt able to partake in because "it's embarrassing having to go to the toilet if I need it" (Laura, young person). Young people thus foresaw facing difficulties in maintaining friendships due to their peers' understanding of IBD.

> "[Young people with IBD] couldn't really be a part of a sort of movie night because they had to go to the toilet all the time, it can feel kind of distant from their friends because their friends don't have what they have and they don't understand, which then internally can cause a kind of conflict and then you may even lose your friends because of that" (Damien, young person)

Schools often provided a pass or so-called "get out of jail card" (Hannah, parent), which permitted young people to leave lessons to use the toilet without needing a teacher's approval. However, using such passes left young people feeling embarrassed because of highlighting their difference. When leaving the home, families described needing to plan ahead to ensure young people had access to a toilet.

Striving for normality

Young people and parents aimed to live a normal life, free of the restrictions of living with IBD. Often this motivated young people to follow their treatment plan, as doing so was perceived to encourage wellness. Remission was viewed as the desired outcome for all families and was even referred to as a “golden ticket” (Maxine, parent) due to its ability to relieve young people of the shackles of living with IBD. Families discussed the possibility of young people entering remission as if this were to be a cure for their IBD, rather than a temporary state of symptom reduction. Furthermore, young people experiencing remission reported they were able to live a so-called normal life and “look past my medical limitations and do what I wanna do” (Damien, young person).

For families, normality was perceived as an existence without the stress or limitations of managing the young person’s health needs. Families discussed how healthy eating supported medical treatments to facilitate remission and maintain periods of wellness, however, some parents strongly disbelieved the role of diet in the management of their child’s IBD. Within online resources, there was a plethora of information stating diets can both cause and cure IBD, therefore, some parents refuted any associations with diet in their child’s treatment plan to protect themselves from accusations of blame over the cause of their child’s IBD:

> “I absolutely dispute it because then you live with that guilt that you’ve done something or given something to your child that has caused this disease. No. I I don’t buy that at all” (Maxine, parent).

IBD medications were often perceived as the gateway to remission, and therefore young people were motivated to maintain their adherence behaviours both before and during entering a period of remission to “take care of themselves so they can get better in the future” (Maria, young person); such motivation was maintained even when prescribed ineffective or unpleasant medications.

> “You should make them think of the benefits and the results and the idea of going into remission and being able to lead a normal life and all I have to do is take a medication that may be a bit inconvenient and may not taste nice...and you can finally have a healthy body” (Damien, young person)

I am not like my friends

To adhere to their treatment, young people described a requirement to engage in behaviours that made them stand out from their peers, which often hindered their compliance. Within social situations, the inability to mirror friends eating habits also caused emotional upset and promoted non-adherence. Prolonged adherence to medications with severe side-effects were challenging for young people, as they perceived their treatment to be shrinking their world rather than opening it up. The persistent need to cancel social events was difficult for friendship groups to understand and left young people feeling socially isolated and questioning the benefits of adhering to their treatment plan.

> “I used to stay at home all the time I was missing loads of school, I wouldn't do anything with my friends, I started to lose quite a lot of friends.” (Erika, young person)
>
> “Thursday with my methotrexate I know on Friday I’m not going to feel well after it, so that just restricts me on what I can do on that day, and trying to explain that to my friends is sometimes a bit hard…with my infliximab too I have to sometimes stay off school after it so I can’t be with my friends so I feel like that really limits me on what I can do in terms of going out and hanging with my friends” (Leila, young person)

Medication perceptions were a crucial factor in young people’s adherence behaviours. IBD medications which provided a respite from symptoms and enabled a better quality of life were preferred by young people and promoted adherence. Additionally, medications that were perceived to be easy to administer and had a lesser impact socially were preferred; “The medication I have, it’s not hard to have access to, you could probably bring, you could just cut out a couple and just put them in your pocket, when you’re going out and just go” (Felix, young person). IBD treatments that permitted discretion were incremental with disclosure of information regarding IBD often being avoided by young people: “it’s not something I want the whole world to know” (Vihann, young person). Attending hospital appointments was also disliked by most young people because it added disruption to their normal lives and contributed to embarrassment of having to leave school whilst being asked “what’s wrong with you” (Amy, young person).

Overall, interactions within hospital settings caused distress for young people, as Laura (young person) explained “I find myself getting quite upset when I go into hospital and stuff…because I don’t want to be going there but obviously, I need, I need to be going there”. Such interactions included undergoing medical procedures such as MRI’s or colonoscopies as well as attending pre-appointment blood tests. However, some families were able to make appointments with nurses who came out to the young person’s home which limited the disruption to young people’s lives, this was subsequently well received by families.

> “I think for young people [hospitals] are quite frightening…there was a lot of people with tubes, MG tubes and things like that, and they obviously, there's a lot of sick people there seeing the doctors, and when [my child] went in for his colonoscopy there was lots of very sick children, and I guess he was sort of thinking, crikey, you know, I could be like that” (Phillipa, parent)

Conflict within the home encouraged young people to display volitional non-adherence behaviours as “whatever [parents] say you might just ignore it and not believe in it simply just to spite them” (Damien, young person). Conflict often arose due to young people’s perceived lack of importance to follow treatment plans; healthcare professionals discussed the need to make young people aware of the necessity of adherence to maintain feelings of wellness. However, parents’ persistent hypervigilance and medication prompts served as a reminder that the young person had a chronic condition which contrasted with the normality they felt or sought during periods of wellness. Subsequently, parents perceived their child thought “oh I’m better why do I need to carry on taking medication” (Fiona, parent). Volitional non-adherence behaviours were displayed as a form of rebellion when young people felt their parents were constantly reminding them of the need to follow their treatment plan.

> “My parents were like every day, have you taken it, have you taken it? Or if I was like yeah, I will take it now and I don’t end up taking it, they’re like have you taken it, have you taken it? And on average, it did start to annoy me and I thought you know what, I might as well not take it and umm see what happens. Because if they made it out like this really really really like big thing that like needed to happen, I’d be like oh I wonder what happens if it doesn't?” (Erika, young person)

Living with stigma

IBD was understood to be an uncomfortable subject as “not many people talk about going to the toilet, do they?” (Laura, young person). Most parents discussed the taboo of IBD and the impact this has on young people’s emotional wellbeing:

> “I wish there was the confidence to, you kinda need to make shit sexy, literally…People don't like talking about bowel movements and farts” (Sadie, parent).

The stigma of needing to use toilets outside of the home was described as overwhelmingly embarrassing for young people, who feared negative consequences to their friendships. Young people felt uncomfortable using the toilet at parties and feared peers formulating untruthful reasons for why they had spent so much time in the toilet; “even if you say I’ve got a condition, people are gonna think you are doing something suspicious or whatever” (Damien, young person).

To avoid stigmatisation and cruel comments, young people often hid their IBD from others. Some parents endorsed this as it “can be both annoying and a bit depressing that you have to answer these questions every time” (Priya, parent). However, when their IBD could not be hidden, young people were frequently faced with hurtful comments from others; often targeted at IBD treatment routines, especially when young people underwent a liquid diet. While families acknowledged this was due to other’s lack of understanding, it was incredibly upsetting and encouraged non-adherent behaviours.

> “I remember taking the liquid diet, and I had to go to school, and I was eating an ice lolly in…like the eating area, and someone threw some chicken at me and they were going urgh what are you eating an ice lolly for you weirdo…it made me feel really bad like eating an ice-cream at school for a few weeks I think, because I was worried what people would think…I used to be really hungry, but I didn't want to [eat] just in case people thought I was weird” (Erika, young person)

To distract young people from the enormity of living with a chronic condition, parents actively encouraged children to learn to accept their diagnosis and adapt their IBD as part of their identity, in the hope that those around their child would do the same and thus, protecting their child from possible stigmatisation and isolation. This was apparent in some young people who discussed the extent to which their diagnosis had become entwined with their identity; “I wouldn’t be me if I didn't have it” (Erika, young person). However, some healthcare professionals suggested merging one’s intrinsic self with their health condition may be unbeneficial for young people’s wellbeing, instead, parents were suggested to place value on the child’s characteristics beyond their IBD.

Encouraging adolescents to view their condition and treatment routine as a welcomed part of normal life was perceived to be beneficial for young people’s emotional wellbeing, as parents believed this would support their child develop a healthy body image and foster a sense of confidence in young people to discuss their IBD with others. Within the home, parents aimed to include the child’s IBD in conversations to normalise their experiences and reduce feelings of embarrassment or uneasiness; “We've always sort of said to her if you're comfortable with it, and you're comfortable to talk to people, it's not an embarrassing thing” (Clare, parent). Some young people used humour as a protective factor against hurtful comments as “[my child’s] very much if he could take the mickey out of himself, then he deflects away from anybody else saying anything to him” (Tina, parent). For these young people, humour was a preferred method of coping with the emotional difficulties of living with IBD and facilitated self-management behaviours. Other young people required additional psychological support due to symptoms of low mood and anxiety induced by living with IBD symptoms and stigmatisation. Those who engaged with psychological services found the support invaluable as it provided young people with another trusted adult to share their worries and concerns with, as well as sharing important self-management skills to promote health and wellbeing. Healthcare professionals equally valued the benefit of referring patients to Psychologists, and wished they had greater access to this.

Joining online IBD support groups allowed young people to build a network of support free of stigmatisation, whilst providing a sense of anonymity. This level of disclosure seemed preferable to young people as they could distinguish between their IBD-support networks and friendship groups. Other online support group members were perceived to “know exactly what you are going through” (Laura, young person) and thus not only relate to their experiences but provide a sense of acceptance over living with IBD. The nature of online communication encouraged young people to reach out for support when they needed it. Young people often reviewed their condition knowledge harshly and felt that they were ill informed in comparison to other young people with IBD, despite accurately and articulately discussing their condition. Online support networks were perceived as a reliable trustworthy resource to further young people’s knowledge and understanding of their experiences and treatment adherence behaviours. A selection of young people felt able to share their diagnosis with friendship groups and in doing so, received practical and emotional support from their friends who were willing to adapt their normal activities to be inclusive of the young person’s health needs.

> “They used to always come to the toilet with me and be like oh no it’s ok I’ll wait for you or when I was ill, we used to come round and we would just not do anything we’d just watch a movie or we'll chill. And now they’re always like ah do you need to empty your [stoma] bag, I’ll come with you…when my [stoma] bag exploded at my friend’s house, she phoned my mum who came around and sorted it out” (Erika, young person)

Managing IBD

To manage their IBD, families and healthcare professionals described the need for young people to take on responsibility for their condition by establishing and following treatment routines within their daily lives, as well as communicating their health needs within medical appointments.

Establishing and following treatment routines

Initially families were involved in the decision-making process surrounding a young person’s treatment. This benefited young people’s adherence as families were able to discuss their preferences in terms of the young person’s lifestyle or personal requirements and the benefits and consequences of maintained adherence to certain treatments. However, being involved in the treatment decision process was overwhelming for some families, as they reported “I am not a medical expert I don’t know if this is right or not” (Maxine, parent). Subsequently, families felt ill-informed to make the decisions and thus relied on healthcare professionals to do so, which could have clinical consequences.

> “You discuss [their treatment] with them and you give them the choice…in my experience most of the time families get confused, they say doctor you decide…I do tell them that I can decide but then the problem is at the first hurdle, the first inconvenience your son or daughter experiences you, you don’t want to continue the treatment you say that was never my choice, that was your choice, I want the other treatment…so I tell them no, you need you, to make up your mind after taking your time, if you want longer time take that longer time but come to a choice and then stick with that choice” (Healthcare professional 3)

Implementing treatment routines initially involved families understanding the process of how to follow young people’s treatment plans; this was often difficult when young people were prescribed multiple medications. Training was provided to families whose children were prescribed injectable medications to ensure successful treatment administration, which was well received by families as injectable medications were “quite easy to mess up” (Vihaan, young person). Learning the process of injecting medications was emotionally challenging for some families, due to the fear of the process going wrong or parental concerns over causing harm; “I was shaking… having hot sweats my hands were clammy…I felt like I was having a panic attack” (Tina, parent). When parents were anxious about administering medication, such emotions were transferred to the young person.

> “You might feel maybe like unconfident about it or you might feel really nervous about it, but then [parents] feeling nervous and like kind of saying ooo I don’t want you to do this because it’s going to hurt you or something like that maybe might make you back off and make you think it’s going to be bad for you” (Amy, young person)

Regardless of the medication type, families aimed to identify an appropriate time to take their medication within the home. For some the easiest way of doing this was by selecting a time within their normal routine which facilitated medication taking, as “if you have it at like a certain time, then I think that would be so much better and so much easier to remember” (Erika, young person). The use of self-implemented treat-based rewards facilitated maintained treatment adherence. Additionally, young people perceived improvements in clinical results as a reward for their adherence behaviours and strengthened their desires to continue to follow their treatment plan. Most young people had experienced a change to their physical activity and sleep patterns due to their IBD symptoms. However, as their condition improved, young people began reengaging with these lifestyle factors and adopting them into their treatment routine to further improve their health; “since I have been like doing more exercise, I feel like [my IBD] is more controlled” (Maria, young person). Young people also formed habits for relevant beneficial lifestyle behaviours to improve their condition management. Healthcare professionals discussed the individuality of dietary guidance and the avoidance of generalised advice; “we didn't really go for a, a blanket sort of diet, it's more specific for each patient” (Healthcare professional 5). To avoid symptom inducing foods families checked food labels to ensure a trigger food’s exclusion.

> “We can adjust [my child’s] diet accordingly and make sure that she's eating as healthy as possible, while also that she's not eating anything that’ll serve as a trigger and that's why [my child’s] reading the contents of a ready meal…we'll have read the box, you know, is there any onions in there, is there any peppers in there, anything like that, which we know are triggers” (Steve, parent)

Young people were required to consistently remember their treatment plan, this was often threatened during times when family routines differed to that of the norm, such as school holidays or weekends. Equally, medications were forgotten due to being busy with educational or social activities; “sometimes like you're busy at night and you just forget, and then you’re just tired and fall asleep” (Jordan, young person). To prompt medication adherence, some young people placed their medications in a clearly visible location. Whilst most visual prompts were implemented by parents, young people preferred such methods as they were perceived to promote autonomous self-management behaviours with little impact on their lives. To further overcome medication forgetfulness, prompting messages were used by families to facilitate a young person’s adherence; often such reminders were implemented by parents.

> “It’s just, having someone, or your phone, or like maybe you're echo dot you’re like smart assistant, just having a reminder every time you normally take it, just to have that and if you don’t have anything, I think it could be probably impossible for me to remember, because I’ve got my phone that tells me, I’ve got my mom which is most and then I’ve got my smart speaker. And without all those I probably wouldn’t know what medication is” (Felix, young person)

Interactions with healthcare professionals

Families believed forming honest and trustworthy relationships with healthcare professionals was highly beneficial for their child’s health and treatment adherence. Upon referral to gastroenterology services, young people encountered medical professionals who demonstrated understanding and empathy over their experiences. This was a stark contrast to their previous encounters with other health professionals, who had suggested the young person’s symptoms were normal childhood experiences or psychological manifestations;

“when we went to see the GP about it, they didn’t really think it was anything serious they kind of just thought that it wasn't really there” (Vihaan, young person). Trust was often formed based on young people perceiving healthcare professionals to be a credible source of information due to their IBD expertise; “They are professionals they know what they're doing” (Jordan, young person). For parents, developing trust with their child’s healthcare professionals was the most important part of their IBD journey.

> “It's massively important because you're sort of trusting them with you know your most important thing aren’t you and you, to have that confidence it doesn't just come straightaway it comes over time. But I think that I knew as soon as I met [the consultant]… I just instantly felt comfortable with how he was going to do it… I knew that he was the right person to look after [my child]” (Clare, parent)

Parents perceived young people were more likely to display adherence behaviours if the advice to do so came from healthcare professionals; “The doctors told him to do it…so he’s doing it” (Beverley, parent). Healthcare professionals further extended the trusting relationship by encouraging honesty from young people about their adherence behaviours. The relaxed tonality within these conversations allowed young people to share potentially uncomfortable omissions of non-adherent behaviours and challenges to following treatment plans. Healthcare professionals also provided an environment whereby young people felt capable to discuss changes to their health. By doing so young people were developing essential self-management behaviours as well as providing healthcare professionals with the required information to alter treatment plans to match young people’s needs. When healthcare professionals directed their questions towards young people, this was preferred by families as it empowered young people to discuss their IBD.

> “I know that like, I’m not just a kid anymore like I know I am more independent about it and I can like figure it out more myself like if [the consultant] has a question, he will always ask me and then if I’m not sure then maybe ask my parents but I think that’s quite good” (Amy, young person)

The parental role

Throughout the interviews, it was clear that parents had an essential role in the management of their child’s health condition. This theme explored the provision of parental support at all costs, parents’ experiences of navigating uncertainty and parental desires to absorb the burden of living with IBD from their child.

Support at all costs

Parenting a child with IBD caused a strain on family functioning however parents viewed their responsibility to provide care for their child as “that comes first doesn’t it” (Clare, parent). Parents ensured their availability to care for their child by limiting their social interactions or making changes to their employment. Nearly all young people expressed their extreme gratitude for their parents’ continuous support:

> “I can’t thank them enough for everything…When I look back and I don’t know how they helped me through that because I can’t imagine any of my friends’ families being like that” (Erika, young person)

It was acknowledged that siblings had not received equal amount of attention or parental involvement during their childhood due to prioritising the child with IBD’s needs; parents felt guilty for their lack of involvement and the emotional impact this had on the household. For healthcare professionals the involvement of parents in a young person’s condition management was vital, and viewed households where parents were not supportive of young people’s IBD needs as a cause of concern. The provision of persistent emotional and practical support was viewed as part of parents’ identity; “I did the motherly thing I was there for her” (Fiona, parent). Parents hoped that in doing so this would motivate their child to discuss their concerns, thus improving their child’s wellbeing. Displaying emotional strength was further conceptualised as part of the parental role and encouraged parents to ignore their own wellbeing needs.

> “My role as a dad, I’m a dad innit, so I’ll make sure that we, we’re there that we’re supporting her like as a father I am there, like you know she can tell me anything she wants. I tell her not to keep it bottled up and if she needs you know someone to talk to even as a friend, so I tell her don’t see me as a dad, you can see me as a friend as well” (Hasim, parent)

Navigating uncertainty

Parents struggled with the relapse and remittance nature of IBD and were worried that their child would experience future episodes of extreme ill health; “I never forget that he's got Crohn’s…it’s always in my mind, in weekly weekly thought…it's always it's always there in the back of my mind” (Tina, parent). Such concerns were enhanced when parents had experienced prolonged periods of distress prior to their child’s diagnosis. Whilst parents longed for an understanding of their child’s symptoms, receiving a diagnosis was a highly emotive experience; both the alienation and uncertainty of IBD caused feelings of immense worry in parents, despite healthcare professional's reassurance. Parents experienced further low mood over their child's diagnosis as they felt unsupported and uncertain over how to manage their child's health. On occasions when parents felt unable to contact healthcare professionals, such as over the weekend, this resulted in feelings of isolation and frustration as their child was "coming home with these symptoms at the weekend, that's when you've got nobody to turn to and that's when it's a really hard place" (Clare, parent). To fulfil the support deficit parents turned to the internet to answer their questions but this often-caused further concerns.

> "We was told by the consultant not to go on Dr Google and to only look at certain website you know the NHS website and Crohn's and Colitis UK umm but I made the mistake of going on others and I was just searching for anything…I was reading the wrong things basically I was reading all the worst case scenarios and it just, it just put me in a terrible state" (Fiona, parent)

Parental worry over future adverse events resulted in parents displaying frequent hypervigilant behaviours over their child's IBD, including continually questioning their child about their health to check for indications of an IBD flare; "I am just constantly checking that [they're] OK daily…check [their] poo's when [they] goes to the toilet" (Phillipa, parent). However, this hypervigilant behaviour encouraged young people to avoid discussing their health with an overly concerned parent to cause both parties less emotional distress. Future life events, such as young people leaving home or moving to adult healthcare were a significant cause for anxiety amongst parents, who felt unable to let go of the management of their child's health. Philippa (parent) discussed their chronic anxiety over their child leaving home, "I'd be worrying about him constantly, but that is going to be the rest of my life I guess anyway." Parents of older teenagers began preparing strategies to continually manage their child's health when their child lived outside of the family home.

> "Those are my worries for the future, how he will, how he will store the his his injections at university, whether he'll remember, will I still, you know, kind of like have the reminder on my phone to, for him to take it. Umm, will will I have to ring him and say have you remembered, because I might not be able to let go of that kind of umm, well, just the control of it really. So, I still feel I'm in control of whether he's taken it or not" (Tina, parent).

Absorbing burden

Parents felt it was their responsibility to shield their child from the burden of managing their condition and take "any stressful situations out of his life, so that he doesn't have the stress…he doesn't have the worry of what could happen" (Tina, parent). To safeguard their child from worry, parents withheld potentially upsetting IBD information. Healthcare professionals facilitated this behaviour by providing parents with the choice of discussing unpleasant aspects of their child's health, without the child present. For some parents, absorbing the burden of living with IBD involved taking over the full management of the child's health, including arranging medical appointments and ordering the young person's medical supplies. Whilst "it was a strain, having to do that regularly" (Julie, parent), this was perceived as part of the normal care parents should provide their child. However, removing condition management behaviours from young people's lives prevents the development of essential self-management behaviours; young people reported "my mum's quite, kind of the one in control" (Felix, young person) of their treatment.

> "I oversee all that, I do his blood tests, he has blood tests every, they were more regular at first, now they are every three months, so I book all of that. He wouldn't have a clue when he's blood tests are due umm well, I do get a message from the hospital but sometimes it's a bit out of sync so I managed all that…all his appointments they have started to come to him actually, because he's just turned [mid-teens], so once he turned [that age] the appointments have started coming in his name but he just gives all the letters to me, so I arrange all his appointments" (Philippa, parent)

Philippa continued to elaborate on how their child was unable to manage their condition without parental support, "I don't feel he's ready to look after his own IBD at the moment, even though he's [in his late teens] he probably thinks he can, but I don't think he can." This was commonly described by parents who felt their children were too young to look after their health independently. However, young people wanted to be given more self-management responsibilities and believed "if my mum said to me Aiden, I want you umm, I'm not going to put [your medication] out for you anymore…I feel like I could" (Aiden, young person). Absorbing their child's self-management responsibilities, often came at a significant cost for parents, who often experienced crisis moments in regard to their mental health. Parents therefore held the view that "it's the parents who need the help and then the parents can help their child" (Maxine, parent) successfully manage their IBD.

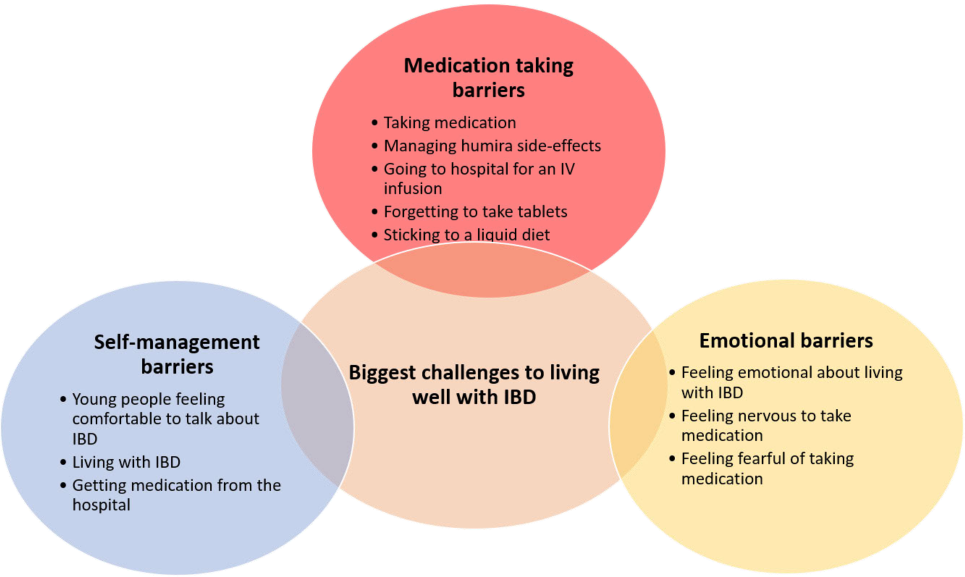
> "I personally needed the support, and I can imagine it's like that for many many others, umm just needing that support at the beginning that's what wasn't there for me so I think that side of things does need does need to be focused on a bit more having that support at the beginning" (Fiona, parent)

3.3.3. The creative task

The creative task was designed to encourage participants to provide their thoughts on effective and ineffective methods of adherence support for young people with IBD. Participants identified various barriers, demonstrating the unique person-centred experiences of living with IBD. Identified barriers could be categorised into three groups; medication taking, self-management, and emotional, depicted in Figure.7. Themes across the barriers allowed for the development of an emerging list of priorities for young people's treatment adherence behavioural needs:

1. Young people need support from understanding others, who can provide helpful adherence advice.
2. Young people perceived parental support could sufficiently overcome their adherence barriers, without the need to perform autonomous self-management behaviours.
3. Young people choose not to adhere to their treatment plan due to parental behaviours such as "nagging", a lack of empathy, or parental anxiety.
4. Young people need further IBD education from credible sources, in the forms of leaflets, videos, and websites.
5. Disclosure preferences determine the extent to which peer support is beneficial for young people.
6. Young people want healthcare professionals to provide emotional and practical support to overcome adherence barriers within consultations.
7. Holding an optimistic view of the future can encourage young people's adherence.

Figure 7. Barriers identified within the creative task



3.4. Discussion

Analysis of interviews with young people with IBD, parents of young people with IBD and healthcare professionals who support young people with IBD, generated three themes demonstrating young people's multifaceted adherence experiences. Findings suggested that adherence behaviours were not stable and often varied in response to complex situational factors, including where the behaviours needed to be performed and the presence of others while performing the behaviours. Such variability supports the view of adherence as a spectrum of behaviours determined by a combination of factors and highlights the need for a person-centred approach to interventions.

Families discussed a cyclical experience of striving for normality while adapting to the abnormality of IBD. A requirement to adhere to treatment plans in social situations, including in the presence of peers were often disliked by young people, who wanted to preserve their right to privacy over their condition. Young people therefore often withheld their IBD from peers. However, participants who had discussed their condition and support needs with their friends reported friendship groups altering activities to be inclusive of the young person's needs. This finding supports previous research by Carter et al. (2020) who suggested that while young people feared disclosing their IBD to friends, they often encountered positive interactions when disclosures were made. Thus, there is a clear need to provide guidance on how young people can successfully facilitate health conversations with peers.

All young people included in the interviews reported experiencing cruel or misinformed comments due to the stigmatisation of IBD. Such experiences left a resounding mark on young people's confidence and psychological wellbeing and promoted non-adherent behaviours. We already know that experiencing IBD stigma results in social isolation, greater prevalence of depression and anxiety, as well as poorer self-esteem, health-related quality of life (HrQoL) and treatment adherence (Gamwell et al., 2018; Taft et al., 2009). Weiss et al. (2006) define health-related stigma as a social process characterised by rejection, blame, exclusion, or devaluation from perceived, anticipated, or experienced adverse peer judgement. The experiences discussed by young people in this study provide support for this definition, highlighting a need for intervention strategies to assist young people to cope with IBD-stigma. Such strategies might include psychological support to enhance resilience and educational resources to increase societal awareness of IBD.

The deficit of peer support gained through social circles was supplemented by participants joining social media groups specifically for young people with IBD. In such groups, young people obtained clarity and a sense of normality regarding their experiences. Talking to people with IBD online also supported young people to maintain a sense of self. Within an adult IBD population, the most common reasons for joining online IBD communities have been reported as identification of similar others, eliciting emotional support and increasing IBD knowledge (Coulsen, 2008). With technology now a normal part of everyday life for teenagers, the current research identified young people were accessing online support groups in the same manner as adults. Social media groups were clearly beneficial for young people's wellbeing in this research, however, as these groups are often unregulated or monitored, it has been suggested that families or healthcare professionals may wish to ensure young people are receiving medically accurate information within these group discussions (Lönnfors & Greco, 2019).

The challenges of parenting a child with IBD have been associated with high levels of depression, worry and IBD-related stress (Akobeng et al., 1999; Cunningham & Banez, 2006; Burke et al., 1994). Within the current research, parents identified themselves as responsible for the management of their child's health and described a world characterised by fear of the unknown and the need to shield their child from harm. The chronic worry of parenting a child with IBD appeared to stem from a lengthy period of watching their child suffer from debilitating symptoms prior to diagnosis and feeling powerless to help. A shorter length of time since a child's IBD diagnosis has been associated with poorer mental health in mothers (Werner et al., 2014). Such research can provide additional context to the current study's findings which displayed the lasting impact a child's diagnosis has on parental wellbeing.

However, parental behaviours such as absolving young people of the burden of managing their own condition, unintentionally prevented young people from acquiring the essential skills to autonomously manage their health and facilitate a successful transition to adult healthcare services. Such parenting practices have been noticed previously by Shaw et al. (2021), who suggested families could benefit from healthcare professionals acknowledging parental experiences and understanding of uncertainty, vulnerability, and risk during the transition process. Following a systematic review of the literature, Philpot & Kuriwski (2019) suggested that families still prefer parents to dominate the interactions with medical professionals during mid-adolescence (14-17 years), despite the required transferal of self-management responsibilities occurring in later adolescence (17+ years). Further clinical consequences have been discussed by medical professionals for a wide range of health conditions which suggests parental overinvolvement in young people's care objectively impacts on the child's treatment outcomes and service provision (van Ingen et al., 2008). Parents were often aware of their child's lack of self-management skills which caused great parental worry about the future and promoted parental hypervigilant behaviours. Such behaviours often caused tension within the home as young people wanted to gain more independence. Feeling hindered to do this subsequently resulted in rebellious volitional non-adherence behaviours. This was more evident when young people and their parents participated within this project, as there was a clear juxtaposition between young people's desires and parental views. In a systematic review of paediatric chronic health conditions, greater family conflict was associated with poor adherence behaviours (Psihogios et al., 2019). Through providing interventional support to reduce parental anxiety and hypervigilant behaviours it may be possible to facilitate the necessary transfer of self-management responsibilities to young people, supporting them to manage their condition independently.

Families held the idea of remission with high-esteem and viewed this as the 'golden ticket' to living a 'normal' life. Young people were motivated to adhere to their treatment plans as a way of actively facilitating disease remission; such motivation was sustained even when medications were ineffective. While the desire to be 'well' facilitates adherence behaviours, most young people continue to experience some IBD symptoms during periods of remission, all be it at a lesser severity (Bielefeldt et al., 2009; Gong et al., 2021). Kitchen et al. (2020) identified variance in young people's understanding and definition of IBD remission. The current study's findings support that of previous research, emphasising the need for further education to ensure families' remission expectations are realistic, to avoid feelings of disappointment and to prevent volitional non-adherent behaviours during periods of remission.

When young people felt their sense of normalcy was threatened, young people were more prone to displaying non-adherent behaviours. IBD symptoms and treatment side-effects prevented young people from partaking in enjoyable activities, resulting in emotional distress and limits to their freedom. While families discussed implementing strategies to overcome such limitations, these were often only able to expose young people to a fragment of preferable activities. The requirements of living with IBD promoted feelings of difference in young people; such feelings often manifested as low mood, anxiety, and loneliness. IBD symptoms have previously been associated with poor emotional wellbeing and overall HrQoL in young people (Randall et al., 2020). Within the interviews, experiencing such emotions were linked with young people wanting to ignore their condition or remove their condition management responsibilities from their lives, and thus displaying non-adherent behaviours. Psychological services may support young people to manage their emotions and develop relevant coping strategies.

In a large systematic review of youths' experiences, having a trusting relationship with healthcare professionals was a significant factor for young people's engagement with healthcare services (Kim & White, 2017). Relationships with healthcare professionals were very important to families and young people in the current study, who often perceived those who looked after their health post-diagnosis as the first healthcare professionals to listen to their needs. Consultations provided a space for young people to discuss their condition and treatment adherence openly and confidently and ask healthcare professionals questions. Having a good relationship with healthcare professionals improved adherence behaviours in young people as they were able to trust and implement medical professionals' advice in their daily lives. Therefore, either a perceptual or actual deficit of such support could have serious clinical consequences, and strategies should be in place to ensure an open trusting dialogue is formed within medical appointments.

In the 1990's shared decision-making was promoted to give patients the opportunity to express their thoughts on their healthcare (Coulter, 1997). Previous research has indicated that children with chronic conditions did not have the autonomy in the shared decision-making process, and often felt ignored (Coyne et al., 2016; Garnett et al., 2016). In contrast to this, the current research found young people were actively involved and listened to during treatment decisions and were thus more likely to promote maintained treatment adherence. However, the enormity of such decisions was often overwhelming for families and subsequently relied on healthcare professionals to make final treatment decisions. The provision of further educational information targeted at young people may increase family's self-efficacy to engage in treatment decisions.

Implementing treatment routines within the home were sometimes difficult for families; most young people discussed forgetting their medication, often due to changes in routines or being distracted by other factors. This was unsurprising as forgetfulness has previously been identified as a common treatment adherence barrier for this population (Gray et al., 2012; Schurman et al., 2011). Families often implemented strategies to prompt adherence such as digital reminders and visual or verbal prompts. Strategies that prompted a sense of normality and autonomy were often preferred by young people. Due to the fragility of implementing treatment routines, a tailored approach may be beneficial when providing young people with adherence behaviour support, to identify strategies and techniques that meet an individual's preferences and needs.

Throughout the interviews, young people discussed wanting to know more about IBD and the medications they were taking; however, the articulate manner in which young people discussed their health is suggestive of a perceived rather than actual deficit in knowledge. Fishman et al. (2011) also identified high levels of IBD general knowledge in young people, however the amount of knowledge appeared to be stable over time, with older adolescents knowing equal amounts to younger participants. The only IBD knowledge deficit noted by Fishman et al. (2011) was in regard to adverse medication side-effects. The current research identified a conscious effort to shield young people from unpleasant information; whilst potentially frightening, an awareness of such possibilities is important for the self-management of IBD in adulthood. Thus, to improve treatment adherence behaviours, young people may benefit from materials which can confirm and/or enhance their IBD knowledge and subsequently increase their self-management self-efficacy.

Few families discussed actively incorporating physical activity and sleep advice into young people's treatment plans. This was surprising due to the identified benefits of adapting both these factors into the self-management of IBD (van Langenberg & Gibson, 2014; Ballessio et al., 2021). Recently avoidance of diets high in fat and sugar and low in fruit and vegetables have been suggested for patients with IBD (Miele et al., 2018). Within the current research, there was a clear divide in families who consciously valued a healthy diet as part of young people's adherence behaviours. Some families practised restrictive diets, which have commonly been reported across the literature, but are often unnecessary and linked to poorer nutrition (Miele et al., 2018; Pituch-Zdanowska et al., 2019; Tomar et al., 2017). Lifestyle factors were most vulnerable to non-adherence during social situations, whereby performing the required adherence behaviours was undesirable. Therefore, further education and support is needed to assist young people to understand the significant health benefits of following lifestyle advice.

The theoretical behavioural model of The Extended Common Sense-Self Regulation Model (Leventhal et al., 2016) can provide an understanding of the spectrum of adherence behaviours identified within the current research. When young people believed there was a necessity to follow their treatment plan, either due to factors such as the allure of remission or the value of healthcare professionals' advice, and had little concerns over doing so, there was a greater display of adherence behaviours. However, when young people were anxious about following their treatment plan, most commonly in social situations, such concerns resulted in non-adherent behaviours. Volitional non-adherence was reported when young people felt there was little need to follow either a section or the entirety of their treatment plan and felt unconcerned about non-adherent behaviours. Medication beliefs have previously been identified as a significant cause of non-adherence in adults with IBD (Jackson et al., 2010). The perceived necessity to take IBD medication may change during an IBD flare, as experiencing symptom relief outweighs an individuals' medication concerns (Hall et al., 2007). It is therefore unsurprising that such treatment perceptions have been identified as modifiable reasons for non-adherence in IBD patients (Moshkovska et al., 2009). Taking such a theoretical stance can assist in the development of future interventions by providing a theoretical understanding of young people's behaviour and the mechanisms driving young people's adherence beliefs and actions.

3.4.1. Strengths and limitations

This is the first qualitative study (to the authors knowledge) to explore the challenges and facilitators to young people adhering to their whole IBD treatment plan (medication as well as lifestyle behaviour modifications). Findings contribute to our understanding of the support needs of young people with IBD and ways in which future interventions could be designed.

The use of a thematic framework method has successfully facilitated the development of themes to demonstrate the complexities of adhering to IBD treatment plans. Additionally, the use of an arts-based task provided a unique opportunity for participants to discuss their views and experiences in a novel way which led to the generation of rich data regarding perceived outcomes of potential adherence intervention strategies.

There was a wide variety of IBD condition factors within the sample, including for example, age, gender, IBD symptom experiences and prescribed medication routines. Equally while the sample predominantly consisted of young people and parents of young people with

Crohn's Disease, the experiences of those diagnosed with Ulcerative Colitis and IBD-Unclassified was also captured within this research. Such inclusivity of experiences enriched the data and the transferability of findings. Inclusion of the views and experiences of young people and parents from across the UK, allowed conclusions to be drawn about the support needs of young people nationally, rather than from one specific NHS trust. The inclusion of nine young people and their parents enhanced this research's understanding of adherence experiences, as comparisons could be directly made between family's treatment adherence challenges and facilitators within the same household.

However, as with previous research, there was a lack of ethnic diversity across participants, with most identifying as White British. Within a large prospective cohort study of IBD incidences in an ethnically diverse UK sample, it was acknowledged that while most participants diagnosed with IBD were White European, participants of Indian ethnicity were more likely to receive an Ulcerative Colitis diagnosis and suffered greater disease severity (Misra et al., 2019). Further research may look to utilise stratified sampling methods to ensure a wider range of ethnicities are included.

Families discussed the experiences of young people whose IBD was currently well controlled. While participants were able to reflect on their experiences before this level of condition management, the interview content may have been different if the sample predominantly consisted of those living with poorly controlled IBD. To counteract potential gaps in experiences, healthcare professionals were able to discuss examples of young people who presented in clinic with poor management.

It is also important to acknowledge that most interviews with parents and young people were conducted during the initial months of the Covid-19 pandemic. Consequently, some participants were living in strict lockdown rules and therefore had been removed from their normal routines and experiences. Both the immediate and long-term disruptions caused by Covid-19 are therefore likely to have impacted the data.

3.5. Conclusion

There is no single behaviour or set of behaviours that facilitate optimum treatment adherence. Rather, young people shared the complexity behind their adherence behaviours and formation of treatment perceptions. Treatments which threatened young people's perception of themselves as a normal teenager, were at greater risk of volitional non-adherence. Equally, a fear of IBD stigmatisation from peer groups often resulted in young people choosing not to disclose their health needs with others and displaying volitional non-adherent behaviours. Forgetfulness was a frequent cause of non-adherence within young people, who felt unable to implement appropriate treatment routines to accommodate health and personal changes. Most young people questioned their personal IBD knowledge and ability to self-manage their condition. The adherence barriers identified within this research can be utilised to develop an evidence-based theory-driven treatment adherence intervention that is effective for young people with IBD. Due to the variety in IBD barriers and the uniqueness of IBD symptomologies and self-management needs, a tailored approach is likely to be best suited to such an intervention, to be accommodating of young people's individualised support needs.

The next Chapter synthesises these findings with those from the systematic review (Chapter two) within the context of using the Behaviour Change Wheel (Michie et al., 2011) to inform the development of an intervention to support young people with IBD's treatment adherence.

Chapter four. The development of a novel evidence-based theory-driven intervention to improve treatment adherence in young people with Inflammatory Bowel Disease (IBD)

4.1. Introduction

Exploratory research prior to the intervention development (detailed in Chapters two and three) enabled a detailed understanding of young people's volitional and non-volitional treatment adherence behaviours. These were determined by several factors, suggesting the need for a tailored intervention to meet the varied needs of young people with Inflammatory Bowel Disease (IBD). Previously, interventions inclusive of tailored support have been identified as beneficial for young people's IBD medication adherence (Maddux et al., 2017).

After reviewing the literature (Chapter two), it became apparent that existing behaviour change interventions for young people (aged 13-18) with IBD only targeted oral medication adherence. However, within the exploratory interviews, participants also discussed the importance of young people's health communications with healthcare professionals to facilitate the formation of appropriate treatment plans (Chapter three). Additionally, lifestyle factors, such as eating a healthy diet, engaging in physical activity, and practising good sleep hygiene, are important self-management behaviours for IBD (Lamb et al., 2019; Rozich et al., 2020; van Langenberg & Gibson, 2014). Families discussed the vulnerability of young people's adherence to lifestyle factors during social situations, as non-adherent behaviours were often more pleasurable and socially acceptable (Chapter three).

Within the reporting of medication adherence interventions identified within the systematic review, there was a significant lack of explicit or inferred use of behaviour change theory within each intervention's development or delivery (Chapter two). Using a behaviour change intervention framework to guide intervention design, can systematically determine appropriate (theoretically driven) intervention components that are most likely to achieve the required behaviour changes (Michie et al., 2011). Using findings from the formative research, the Behaviour Change Wheel (BCW) approach (Michie et al., 2011) was selected to inform the development of an evidence-based and theory-driven intervention to improve treatment adherence in young people with IBD.

4.1.1. Aim

To use exploratory research within the application of the BCW to develop a behaviour change intervention to improve young people with IBD's treatment adherence.

4.2. Behaviour Change Wheel

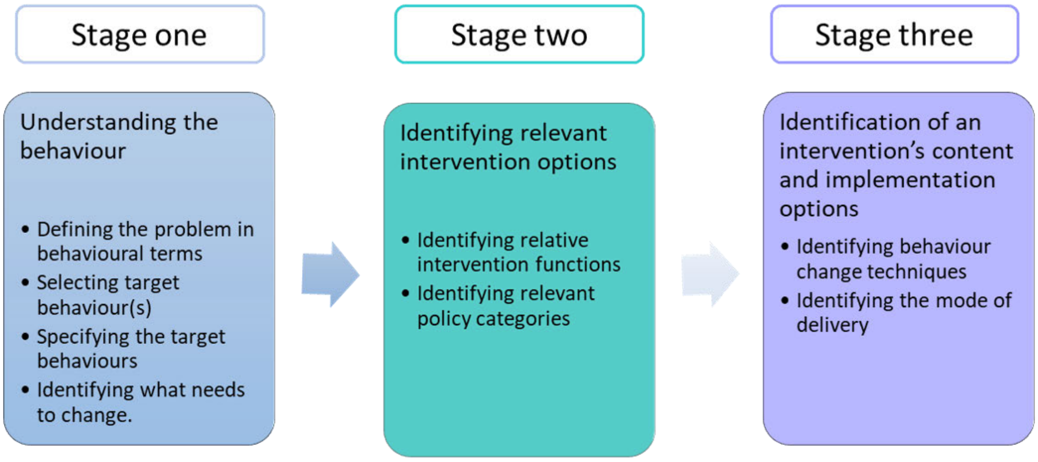
The Behaviour Change Wheel (BCW), proposed by Michie et al. (2011), is a framework derived from behaviour change theory for developing evidence-based and theory-driven behaviour change interventions. It is composed of three layers, the Capability, Opportunity, Motivation and Behaviour (COM-B) model of behaviour is within the BCW's centre, which details three behavioural functions each with two sub-categories. Capability refers to an individual's ability to engage in the behaviour, and includes both physical capability (e.g., physical skill or strength) and psychological capability (e.g., knowledge or psychological stamina). Opportunity is inclusive of factors outside of the individual that make performance of the behaviour possible or act as a behaviour prompt, and can be further categorised as social opportunity (e.g., social cues and norms) and physical opportunity (e.g., time or resources). Motivation refers to the brain processes that energise and direct behaviour and is inclusive of automatic motivation (e.g., wants and needs) and reflective motivation (e.g., plans and evaluations). A deficit in any of these behavioural functions will inhibit the performance of the required behaviour (Michie et al., 2011).

The COM-B model can be highly beneficial for the understanding of adherence behaviours, as it facilitates the translation of empirical determinants (identified through exploratory research) into theoretical determinants or constructs (e.g., reflective motivation, psychological capability etc.). This understanding is profound in the development of a working theoretical model of behaviour. Jackson et al. (2014) mapped commonly reported reasons for medication non-adherence onto the COM-B model's constructs; forgetting to administer medication was categorised as the individual's psychological capability to perform the behaviour, whereas an individual's treatment beliefs were theoretically conceptualised as reflective motivation. This therefore provides support for the feasibility of using the BCW to inform the selection of intervention functions or techniques in the design of treatment adherence interventions. Within the middle layer of the BCW are nine possible intervention functions, such as education, modelling, and enablement, which can be used to maximise the COM-B components identified as needing to change, following a behavioural analysis (Michie et al., 2011). The BCW's outer layer houses seven potential policy categories, such as service provision or regulation, that can be utilised to deliver the previously selected intervention functions (Michie et al., 2011).

The BCW further assists in the identification of appropriate Behaviour Change Techniques (BCTs) to include in behaviour change interventions. BCTs are the active ingredients of an intervention and are characterised by an observable and replicable nature (Michie et al., 2014). The Behaviour Change Technique Taxonomy v1 (BCTTv1) allows for the standardized definitions of 93 hierarchically clustered techniques grouped into 16 categories (Michie et al., 2013). BCT taxonomies have further been developed to focus on health-related behaviours such as physical activity, healthy eating, and alcohol consumption (Michie, et al., 2011; Michie et al., 2012).

When designing the current intervention using the BCW approach, I followed the three-stage process (Figure 8), as outlined by Michie et al. (2014) and discussed below. As recommended by Michie et al. (2014), I did not view each stage in a linear fashion, rather I utilised the flexibility within the approach to revise previously achieved stages and steps to be adaptive in response to further considerations throughout the intervention's design.

Figure 8. Stages of the Behaviour Change Wheel Approach



Stage one: Understanding the behaviour

Within the first stage of designing the intervention, I developed an understanding of the behaviours targeted within the intervention, by following a four-step process. First, I defined the problem in behavioural terms, with specific detail provided about the behaviour as well as the target individual or populations involved in the behaviour. Second, identified treatment adherence behaviours were analysed, allowing me to generate a list of behaviours relevant to the adherence problem (candidate behaviours), which were then evaluated to identify the most beneficial behaviours to target within the intervention. Third, each target behaviour was specified to include what performing the behaviour entails, who needs to perform the behaviour, as well as where, when, and how often will the target population perform the behaviour. Finally, each target behaviour was reviewed, using the knowledge obtained from my systematic review (Chapter two) and qualitative research (Chapter three) as well as psychological theory. Here my aim was to identify what needed to happen for the target behaviour to be completed, across the six COM-B subcomponents and to identify if there was a need to change such behaviours within the intervention.

Stage two: Identifying intervention options

During stage two of the BCW approach, I was guided by the BCW framework and the APEASE criteria (Table 7), as detailed by Michie et al. (2014), to make informed decisions about the intervention's use of intervention functions and policy categories. Following the behavioural analysis in stage one, I selected appropriate intervention functions to facilitate the identified behaviour change needs. Relevant policy categories were then selected to assist in the delivery of relevant intervention functions (Michie et al., 2014).

Stage three: Identifying the intervention content

Within the final stage of the BCW, I developed an outline of the intervention's content, through the identification of relevant BCTs and mode(s) of delivery. Appropriate BCTs for each intervention function across the identified target behaviours were assessed individually using the APEASE criteria (Table 7). Within the final step of the BCW approach, I selected the intervention's mode(s) of delivery, through employing the APEASE criteria (Table 7).

Table 7. APEASE criteria (Michie et al., 2014)

The APEASE criteria	
A -	*Affordability*
P -	*Practicability*
E -	*Effectiveness or cost-effectiveness*
A -	*Acceptability*
S -	*Side-effects / safety*
E-	*Equity*

4.2.1. Considerations before utilising the BCW approach

When following the BCW approach to design the intervention, it was important to identify and work within a realistic scope, to ensure the newly designed intervention would be feasible to implement. The intervention was developed to be inclusive of all young people (aged 13-18) who have been diagnosed with IBD, regardless of their specific diagnosis (e.g., Crohn's Disease, Ulcerative Colitis or IBD-Unclassified) or prescribed medications (e.g., Exclusive Enteral Nutrition (EEN), oral medications, injections or intravenous (IV) infusions). The intervention also aimed to support young people living with or without a stoma. In discussion with my supervision team, it was agreed that changing the behaviour of healthcare professionals, school staff and peer groups was outside of the scope of this intervention, but could be the subject of future interventions. Additionally, while it was identified that parents have a significant role in young people's adherence behaviours, young people would be the primary population for targeting within the intervention. Parents were thus only included where necessary to facilitate a young person's behaviour. Changes to the physical environment were also deemed unfeasible to include within the current intervention due to the potential financial costs and resources required.

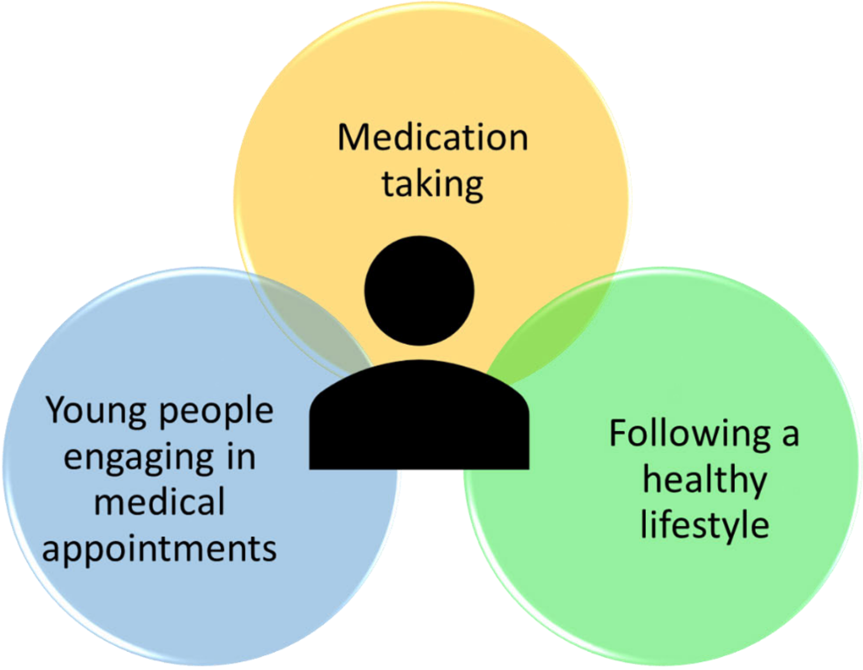
Additionally, two health behaviour theories which had previously been identified as providing a relevant understanding of the target populations behaviour (Chapter three), informed the decisions made across the BCW process. Social Cognitive Theory (SCT) (Chapter one) defines the importance of self-efficacy for behaviour change, and states self-efficacy is significant enough to promote behaviour change with or without interacting with the other SCT behaviour components (Bandura, 1986). Bandura (1977) proposed self-efficacy is developed through four different sources; previous personal success; vicarious experiences; verbal persuasion by others and emotional arousal. During the exploratory interviews (Chapter three), it was identified that young people would benefit from interventions targeting their treatment plan self-efficacy, as a lack of belief in ability or knowledge were identified as a significant adherence barrier.

Within the exploratory interviews, young people's treatment perceptions were identified as an influential factor for non-adherence behaviours (Chapter three). The Extended Common Sense-Self Regulation Model (Extended CS-SRM) (Chapter one) provides a theoretical understanding of the formation of treatment perceptions; a formulation of an individual's perceived need and concern over their treatment (Leventhal et al., 2016). In addition to illness perceptions and emotional responses following the identification of an illness threat, such as being diagnosed with IBD, these factors inform how young people cope with the threat of illness (Leventhal et al., 2016).

4.3. Outcomes of the BCW approach - Stage one: Understanding the behaviour

Taking an inclusive stance on young people's self-management responsibilities resulted in the identification of three behaviours that young people perform when adhering to their treatment plan: medication adherence, engaging in medical appointments and adherence to lifestyle advice. It was therefore apparent all three elements of this research's working definition of a young person's treatment plan, as displayed in Figure 9, were important behaviours to consider for the current intervention. To demonstrate clarity within the decision-making process, the first three steps within stage one of the BCW approach, are reported cohesively for each adherence behaviour.

Figure 9. Components of treatment adherence behaviours in young people with IBD



4.3.1. Medication taking

Medication taking and the frequency of these behaviours will vary depending on the young person's prescribed medication routine. For example, oral medications are normally ingested with a meal once a day, whereas injectable medications are typically self-administered weekly or fortnightly (Carroll et al., 2019). Therefore, when completing the first step of the BCW, medication adherence was defined as taking medication in accordance with the agreed treatment routine schedule. Due to the wide range of medication types, the definition of where behaviours occurred (at home, in hospital, at school) as well as the definition of who is involved in the behaviour (young people, parents, healthcare professionals, and school nurses) were inclusive to reflect the varied IBD treatment routines.

Each IBD medication type; IV infusions, oral medications, injectables, and EEN was considered separately to identify all relevant candidate behaviours (Table 8). All medication types were identified as requiring a young person to accept or rebook appointments. Due to the unique process of IV infusions, a further two medication specific candidate behaviours were identified; attending a hospital appointment to receive the treatment and going through with the medication procedure. The remaining medications (oral medications, injectables, EEN) demonstrated a significant overlap in the following candidate behaviours: attending appointments to be given a prescription; going to the hospital pharmacy to collect medication; storing medication safely within the home; young people taking medications at the correct time and parents administering medications at the correct time. Injectable medications required young people and caregivers to attend additional appointments with IBD Nurses to learn how to administer the medication.

Table 8. Candidate behaviours for medication taking

	Medications			
Identified candidate behaviour	IV Infusions	Oral medications	Injections	EEN
Accepting/rebooking appointment	X	X	X	X
Accepting/rebooking the appointment with a dietician				X
Attending medication delivery appointment	X			
Young people attending appointments to obtain a prescription		X	X	X
Going to hospital pharmacy to collect medication		X	X	X
Safely storing medication at home		X		
Safely storing medication in the fridge			X	X
Organise appointment with an IBD nurse to learn how to take medication			X	
Attend appointment with an IBD nurse to learn how to take medication			X	
IBD Nurse demonstrates how to take the medication			X	
Remove medication from fridge 30 minutes before taking			X	
Only consuming EEN drinks				X
Young people taking their IBD medication at the correct time		X	X	X
Parents administering medications at correct time		X	X	X
Going through with the medication procedure	X			

Following an assessment of the potential impact and likelihood of behaviour change, two behaviours were identified as being the most beneficial to target within the intervention; young people attending appointments to obtain a prescription, and young people taking their IBD medication at the correct time. To be inclusive of target behaviours for IV infusions, attending a hospital appointment to receive treatment was viewed as akin to young people attending appointments to obtain a prescription, due to the significant similarities between the behaviours.

The behaviour of young people attending appointments to obtain a prescription is performed by a young person, however it was acknowledged that a caregiver would need to be present when the behaviour was performed (Table 9). In regards to taking medication at the correct time, this was defined as a behaviour for the young person to conduct on their own, without the assistance of their caregivers (Table 9).

Table 9. Specification of medication taking target behaviours

	Target behaviour	
	Young people attending appointments to obtain a prescription	**Young people taking medication at the correct time**
Who needs to perform the behaviour?	Young person	Young people
What do they need to do differently to achieve the desired change?	Attend hospital appointments in order to receive their prescription	Take medication at the correct time, as prescribed
When do they need to do it?	When an appointment is scheduled by a healthcare profession	Every time a medication dose is required
Where do they need to do it?	On hospital premises	At home
How often do they need to do it?	Every time an appointment is scheduled by a healthcare professional	As prescribed by a healthcare professional
With whom do they need to do it?	Parent/carer	Alone

4.3.2. Young people engaging in medical appointments

Within the exploratory interviews young people discussed attending outpatient appointments with a range of healthcare professionals including Paediatric Gastroenterologists, IBD Specialist Nurses, Dieticians, and Psychologists (Chapter three). To gain a greater benefit within these consultations, young people are encouraged to actively engage in their appointments to develop a trusting relationship with their healthcare professionals (Kim & White, 2017). During the exploratory interviews (Chapter three), appointments were identified to occur in young people's homes as well as in a hospital setting prior to the Covid-19 pandemic. As well as including conversations between young people and healthcare professionals, caregivers were also identified as being included in the appointment process as their behaviours during consultations can facilitate or inhibit a young person's engagement, for example, parents refraining from answering questions on their child's behalf.

The identified candidate behaviours were categorised as behaviours required before and during consultations (Table 10). Prior to the appointment, young people would need to accept/rebook appointments as well as record changes to their health. During appointments, candidate behaviours were identified for both young people and healthcare professionals.

For young people, this included the process of traveling to and attending appointments; discussing changes to their health within appointments; offering health information without a prompt; answering questions when asked and asking questions during appointments. Within consultations, candidate behaviours for healthcare professionals included: asking questions directly to the young person and answering patients' concerns, as well as attending the appointment.

During my evaluation of the potential impact and likelihood of behaviour change, three candidate behaviours regarding young people's engagement within medication appointments were identified as beneficial to target within the intervention: young people answering questions when asked during appointments; young people asking questions during appointments and young people offering health information without a prompt within appointments. No behaviours were selected for healthcare professionals' behaviour as changing such behaviour was outside of the scope of the intervention, as previously discussed.

Table 6. Candidate behaviours for engaging in medical appointments

	Engaging in medical appointments		
Identified candidate behaviour	**Pre-appointment**	**During appointment**	
	Young person	Young person	Healthcare professional
Accepting/rebooking the appointment	X		
Recoding changes to condition in-between appointments (e.g., symptoms)	X		
Traveling to appointment		X	
Attending the appointment		X	X
Reporting changes to condition during the appointment		X	
Offering health information without a prompt within the appointment		X	
Answering questions when asked within the appointment		X	
Asking questions during appointment within the appointment		X	
Asking questions directly to the young person			X
Answering young people's concerns			X

It was identified that young people were the individuals who needed to perform each identified target behaviour during all hospital appointments, however it was recognised that these behaviours could only be performed in conjunction with a healthcare professional (Table 11). For young people to offer health information without being prompted to do so, young people also need to independently monitor their condition in-between health appointments (Table 11).

Table 7. Specification of engaging in medical appointments target behaviours

	Target behaviour		
	Young person answering questions when asked during medical appointments	**Young person asking questions during appointments**	**Young person offering health information without a prompt within appointments**
Who needs to perform the behaviour?	Young person	Young person	Young person
What do they need to do differently to achieve the desired change?	Answer questions asked by a healthcare professional	Ask a healthcare professional a question relevant to their health condition	Offering information to a healthcare professional about their condition without being prompted
When do they need to do it?	When attending a hospital appointment	When attending a hospital appointment	When attending a hospital appointment
Where do they need to do it?	On hospital premises	On hospital premises	On hospital premises
How often do they need to do it?	During each hospital appointment	During each hospital appointment	For each hospital appointment
With whom do they need to do it?	With a healthcare professional	With a healthcare professional	With a healthcare professional / Alone

4.3.3. Following a healthy lifestyle

Within appointments, healthcare professionals may recommend young people follow a healthy lifestyle and provide patient-centred advice on how to achieve this. For example, healthcare professionals may recommend a young person alters their diet or sleep behaviours. As this information is given within appointments, the behaviour was defined as occurring both in a hospital setting and within a young person's home. Those involved in this behaviour include healthcare professionals and young people. Caregivers were also included in behaviours surrounding eating a healthy diet, as they are likely to be involved in the provision of meals within the home environment.

Three topics were included in this research's definition of following a healthy lifestyle: eating a healthy diet, being physically active, and having good sleep hygiene, all of which were discussed by families and healthcare professionals in Chapter three. Due to the differences in lifestyle behaviours, a list of candidate behaviours was compiled for each of these behaviours individually (Table 12). While most identified behaviours were specific to the lifestyle topic, there were three overlapping candidate behaviours for each factor: accepting/rebooking the appointment; attending appointment to be given advice and following advice from a healthcare professional. Upon evaluating all identified candidate behaviours, three target behaviours were selected: young people following healthcare professional's advice on diet; young people following healthcare professional's advice on sleep behaviours and young people following healthcare professional's advice on physical activity.

Table 12. Candidate behaviours for following a healthy lifestyle

	Lifestyle behaviours		
	Diet	Sleep	Physical activity
Identified candidate behaviour			
Accepting/rebooking the appointment	X	X	X
Attending appointment to be given advice	X	X	X
Following advice from a Healthcare Professional	X	X	X
Purchasing relevant foods	X		
Cooking/preparing appropriate meals	X		
Young person eating appropriate meals	X		
Turn off digital screens 30 minutes before going to bed		X	
Engage in a relaxation activity before going to sleep		X	
Go to bed at the same time every day		X	
Wake up at the same time every day		X	
Engage in 150 minutes of moderate intensity physical activity a week			X
Attending a leisure centre/fitness centre to exercise			X
Attending a park/recreational space to exercise			X
Purchasing equipment to exercise at home			X

Each behaviour was defined as being performed within the home or wider environment, at a time relevant to the target behaviour. For example, sleep behaviours will be conducted in the evening whereas following dietary advice should be maintained throughout the day (Table 13). Similarly, the frequency of the behaviour will depend on the advice given, for example following advice on physical activity may require young people to complete the behaviours several times a week; whereas behaviours to follow dietary advice require young people to complete the target behaviour multiple times a day (Table 13). All three target behaviours can be viewed as behaviour young people complete alone or with family and friends; although caregivers are more likely to be involved in the target behaviour of following healthcare professionals' advice on diet, as they are often the main food provider within the home (Table 13).

Table 8. Specification of following a healthy lifestyle target behaviour

	Target behaviour		
	Young person following healthcare professionals' advice on diet	**Young person following healthcare professionals' advice on sleep behaviours**	**Young person following healthcare professionals' advice on physical activity**
Who needs to perform the behaviour?	Young person	Young person	Young person
What do they need to do differently to achieve the desired change?	Follow advice given by the healthcare professional regarding diet	Follow advice given by the healthcare professional regarding sleep	Follow advice given by the healthcare professional regarding physical activity
When do they need to do it?	Morning Afternoon Evening	In the evening	As recommended by the healthcare professional
Where do they need to do it?	At home / Outside of the home	In their bedroom	At home / Outside of the home
How often do they need to do it?	Every time the young person eats a meal	Every day	As often as advised
With whom do they need to do it?	Alone, or with family, or with friends	Alone	Alone, or with family, or with friends

4.3.4. COM-B behavioural analysis

Using knowledge obtained from exploratory research (Chapters two and three), target behaviours were reviewed individually for each COM-B component (Michie et al., 2011). Here the aim was to identify what needs to occur to facilitate the target behaviour's performance and decipher whether there is a need for change to successfully perform the target behaviours. Outcomes from the behavioural analysis are reported for each group of target behaviours separately.

Medication taking

Within the behavioural analysis, there were multiple psychological capability components identified for the two target behaviours. To enhance young people's appointment attendance to obtain a prescription, the intervention targets young people's understanding of what is being discussed during appointments, as well as the process of attending appointments to obtain a prescription. The intervention further targets young people's knowledge of how and when to take their medication at the correct time; how to form a medication routine and how medication taking can benefit IBD patients' health. Additionally, the intervention addresses young people's psychological capability to remember to administer their medication correctly. While it was identified that young people would need the physical skills to take their medication, this is offered as part of normal care and therefore, not deemed suitable to target within the current intervention.

Young people need the physical opportunity of having the time and transport to attend appointments. However, as previously discussed, providing sufficient resources to attend appointments is not possible within the scope of the current intervention. Equally, to take their medication at the correct time, young people must have the physical opportunity to access their medication. This behaviour was not targeted within the current intervention, as it was deemed all young people would have suitable access to their medication. Having the acceptance of family members and friends to perform both target behaviours is important for young people's social opportunity. However, as it was beyond the limitations of the current intervention to change peer group's reactions to young people's medication taking, it was decided the intervention would target how young people articulate their needs with others as well as forming coping strategies when such acceptance is not provided. While the aim of the current intervention is to target young people's adherence behaviours, it is narrow sighted to ignore the role of parents in the facilitation of such behaviours, therefore it was decided to include an additional parental resource within the intervention, which provides a rationale for caregivers on the benefits of young people engaging in autonomous adherence behaviours.

The COM-B behavioural analysis, identified young people needed further support to increase both their automatic and reflective motivation for the identified target behaviours. It was decided the intervention would facilitate the belief that performing both target behaviours are important for health as well as strengthen young people's intentions to perform the target behaviour, thus enhancing young people’s reflective motivation. Additionally, to address young people’s automatic motivation needs, it was concluded the intervention would elicit a positive view around performing both target behaviours.

Young people engaging in medical appointments

No aspects of young people’s physical capability to engage in medical appointments were identified as needing to change. It was identified the intervention needed to target young people’s psychological capability through providing resources on how to ask and answer questions, as well as knowing how to offer health information without a prompt, during appointments with healthcare professionals. Further support was needed to enhance young people’s psychological capability to monitor their health in-between appointments to facilitate the target behaviour of offering information without being prompted during consultations.

To perform the target behaviours, young people needed the physical opportunity to attend healthcare appointments, however as this was likely to be a determinant of caregivers’ behaviour, this was beyond the scope of the intervention. During the behavioural analysis, it was identified healthcare professionals influence young people’s social opportunity to perform all three target behaviours, however, it was outside of the confines of the current intervention to target healthcare professionals’ behaviour. Developing feelings of agency and identity within young people was evaluated as a likely means to increase the social opportunity to answer questions during medical appointments and was therefore targeted within the intervention. The social opportunity to answer healthcare professionals’ questions was assessed as being further provided when caregivers allow their child to do so independently, therefore an additional parental resource within the intervention provided caregivers with advice on the benefits of allowing young people to demonstrate autonomy in medical appointments.

For all target behaviours, reflective motivation was targeted to increase intervention user’s beliefs in their ability to engage during medical appointments, and that doing so will be beneficial for their general health and long-term condition management. Young people’s reflective motivation was further targeted within the intervention, to encourage the formation of intentions to perform the identified target behaviours, as well as feelings of confidence and empowerment to do so. Furthermore, it was identified the intervention needed to enhance young people’s automatic motivation to engage in medical appointments, through encouraging young people to anticipate a positive emotional response following the performance of all three target behaviours, specifically when providing truthful information, such as disclosing the frequency of non-adherent behaviours.

Following a healthy lifestyle

The COM-B behavioural analysis suggested young people needed additional knowledge to understand the lifestyle advice given to them by healthcare professionals, as well as how to form a behavioural routine, this was therefore included within the intervention to strengthen young people's psychological capability. The analysis further identified the intervention needed to provide additional support to increase young people's understanding of the relevance of sleep behaviours, including a greater understanding of what good quality sleep is, why sleep is important for health, how to manage disruptive sleep, and the relationship between medication adherence and sleep. Additional support needs were identified for the intervention to address young people's food preparation knowledge. While some change was needed for young people's physical capability to follow advice on diet and physical activity, this was assessed as requiring the provision of additional resources, outside the scope of the current intervention and therefore was not addressed within the intervention.

Factors relating to young people's physical opportunity to follow their healthcare professionals' advice on diet and physical activity was identified as needing to change within the COM-B behavioural analysis. However, as previously discussed, intervening with these factors was beyond the scope of the current intervention. To address young people's social opportunity to follow all three target behaviours, it was decided the intervention would encourage young people to feel supported to make the required changes and to believe it is socially acceptable to follow lifestyle advice. The most effective means of addressing young people's social opportunity to perform the target behaviours, was identified as providing an additional resource to parents/caregivers, outlining the benefits of supporting intervention users to follow lifestyle advice.

There was a further identified need for the intervention to strengthen young people's reflective motivation through enhancing young people's intentions and perceived ability to carry out lifestyle advice as well as encouraging young people to view following lifestyle advice as beneficial for their health. The COM-B behavioural analysis also identified a need to address deficits in young people's automatic motivation to want to follow lifestyle advice in the absence of symptom improvements or immediate negative outcomes if the advice is not followed. Automatic motivation was further targeted to strengthen intervention users' desire to follow lifestyle advice despite non-adherent behaviour being more pleasurable.

Summary of COM-B behavioural analysis outcomes

Within the COM-B behavioural analysis, all eight target behaviours identified a need for change in young people's psychological capability, social opportunity, reflective and automatic motivation to facilitate appropriate treatment adherence behaviours (Table 14). A further need for change was identified for young people's physical capability and opportunity, however these were evaluated to be beyond the scope of the current intervention, as this would require the provision of additional resources and/or, the development of a behaviour change intervention for individuals other than young people.

Table 14. Behavioural analysis using the COM-B model

Target behaviour	Capability		Opportunity		Motivation	
	Physical	Psychological	Physical	Social	Reflective	Automatic
Young people attending appointments to obtain a prescription	▤	■	▤	■	■	■
Young people taking their IBD medication at the correct time	▤	■	▤	■	■	■
Young people answering questions when asked during appointments	□	■	▤	■	■	■
Young people asking questions during appointments	□	■	▤	■	■	■
Young people offering health information without a prompt within appointments	□	■	▤	□	■	■
Young people following healthcare professionals' advice on diet	▤	■	▤	■	■	■
Young people following healthcare professionals' advice on sleep behaviours	□	■	▤	■	■	■
Young people following healthcare professionals' advice on physical activity	▤	■	▤	■	■	■

Key	
No behaviour identified	□
Change needed but beyond the scope of the intervention	▤
Change needed	■

Additional adherence support needs identified during the COM-B behavioural analysis

Within the identified need for change in young people's psychological capability, there was a clear association with explanations of resilience and the deficits of knowing how to perform the behaviour correctly when faced with barriers to do so. Definitions of resilience are inclusive of three behavioural components. First, the ability to adapt to adverse life events, second, the capacity to succeed following negative situations and finally the ability to engage with a perceived risk (Werner-Wilson et al., 2000). Due to the unpredictability in disease trajectory, individuals with IBD are confronted with frequent adverse events and are required to be adaptive to allow for the successful management of their condition. Previous research has suggested developing resilience behaviours during adolescence can provide greater protection against future IBD adverse events in adulthood (Ahola Kohut et al., 2021). Resilience behaviours are further linked to better health outcomes in adults with IBD, including better quality of life (QoL), lower disease activity, and fewer hospitalisations (Sehgal et al., 2021; Taylor et al., 2018). However, just over a quarter of adults with Crohn's Disease and a fifth of adults with Ulcerative Colitis self-reported high levels of resilience (Sehgal et al., 2021). It has recently been argued that fostering resilience in young people with chronic health conditions should be a goal for healthcare professionals (Pettoello-Mantovani et al., 2018), and valued in paediatric healthcare, due to the relevance of resilience for patients' health (Stewart et al., 1997). Therefore, addressing resilience behaviours within the current intervention may not only benefit young people's current treatment adherence behaviours but also their future health.

The noticed deficits in young people's reflective motivation, such as young people believing they are capable of adhering to their treatment plan, were suggestive of the need to increase young people's self-efficacy (an individual's beliefs about their capability to complete a behaviour) (Bandura, 1977), to strengthen young people's adherence intentions. Previous research has demonstrated the importance of self-efficacy as a determinant of health and facilitator for adaptive coping strategies in patients with IBD (Chao et al., 2019; Dur et al., 2014; Stone et al., 2022). In a survey of young adults, less than 50% were able to demonstrate sufficient self-efficacy for their IBD self-management; with all participants self-reporting their perceived inability to schedule health appointments (Krauthammer et al., 2020). Subsequently, increasing young people's self-efficacy is an aim of the transition period from paediatric to adult healthcare (Zijlstra et al., 2013), therefore, the inclusion of materials to improve young people's self-efficacy within the intervention is likely to be highly beneficial for the target population.

The intervention will look to enhance young people's beliefs that performing adherence behaviours will benefit their health (e.g., their reflective motivation); one way of approaching this could be through increasing participants' optimism. Living with IBD is anxiety inducing for young people, who often question how much their adult lives will be impacted by their condition, however, encouraging a positive outlook can assist young people to remove perceptual life restricting IBD barriers (Roberts et al., 2021). Individuals who maintain an optimistic view of the future are more likely to utilise adaptive or problem focused coping strategies, both of which are beneficial in the management of chronic conditions (Avvenuti et al., 2016; Wrosch & Scheier, 2003). An optimistic outlook is further associated with a greater health related QoL (HrQoL) in adolescents with IBD (Tominlson et al., 2021). During transition from paediatric to adult healthcare, uncertainty about the future can be a barrier to transition (Fiengold et al., 2021). The promotion of an optimistic outlook within the intervention is therefore likely to encourage young people to view following their treatment plan as beneficial for their health and increase future possibilities within adulthood.

4.4. Outcomes of the BCW approach - Stage two

To decipher appropriate intervention functions and policy categories for the current intervention, I assessed each target behaviour individually, before the outcomes were combined for each intervention function and policy category to ensure the creation of a cohesive intervention for all eight target behaviours.

4.4.1. Identifying intervention functions (Table 15)

Included Intervention functions

Education was identified as a suitable intervention function for all eight target behaviours. The utilisation of educational materials will enhance intervention user's knowledge (psychological capability), as well as young people's ability to develop plans to perform a behaviour (reflective motivation). The intervention function of incentivisation was reviewed to be non-cost-effective; however, encouraging young people to self-incentivise when they have performed a desired behaviour was reviewed against the APEASE criteria as being highly suitable for the intervention. Within Chapter three, young people who rewarded themselves following the completion of an adherence behaviour (for example administering a dose of humira) strengthened young people's intentions to adhere to their treatment. Therefore, self-incentivisation was selected for the intervention to increase young people's intentions (reflective motivation) and desires (automatic motivation) to perform adherence behaviours. Training (e.g., the provision of skills), was viewed as an acceptable format to strengthen young people's automatic motivation and psychological capability to perform each target behaviour.

Table 9. Selected intervention functions for each target behaviour and COM-B behavioural component

Intervention Function	Target behaviour	COM-B Component			
		Capability	Opportunity	Motivation	
		Psychological	Social	Automatic	Reflective
Education	Young people attending appointments to obtain a prescription	X			X
	Young people taking their IBD medication at the correct time	X			X
	Young people answering questions when asked during appointments	X			X
	Young people asking questions during appointments	X			X
	Young people offering health information without a prompt within appointments	X			X
	Young people following healthcare professionals' advice on diet	X			X
	Young people following healthcare professionals' advice on sleep behaviours	X			X
	Young people following healthcare professionals' advice on physical activity	X			X
Incentivisation	Young people attending appointments to			X	X

	obtain a prescription			
	Young people taking their IBD medication at the correct time		X	X
	Young people answering questions when asked during appointments		X	X
	Young people asking questions during appointments		X	X
	Young people offering health information without a prompt within appointments		X	X
	Young people following healthcare professionals’ advice on diet		X	X
	Young people following healthcare professionals’ advice on sleep behaviours		X	X
	Young people following healthcare professionals’ advice on physical activity		X	X
Training	Young people taking their IBD medication at the correct time	X	X	
	Young people taking their IBD medication at the correct time	X	X	
	Young people answering questions when asked during appointments	X	X	
	Young people asking questions during appointments	X	X	

	Young people offering health information without a prompt within appointments	X		X	
	Young people following healthcare professionals' advice on diet	X		X	
	Young people following healthcare professionals' advice on sleep behaviours	X		X	
	Young people following healthcare professionals' advice on physical activity	X		X	
Environmental Restructuring	Young people attending appointments to obtain a prescription		X		
	Young people taking their IBD medication at the correct time	X	X		
	Young people answering questions when asked during appointments		X		
	Young people following healthcare professionals' advice on diet	X	X		
Modelling	Young people attending appointments to obtain a prescription		X	X	X
	Young people taking their IBD medication at the correct time		X	X	X
	Young people answering questions when asked during appointments		X	X	X

	Young people asking questions during appointments		X	X
	Young people offering health information without a prompt within appointments		X	X
	Young people following healthcare professionals’ advice on diet	X	X	X
	Young people following healthcare professionals’ advice on sleep behaviours		X	X
	Young people following healthcare professionals’ advice on physical activity	X	X	X
Enablement	Young people attending appointments to obtain a prescription	X		X
	Young people taking their IBD medication at the correct time	X	X	X
	Young people answering questions when asked during appointments	X	X	X
	Young people asking questions during appointments		X	X
	Young people offering health information without a prompt within appointments		X	X
	Young people following healthcare professionals’ advice on diet	X	X	X

	Young people following healthcare professionals' advice on sleep behaviours	X	X	X
	Young people following healthcare professionals' advice on physical activity	X	X	X

The intervention function of environmental restructuring was only perceived as acceptable for half of the target behaviours. The construct of psychological capability and social opportunity were evaluated to benefit from environmental restructuring; however, the intervention function was not perceived to be appropriate for the intervention user's automatic motivation, as it was unlikely to impact young people's desire to display adherence behaviours. The use of modelling met the APEASE criteria to improve social opportunity for all eight target behaviours. Modelling adherence behaviours was viewed to be more financially viable and effective for the target population if delivered within videos of other young people with IBD performing such behaviours. Enablement was appropriate for the identified target behaviours, but only for young people's social opportunity, automatic and/or reflective motivation. Deficits in young people's psychological capability were best suited to the intervention functions education and training, therefore enablement was viewed to have little effect on this COM-B construct.

Excluded intervention functions

Across the eight target behaviours, persuasion, coercion, and restriction were identified as being inappropriate for the current intervention. While persuasion and coercion can be beneficial to target automatic and reflective motivation (Michie et al., 2014), it was deemed unacceptable to create an expectation of punishment or negative consequence if young people do not display adherence behaviours, as this may induce unnecessary feeling of shame or inadequacy in young people. Equally, using restriction to reduce young people's social opportunity to engage with unwanted behaviours was assessed to be ineffective for the target population, as there was no clear behaviour or set of behaviours to restrict.

4.4.2. Identify policy categories

Included policy categories

The provision of a service to facilitate behaviour change in young people was reviewed using the APEASE criteria (Table 7) to be an acceptable, practical, and effective intervention function delivery method for all eight target behaviours. While not typically thought of as effective for environmental restructuring (Michie et al., 2014), service provision was evaluated as being an effective and practical way of encouraging changes in young people's social context across the eight target behaviours.

Excluded policy categories

Within the current intervention, the use of: fiscal measures, regulation, legislation, and environmental/social planning, were reviewed as being unpractical to support behaviour change across the eight target behaviours. Currently good practice guidelines already exist for the treatment of paediatric IBD, therefore additional guidelines were assessed to be ineffective. The policy category of communication/marketing could potentially enact some behaviour change, however as identified in Chapter three, the target population need user-centred support to facilitate adherence behaviours. Therefore, the policy category communication/marketing was not acceptable for the current intervention, due to its generalised approach to facilitate behaviour change.

4.5. Outcomes of the BCW approach - Stage three

4.5.1. Identifying BCTs (Table 16)

To display the relevance of the included BCTs for an interconnected intervention, inclusive of all target behaviours, identified BCTs are reported below for each intervention function.

Education

Across all eight target behaviours the BCT *5.1. Information about health consequences* was viewed as being appropriate for the intervention, to target young people's perceived lack of IBD knowledge, with the aim to increase young people's psychological capability.

Incentivisation

As mentioned previously, it was unfeasible to offer financial or material incentives within the current intervention; instead, the intervention would therefore encourage young people to provide their own rewards for the performance of adherent behaviours, thus increasing young people's desire to perform the behaviour (automatic motivation). To facilitate this, two BCTs: *2.3. Self-monitoring of behaviour* and *10.9. Self-reward*, were identified as effective across all target behaviours.

Training

Due to the nuances in the identified target behaviours, there was variability in the BCTs identified for the intervention function of training. For the target behaviours of engaging in health appointments, the BCT *8.1. Behavioural practice/rehearsal* was reviewed as being appropriate to develop young people's health communication skills. As suggested by Michie et al. (2014), the BCT *8.3. Habit formation* was also viewed as appropriate for the forementioned target behaviours. A further three BCTs were identified across all target behaviours to support the provision of behavioural training: *6.1. Demonstration of the behaviours*; *4.1. Instruction on how to perform a behaviour* and *2.3. Self-monitoring of behaviour*. This mapped out an intervention structure whereby young people are informed on how to perform the behaviour alongside observing a demonstration of the behaviour; further training is provided to young people on how to self-monitor their own behaviour and therefore, enhancing young people's self-efficacy to perform the behaviour.

Modelling

The BCT *6.1. Demonstration of the behaviour*, was identified as appropriate to support the intervention function of modelling, thus strengthening the COM-B construct of social opportunity. Short videos demonstrating the behaviour to young people were perceived as the most practical method of delivering this BCT within the intervention function, to be both cost effective and ensure standardisation of the BCT's delivery

Table 10. Selected BCTs for each target behaviour

BCT's	**Target behaviours**							
	Young people attending appointments to obtain a prescription	Young people taking their IBD medication at the correct time	Young people answering questions when asked in appointments	Young people asking questions during appointments	Young people offering health information without prompt within appointments	Young people following healthcare professionals' advice on diet	Young people following healthcare professionals' advice on sleep behaviours	Young people following healthcare professionals' advice on physical activity
1.4. Action planning	X	X	X	X	X	X	X	X
12.5. Adding objects to the environment		X						
8.1. Behavioural practice/rehearsal			X	X	X			
6.1. Demonstrating of the behaviour	X	X	X	X	X	X	X	X
1.1.Goal setting (behaviour)	X	X	X	X	X	X	X	X
8.3. Habit formation			X	X	X			
5.1. Information about health consequences	X	X	X	X	X	X	X	X
4.1. Instruction on how to perform a behaviour	X	X	X	X	X	X	X	X
1.2. Problem solving	X	X	X	X	X	X	X	X
7.1.Prompts and cues		X						
11.2. Reduce negative emotions	X	X	X	X	X	X	X	X
12.1. Restructuring the physical environment		X						
12.2. Restructuring the social environment	X	X	X	X	X	X	X	X
2.3. Self-monitoring of behaviour	X	X	X	X	X	X	X	X
10.9. Self-reward	X	X	X	X	X	X	X	X
3.1. Social support (Unspecified)	X	X	X	X	X	X	X	X
15.1. Verbal persuasion about capability	X	X	X	X	X	X	X	X

Environmental restructuring

For all relevant target behaviours, the BCT *12.2. Restructuring the social environment* was assessed as being appropriate to facilitate the social opportunity for young people's adherence behaviours. BCTs *12.1. Restructuring the physical environment*; *12.5. Adding objects to the environment* and *7.1. Prompts/cues* were also viewed as potentially effective to strengthen young people's psychological capability and automatic motivation to enact the target behaviour of taking medication correctly.

Enablement

When applying the APEASE criteria across all eight target behaviours, BCTs *1.4. Action planning*; *1.2. Problem solving* and *1.1. Goal setting (behaviour)* were perceived to effectively promote behaviour change within the intervention, through targeting young people's automatic motivation. Three further BCTs were identified to promote behaviour change in young people through strengthening young people's views on their ability to perform the behaviour (reflective motivation) and thus increase their self-efficacy to adhere to their treatment plan: *11.2. Reduce negative emotions*; *15.1. Verbal persuasion about capability* and *3.1. Social support (unspecified)*. The BCT *2.3. Self-monitoring of behaviour* was reviewed as appropriate and effective for the current intervention, to allow young people to monitor their behaviour change success, and thus strengthen their intensions and perceived ability to overcome additional barriers. Additionally, the BCT *12.2. Restructuring the social environment*, was evaluated as being appropriate for this intervention function, to further strengthen young people's social opportunity to adhere to their treatment plan.

4.5.2. Selecting the intervention's modes of delivery

Face to Face or Remote

While there have been noticeable benefits to facilitating IBD oral medication adherence interventions face-to-face on an individual level and within groups (Hommel et al., 2012; Maddux et al., 2017), the current intervention reviewed these modes of delivery as unpractical. This was due to the requirement for one or more individuals to facilitate the intervention, incurring a financial cost and hindering the intervention's sustainability. A distance mode of delivery was therefore considered to be more sustainable (due to the lower financial facilitation costs), as well as minimising access barriers for participants (e.g., time restrictions, travel costs). Rather the intervention would provide users with access to the intervention's content at a time and location of their choosing.

Population or individual level

The provision of the intervention on an individual level (e.g., using a phone helpline or an individually assessed computer programme) was assessed to need an individual to facilitate the intervention; this was therefore not an appropriate sustainable mode of delivery for the current intervention. Subsequently, the intervention was best suited to a population level mode of delivery whereby the intervention can reach a wider group of young people with IBD in a more financially sustainable manner.

Type of media

For the present intervention, the use of broadcast, print and outdoor media were generally viewed as an ineffective mode of delivery, due to the lack of specificity in accessing the target audience. However, it was acknowledged that informational posters or leaflets in paediatric waiting rooms may have a small benefit. The use of digital media was viewed as highly appropriate for the intervention's mode of delivery, as most young people are familiar with such technology and would have access to the internet either on a laptop or mobile device. Digital health interventions, have previously been identified as a relevant and engaging delivery method to provide treatment adherence support for young people with chronic health conditions (Murphy et al., 2022; Nightingale et al., 2017). For the current intervention, the use of a website or mobile phone App were viewed to be equally effective for the target population; therefore, a website as well as an accompanying WebApp (a smartphone application of a website), was evaluated to be the most appropriate modes of delivery for the current intervention.

4.6. Synthesis of BCW Outcomes

After working through the stages of the BCW, it was clear that the intervention needed to target young people's psychological capability, social opportunity, reflective and automatic motivation to improve treatment adherence for the eight identified target behaviours. The intervention functions of education, incentivisation, training, modelling, enablement, and environmental restructuring were selected as a means for behaviour change and facilitated through the policy category of service provision. Across the eight target behaviours, seventeen BCTs were chosen to enact changes in young people's treatment adherence behaviours. To reduce facilitation costs and increase the intervention's sustainability, delivering the intervention using digital media such as a website or a WebApp, at a distance population level was assessed as appropriate and effective for the current intervention.

The newly developed intervention was designed to target young people's adherence behaviours, however during the BCW process and within exploratory interviews (Chapter three), it was highlighted that parents are instrumental for young people's social opportunity to perform the identified target behaviours. Therefore, it was decided the intervention would include an additional parental resource, to provide a rationale for caregivers on the benefits of supporting young people to achieve their adherence needs.

4.7. Designing the intervention content

The rest of this Chapter will discuss the design of the new treatment plan adherence intervention, as the result of the BCW process and exploratory research outcomes (Chapters two and three). However, to ensure the acceptability and feasibility of the intervention for the target population, a Patient and Public Involvement and Engagement (PPIE) group of young people was formed to further co-develop the intervention's content and design within a series of online workshops (detailed in Chapter 5). Therefore, interventional components discussed within the following sections of this Chapter are referred to as "proposed" module topics and content, to allow for possible future revisions suggested by the PPIE group.

The outline of ten interactive modules have been designed each focusing on a relevant treatment adherence behaviour for young people with IBD. All intervention users initially complete the introductory module titled "What does it mean to live well with IBD?" After this young people are able to select modules, they feel are relevant to their needs, in an order that suits their preference. Once a core module has been completed, the intervention is programmed to 'lock' remaining modules for seven days to enable young people to work through the interactive materials at a suitable pace to facilitate behaviour change. Young people are instructed to open the summary session when they feel they have completed all modules relevant to their treatment adherence needs.

4.7.1. Proposed module topics

Topic 1. What does it mean to live well with IBD?

Within the introductory session intervention users are presented with educational and training materials on the behaviours required to follow their treatment plan; including the eight target behaviours identified in stage one of the BCW approach. The initial session further defines the included module topics and their relevance for young people's self-management behaviours. Young people are also able to learn how to interact with the intervention's content within this topic, including how to tailor the information within modules to best meet their needs.

Topic 2. Talking to others about IBD

This module aims to improve young people's social opportunity to perform treatment adherence behaviours. As highlighted in Chapter three, young people find it challenging to talk to family members, peers, and school staff about their IBD. This topic explores the benefits of sharing information about your condition with other people and provides young people with training on how to discuss their support needs with others.

Topics 3-5. Feeling confident to…

Three modules explore how young people can feel confident to complete self-management behaviours and perform appropriate adherence behaviours of taking medication, engaging in medical appointments, and following lifestyle advice. While the modules use the term of confidence, this is selected to represent the concept of self-efficacy (Bandura, 1977).

Topics 6-8. Feeling able to continue to …

The three modules titled "Feeling able to continue to…" aim to develop and promote resilient behaviours. To be appropriate for the target population a decision was made to replace the term resilience with 'feeling able'. The resilience modules include the three treatment adherence behaviours of taking medication, engaging in medical appointments, and following lifestyle advice.

Topic 9. Feeling positive about the future

This module looks to increase young people's optimism for the future, by providing positive and realistic information about what it is like to live with IBD during adulthood. This includes young adults sharing information on how they were able to achieve their life ambitions as well as following their prescribed treatment plans.

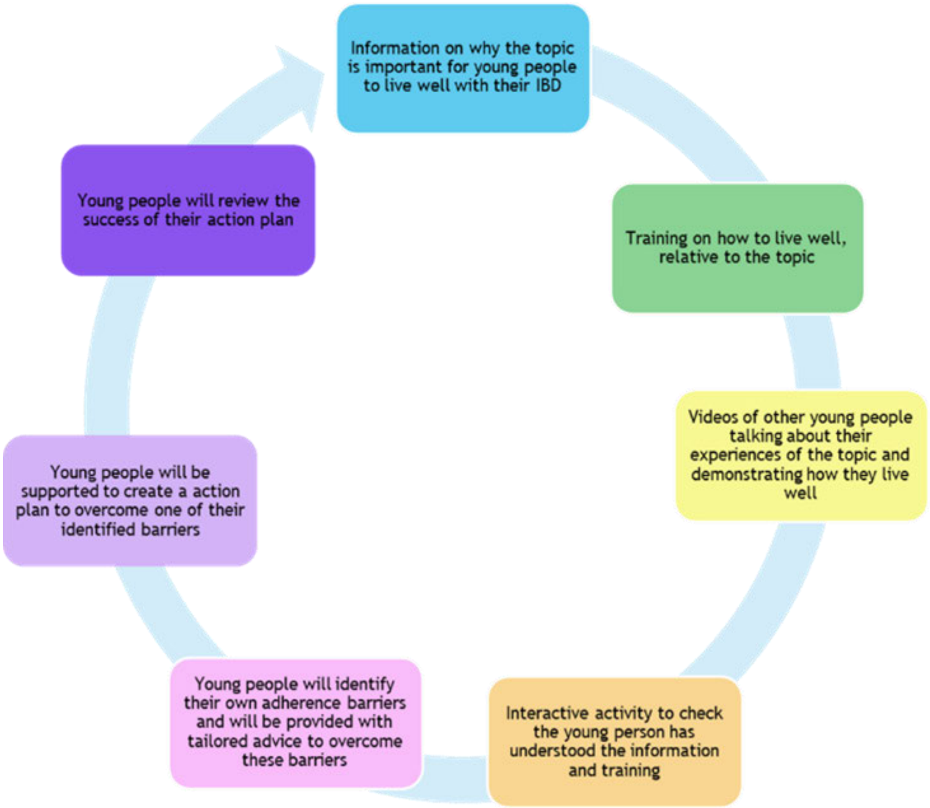
Topic 10. Summary session

The final module contains tailored interactive module summaries of information accessed by the intervention user. The module will further showcase the goals set within the intervention and the success young people have achieved during their participation.

4.7.2. Proposed module content

The intervention's content consists of an appropriate use of language and tone for the audience. Instant definitions of medical terminologies are provided, to enhance young people's health knowledge, and improve communication with healthcare professionals, who often use medical jargon during consultations. Interactivity is a key feature of each module and allows participants to shape the module's content to mirror their own personal treatment plan. Within each module there are seven elements to support young people's behaviour change; education, training, social support, demonstration of knowledge, tailored support, action planning and reviewing action plans (Figure 10).

Figure 10. Intervention module content



In addition, components within each module aim to develop young people's treatment adherence self-efficacy, through vicarious experiences, previous personal success, emotional arousal, and verbal persuasion about capability (Bandura, 1977). It is further possible that some target behaviours (e.g., engaging in medical appointments and following lifestyle advice), are not conceptualised as part of treatment adherence, as the term treatment is often used to refer to medication only, therefore, relevant intervention functions within each module will utilise the components of the Extended CS-SRM (Leventhal et al., 2016) to highlight the necessity of young people adhering to their entire treatment plan, by providing intervention users with relevant information about the benefits of doing so. However, the intervention will not look to cause feelings of shame or guilt in young people who are non-adherent, rather the language used will demonstrate the importance of adherence while acknowledging the difficulties of performing such behaviours. Similarly, the intervention will look to reduce young people's treatment adherence concerns, through discussing possible treatment side-effects and sharing other young people's experiences. Altering participants' perceived treatment necessity and concerns is likely to positively impact the coping strategies young people use to manage their condition and are thus more likely to effectively adapt to future condition changes (Leventhal et al., 2016).

Education

The ability for intervention users to identify information relevant to their own adherence needs is essential for the development of key health self-management skills. All modules begin with topic relevant information, that young people can engage with in a meaningful way to match their treatment plan and adherence behaviour needs; for example, within the module “feeling confident to take medication” young people can select which medications to learn more about, rather than being presented with a plethora of information that may not be suitable. To facilitate behaviour change, this element will use the BCTs *5.1. Information about health consequences* and *4.1. Instruction on how to perform a behaviour*. Each of the eight selected intervention target behaviours are important for young people’s treatment adherence; however, it is possible that the necessity to perform these behaviours are not fully understood by young people, especially when they are experiencing periods of symptom remittance (Hall et al., 2007). Therefore, the language within the educational materials highlights the necessity of following treatment plans as well as addressing young people’s concerns of doing so; the BCT *11.2. Reduce negative emotions* is included to support this.

Training

Training materials are included to demonstrate how to perform a specific treatment adherence behaviour; and will include the BCTs: *8.1. Behavioural practice/rehearsal*; *6.1. Demonstrating of the behaviour*; *8.3. Habit formation*; *4.1. Instruction on how to perform the behaviour* and *15.1. Verbal persuasion about capability.* Interactive activities are also included to allow young people to practice the behaviours and/or receive pre-programmed feedback on their understanding and capability to demonstrate the behaviour; the use of such feedback is unlikely to be sufficient for the BCT *2.2. Feedback on behaviour*, but may still improve young people’s self-efficacy to perform a behaviour.

Social support

Embarrassment over IBD related matters can result in feeling of loneliness, depression, and anxiety in young adults with IBD (Qualter et al., 2021). To reduce such negative emotions support videos including young people talking about their IBD experiences are included in each module. Within such videos the following BCTs will be elicited: *5.1. Information about health consequences*; *4.1. Instruction on how to perform a behaviour*; *6.1. Demonstrating the behaviour*; *3.1. Social support (Unspecified)* and *11.2. Reduce negative emotions*. Watching other young people like yourself explaining their treatment adherence challenges and demonstrating appropriate adherence behaviours, is likely to develop intervention user's self-efficacy through vicarious experiences (Bandura, 1977).

Demonstration of knowledge

Each module is inclusive of three different types of interactive activity; inclusive of multiple-choice quizzes, word searches and matching pair activities. Intervention users will receive rewarding messages upon an activity's successful completion. The use of interactive activities to demonstrate participants' knowledge is three-fold. First, activities will confirm young people's understanding of the content displayed to them in the initial parts of the module, ensuring information is being actively engaged with rather than passively read. Second, it will increase the interactive nature of the intervention to prevent participant disengagement. Finally, it provides young people with a further opportunity to enhance their treatment adherence self-efficacy through demonstrating their knowledge.

Tailored support

Young people are asked to self-identify their treatment adherence barriers relevant to each topic, the intervention provides tailored support options to assist young people to overcome such barriers. A variety of BCTs are included to facilitate useful solutions to young people's adherence challenges, including: *12.5. Adding objects to the environment*; *11.2. Reduce negative emotions*; *12.1. Restructuring the physical environment*; *12.2. Restructuring the social environment*; *15.1. Verbal persuasion about capability* and *7.1. Prompts/cues*. However, only BCTs relevant to a young person's identified barriers are presented to an individual. It is possible the use of tailored support may guide young people to employ adaptive coping strategies, lessening the impact of emotional arousal in stressful situations, thereby strengthening young people's self-efficacy to adhere to their treatment plan in previously anxiety provoking situations (Bandura, 1977). The language used within the tailored support is inclusive of positive statements, targeting young people's reflective and automatic motivation to demonstrate the required behaviours and behaviour intentions. The use of such language is intended to positively influence young people's self-efficacy to overcome barriers and develop adherence behaviours.

Action planning

In the final part of the module, the intervention guides young people to develop a behavioural action plan to overcome their most significant treatment adherence barrier; thus, involving the BCTs *1.4. Action planning*, *1.2. Problem solving* and *1.1. Goal setting (behaviour)*. The action planning process will guide young people to create implementation intensions; specifying what they intend to do, as well as when and where they intend on performing the behaviour. Information is also shared with participants on the importance of ensuring their goals are both realistic and achievable. Young people are further supported to develop a plan to review if they have achieved their behaviour change intentions, including how to self-reward their action plans success; utilising the BCTs *2.3. Self-monitoring of behaviour* and *10.9. Self-reward*. The created action plan will be saved to the young person's intervention profile, and can be accessed at any point by the young person.

Reviewing action planning success

Seven days after the creation of an action plan, the intervention prompts participants to evaluate their success. As some goals take longer than seven days (for example young people may be waiting multiple weeks until their next healthcare appointment), young people can review their action plan on a later date, if necessary.

When reviewing their experiences, young people are able to select one of three options. First, young people can report they have achieved their goal; second young people can report they are still working towards achieving their goal, and finally young people can report that they are struggling to achieve their goal. Young people who identify as either working towards or who are struggling to achieve their goal are provided with additional information about overcoming implementation intention barriers as well as ensuring their goal is both realistic and appropriate. Young people also have the option to edit their action plan if they feel this is necessary. When participants have achieved their goal, a congratulatory statement is shared with the individual, who is encouraged to reward themselves for their achievements. Within this element the following BCTs will be implemented: *2.3. Self-monitoring of behaviour*, *10.9. Self-reward* and *15.1. Verbal persuasion about capability*. As young people work through the intervention modules and achieve success in implementing their action plans this is likely to increase their self-efficacy to implement further behaviour changes, due to their previous personal success (Bandura, 1977).

4.7.3. Proposed caregiver resources

As identified during the BCW intervention design process and exploratory research (detailed in Chapters two and three), caregivers are influential over young people’s social opportunity to adhere to their treatment plan. Therefore, additional parental resources are provided for parents/caregivers, which detail the benefits of young people engaging in autonomous adherence behaviours. Caregivers also have access to the same educational information as young people for each module topic; allowing parents to be informed about the importance of the topic at the same level as their child, thus allowing neither party to be ‘experts’.

4.8. Intervention development summary

The use of the BCW approach within the design of the intervention provided a systematic process that encouraged theoretical evaluation and appraisal of each decision. Ten online interactive modules were developed to support young people’s treatment adherence needs. The content of the intervention has been designed to be tailored by young people to ensure the provision of relevant intervention materials. Within each module young people are supported to develop user-centred behaviour change goals to improve their treatment adherence behaviours.

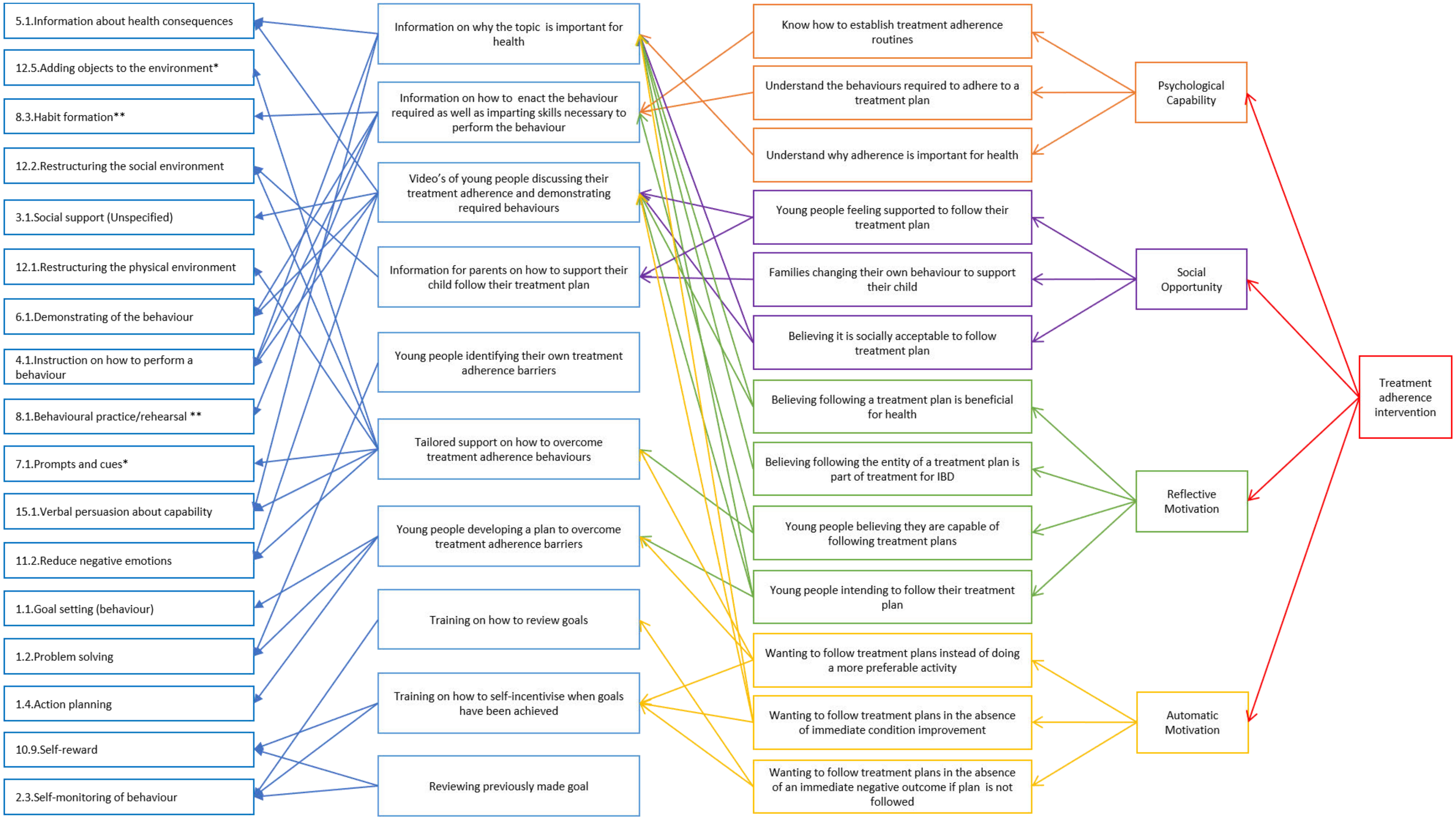
The use of the BCW approach identified four COM-B components for the intervention to target: psychological capability, social opportunity, and reflective and automatic motivation. The intervention modules also contain valuable self-management behaviours such as self-efficacy, resilience, and optimism. Each element of the intervention has been formulated to include relevant BCTs to facilitate the desired behavioural change, dependent on a young person’s needs (Figure 11); as well as relevant theories of behaviour change (SCT, Bandura, 1986; Extended CS-SRM, Leventhal et al., 2016). To further support young people’s behaviour change, separate resources for caregivers will be included.

Strengths and limitations

To the author’s knowledge this is the first intervention for young people (aged 13-18) with IBD, designed using the BCW approach, inclusive of three vital aspects of treatment adherence: medication taking, engagement in medical appointments and following lifestyle advice. In addition, the intervention is relevant to all IBD medications, including those administered within a hospital setting. The intervention is further novel in its support for young people with IBD to engage with content in a manner that is meaningful to them and their needs, rather than working through a generic pre-determined support package.

However, the intervention's development is not without limitations. During the COM-B behavioural analysis, it was identified that some change was needed to enable young people to possess the physical capability and opportunity to perform each target behaviour. Similarly, healthcare professional behaviours were identified as a barrier to young people's social opportunity to engage within medical appointments. However, changing these identified behaviours were beyond the limitations of the current intervention. Future researchers may seek to explore these components further and design interventions specifically aimed to target such behaviours.

Figure 11. Intervention component overview



4.9. Conclusion

This Chapter has detailed the development of a novel treatment adherence intervention for young people with IBD, through the successful use of the BCW approach (Michie et al., 2011). Health behaviour theories, including the SCT, specifically the role of self-efficacy (Bandura, 1977; Bandura, 1986) and the Extended CS-SRM (Leventhal et al., 2016), as well as the outcomes of exploratory research (detailed in Chapters two & three) informed the intervention's development. The intervention includes ten interactive modules, each focusing on a separate behaviour required to live well with IBD and can be tailored by an individual to meet their treatment adherence needs. COM-B constructs of psychological capability, social opportunity and reflective and automatic motivation are specifically targeted within each module, and along with relevant BCTs, support behaviour change in young people's treatment adherence behaviours. The outcome of each module is for young people to develop an action plan to overcome their adherence barriers through the provision of relevant information and tailored support. To ensure the intervention is engaging for the target population, the next stage of the research aimed to draw on the expertise and experience of young people with IBD (Chapter five).

Chapter five: Use of a Patient and Public Involvement and Engagement (PPIE) group to further develop a novel evidence-based theory-driven intervention to improve treatment adherence in young people with Inflammatory Bowel Disease (IBD)

5.1. Introduction

There has been considerable growth in the inclusion of members of the public within research projects across Europe (Biddle et al., 2021). Patient and Public Involvement (PPI) aims to build a formal partnership between researchers and members of the public, whereas public engagement research (PE) looks to share knowledge, inclusive of debate and dialogue activities with members of the public (Holmes et al., 2019). Patient and Public Involvement and Engagement (PPIE) is an umbrella term used to encapsulate both PPI and PE (Holmes et al., 2019). PPIE research is championed by the National Institute of Health Research (NIHR), who define such projects as those conducted with or by patients, potential patients, carers, and service users, instead of for or about them (INVOLVE, 2012).

PPIE research with young people is vital as their experience and knowledge provide a unique insight into the lives of those whom the research is aiming to support (Abrehart et al., 2021). It is essential that members of PPIE groups are defined as partners in research rather than participants, as their contributions are equal in value to researchers (Locock & Boaz, 2019). Further NIHR guidance on conducting co-production research highlights five key principles of such projects: sharing of power; inclusivity of perspectives and skills; respecting and valuing the knowledge of group members; reciprocity, and building and maintaining relationships (Hickey et al., 2018). When designing PPIE activities, researchers must remain flexible in their approach to ensure PPIE is tailored to the aims of the research project (Hoddinott et al., 2018).

The inclusion of paediatric patients in research projects allows clinical populations the opportunity to be heard, feel valued and utilise their experience to find solutions to challenges they have faced (Alderson, 2001; Bray et al., 2022). It is therefore unsurprising that co-design interventions with young people ensures the creation of acceptable, engaging, and relevant interventions (Boote et al., 2016; Coyne et al., 2016; Smith et al., 2022; Wheeler et al., 2022). When designing adolescent health interventions, it is important that health agendas are united with target users' values and needs (Strommer et al., 2021), rather than those of the adult researcher. Therefore, the formation of a PPIE group of young people to co-design the newly developed intervention (detailed in Chapter four), is likely to strengthen the acceptability of the intervention for the target population.

INVOLVE (2012) outline three approaches to PPIE research: consultation, collaboration, and user-control. Consultation refers to asking members of the public to share their views with researchers to inform the research decision-making process (INVOLVE, 2012). Consultancy research may thus be suited to PPIE group members feedback on core components of an intervention (Boote et al., 2016). In a recent review, it has been suggested that most youth PPIE groups are consultants for adult-led decisions (Rouncefield-Swales et al., 2021).

Alternatively, collaborative approaches seek to form a partnership, whereby PPIE groups work with research teams to make shared research decisions (INVOLVE, 2012). Pembroke et al.'s (2021) collaborative workshops provide an example. Here, young people were able to co-script and star in an educational video to promote youth question asking within diabetes clinics, demonstrating that including young people in a collaborative manner can more effectively develop an intervention's content and design. The sharing of power is also important in PPIE research, however consultation and collaborative approaches may not always work to reduce the power dynamic between researchers and patients, as the researcher is often viewed as the expert within the project (Turnhout et al., 2020). This suggests when conducting consultation or collaborative PPIE research groups, adequate thought must be given as to how researchers can reduce their perceived expert status.

User-controlled approaches allow PPIE members to control, direct and manage the research, including making choices at each stage of the research, from conception to dissemination (INVOLVE, 2012). Walsh et al.'s (2018) user-control approach for example, facilitated a PPIE group to identify relevant target behaviours and make early intervention design decisions, supported by the Behaviour Change Wheel approach (Michie et al., 2011). The PPIE group met with the lead researcher 18 times over 30 months, to discuss and make decisions regarding different elements of the diabetes intervention (Walsh et al., 2018). Thabrew et al. (2018) highlight challenges with this approach, suggesting facilitators may need to moderate PPIE decisions when designing interventions, as it will likely not be possible to accommodate everyone's ideas or preferences.

For the current research, a PPIE group of young people with Inflammatory Bowel Disease (IBD) was formed to co-develop the intervention. Prior to the creation of the PPIE group, each of the three PPIE approaches outlined by INVOLVE (2012) were carefully considered. It was subsequently clear that taking a consultation approach, would not allow young people to have a rich involvement in the intervention's development. Equally, it was not appropriate to select a user-centred approach, as asking PPIE group members to continue developing the designed intervention content, detailed in Chapter four, is incompatible with the ethos of user-centred research. Therefore, after reviewing the benefits of each PPIE approach, it was decided that a collaborative approach would best suit the current research, as this would allow young people to work alongside myself to transform complex theoretical constructs into engaging intervention activities. However, to enhance the acceptability of the intervention and reduce power imbalances between myself and the PPIE group, user-centred decisions were incorporated within each workshop, giving young people autonomy over the intervention's aesthetic design and module components.

Including fun techniques or ice-breakers in co-design workshops facilitates a relaxed atmosphere for young people (Thabrew, et al., 2018). Arts-based tasks, such as drawing, mapping, collaging, photography, Lego brick building and Play-Doh modelling, can support the production of new ideas and rich visual data, as well as allowing young people to take ownership of their creations (Aufegger et al., 2020; Bowen et al., 2013; Carter & Ford, 2012; Lyon & Carabelli, 2016; Ozkul, 2022; Tumanyan & Huuki, 2020; Vusio et al., 2021). The inclusion of arts-based methods provides young people with the opportunity to express their thoughts and experiences in a different way and is void of the imposed sense of how a question should be answered (Caldairou-Bessette et al., 2020; Fargas-Malet et al., 2010; Punch, 2002). It is subsequently a researcher's responsibility to provide participants with the autonomy over their creation's interpretation and not ignore these within the analysis (Carter & Ford 2012; Caldairou-Bessette et al., 2020; Wheeler et al., 2022). Participating in arts-based PPIE research projects can further encourage empowerment and self-esteem in young people (Flotten et al., 2020). It is therefore unsurprising that arts-based methods have been a useful and effective tool when co-designing interventions with young people (Bowen et al., 2013; Kirtland et al., 2019; Langley et al., 2020; Walker et al., 2009; Wolstenholme et al., 2019). Bowen et al.'s (2013) use of arts-based activities based on popular television programmes, such as Big Brother, increased young people's engagement in the co-production activities to design a new support service for young people with diabetes.

Digital creative co-production techniques, such as virtual post-it notes or idea boards can further be effective when facilitating online co-design workshops (Bray et al., 2022). Furthermore, conducting co-production workshops online can reduce potential attendance barriers and promote inclusivity within the research project (Bray et al., 2022). However, arts-based intervention co-design methods may not be engaging for all young people, and those who join such projects may hold a pre-existing interest in artistic outputs (Carter & Ford, 2012; Fargas-Malet et al., 2010; Lyon & Carabelli, 2016).

This Chapter will outline how a novel treatment adherence intervention was co-developed with a PPIE group of six young people with IBD. The term PPIE was selected to be reflective of the group's engagement with the intervention co-design process. A collaborative PPIE approach was taken, however, there was a conscious effort to allow for user-centred decisions about the intervention's content, module components and aesthetic design to enhance the acceptability of the intervention. Arts-based tasks were facilitated in each PPIE workshop to support the co-design process. In part due to Covid-19 and in part due to widening access to the PPIE group, co-design workshops were run online using the Zoom platform.

5.1.1. Research aims

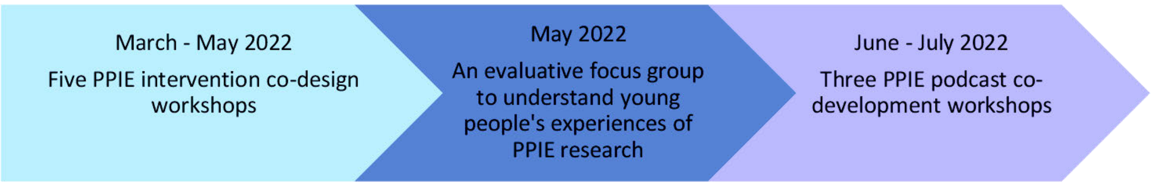
To co-develop the intervention’s content and design with young people with IBD, as well as to gain young people’s views on the acceptability of the prototype intervention. Furthermore, the Chapter aims to evaluate young people’s experiences of taking part in PPIE research projects.

5.2. Methods

5.2.1. Design

Young people’s involvement in this project can be separated into three stages (Figure 12). First, a five-session online PPIE group of young people with IBD was conducted between March-May 2022. The INVOLVE (2012) guidance was followed in the group’s formation and facilitation. Within these workshops, young people co-developed means of translating theoretical constructs into a series of practical intervention activities delivered within a novel treatment adherence intervention. To achieve this, each workshop contained collaborative discussions and a variety of arts-based techniques. Group discussions were based on the intervention components developed in Chapter four. Second, a single focus group was conducted to evaluate young people’s experiences of participating in the PPIE workshops, two weeks after the final PPIE workshop. Finally, three additional PPIE sessions were facilitated between June-July 2022 to develop a prototype podcast. This was a youth-led initiative to support provision of tailored support within the intervention.

Figure 12. Stages of youth PPIE research



5.2.2. Sample & Recruitment

A combination of sampling and recruitment techniques were used to recruit young people (aged 13-18) with IBD to take part in online PPIE workshops. First, a Consultant Paediatric Gastroenterologist used purposive sampling to identify young people (aged 13-18) diagnosed with IBD from the IBD service at a Specialist Children's Hospital. The Consultant provided eligible individuals with a letter of invitation, containing a QR code link to an online information sheet (Appendix.19 and Appendix.20). Second, adverts were placed on Crohn's and Colitis UK's social media platforms, which used opportunistic and snowballing sampling approaches to recruit young people (aged 13-18) with IBD. Again, young people who were interested in joining the PPIE group were provided with further information before agreeing to take part (Appendix.19 and Appendix.20). All participants provided informed consent (Appendix.21 and Appendix.22). Young people aged below 16 years provided assent with parental consent.

After the fifth PPIE workshop, PPIE group members who had consented to be contacted regarding future research, were invited to a focus group (Appendix.24 and Appendix.25). Young people, who were interested in participating in the focus group were invited to contact a member of the research team, who would answer their questions before gaining consent (Appendix 26 and Appendix 27).

5.2.3. PPIE Group Workshops

All PPIE workshops were digitally recorded to allow the facilitator to review each session and make relevant notes. Each participant was given a pseudonym to remain anonymous within the reporting of the PPIE workshops. Once sufficient notes had been made, including the retention of relevant PPIE group members' quotes, the recordings were deleted. To preserve a visual representation of the outcomes of arts-based tasks, young people were asked to send photographs of their creations to the researcher during each workshop.

Initially young people were invited to join an online introductory session. Here, the research project's aims and the PPIE group's involvement were explained. Those in attendance could then make an informed decision about whether they would like to formally join the group. The remaining four online PPIE workshops explored young people's views on how to ensure the proposed intervention's content and mode of delivery was engaging for young people.

Across the PPIE workshops, young people were able to co-develop the intervention's delivery methods, aesthetic design, and functionality of the core module components; education, training, support videos, knowledge demonstration activities, tailored support, action planning, and goal review (Table 17).

During the PPIE workshops a variety of arts-based methods were used to support young people in expressing their thoughts and opinions. For these tasks to take place, young people (aged 16-18) and parents of young people (aged 13-15), were asked to provide a postal address to send an activity pack to within the consent form.

Each activity pack contained; 130 Lego bricks; four tubs of Play-Doh; four sheets of Emoji stickers; A5 and A6 card; a selection of coloured A4 paper; post-it notes in a variety of colours and shapes; felt tip pens; pencils and an A5 notebook (Image.1). Digital creative methods were also included in the workshops using Mentimeter and Google Jamboard.

Image 1. Example of activity pack contents

Each workshop lasted around 105 minutes and contained a mixture of discussions, arts-based tasks, and comfort breaks. An MSc student assisted the PPIE workshops delivery by moderating the online discussion board. Within the workshops young people reviewed and co-transformed the theoretical intervention components into an interactive prototype. Young people were encouraged to share their views regarding other group members suggestions, as well as providing a clear rationale for their own ideas. Towards the end of each discussion, the group came to a collaborative decision about how an intervention component should be presented within the intervention. Decisions made by the group were incorporated into a prototype intervention module which ensured relevant and engaging formats were used to implement relevant Behaviour Change Techniques (BCTs) (Michie et al., 2015) (Table 17).

Within the fifth workshop, the group were able to observe how their ideas had been incorporated into a prototype intervention module. Group members interacted with the prototype and provided feedback on the module’s functionality and acceptability. When facilitating group sessions, attention was paid to the use of plain English to communicate complex constructs and avoid feelings of uncertainty amongst group members. The aim here was to remove negative stigma attached to the perceptions of an intervention. As such the term “support programme” was adopted, rather than intervention.

To ensure sufficient time to co-develop a prototype podcast, an additional three PPIE workshops were offered to the group following (what was expected to be) the final session. These workshops included planning the podcast dialogue, recording the podcast, and reviewing recorded material, making amendments where necessary. The PPIE group’s podcast plan was checked by an IBD nurse at a Specialist Children’s Hospital, prior to recording, to ensure the support offered was medically accurate.

As a token of thanks, young people received a £15 shopping voucher after each PPIE session they took part in. In addition to this, young people were given the opportunity to attend a workshop on the benefits of conducting scientific research to understand human behaviour. All young people were asked to complete a short online demographic questionnaire before joining the PPIE group (Appendix.23).

Table 17. Targeted COM-B constructs and included Behaviour Change Techniques (BCTs) for each intervention module component. *Psychological Capability (PC); Social Opportunity (SO); Reflective Motivation (RM); Automatic Motivation (AM)

	Intervention Components				
BCTs	Education and Training (PC; SO; RM; AM)	Support Videos (SO; RM; AM)	Tailored Support (RM; AM)	Action Planning (RM; AM)	Goal Review (RM)
1.4.Action planning				X	
12.5.Adding objects to the environment			X		
8.1.Behavioural practice/rehearsal	X				
6.1.Demonstrating of the behaviour	X	X			
1.1.Goal setting (behaviour)				X	
8.3.Habit formation	X				
5.1.Information about health consequences	X	X			
4.1.Instruction on how to perform a behaviour	X	X			
1.2.Problem solving				X	
7.1.Prompts and cues			X		
11.2.Reduce negative emotions		X	X		
12.1.Restructuring the physical environment			X		
12.2.Restructuring the social environment			X		
2.3.Self-monitoring of behaviour					X
10.9.Self-reward					X
3.1.Social support (Unspecified)		X			
15.1.Verbal persuasion about capability	X		X		

5.2.4. PPIE Evaluation Focus Group - Data Collection & Analysis

An online focus group was conducted with PPIE group members, over Zoom. Participants were encouraged to select a quiet location, where they would feel comfortable. Questions within the focus group sought to understand young people's experiences of taking part in the PPIE workshops (Appendix.28). The focus group lasted 90-minutes. Prior to the focus group, all participants completed a study specific consent form as well as a short online demographic form (Appendix.29). As a token of thanks, young people were compensated for their participation with a £15 online shopping voucher.

The focus group was audio-recorded and transcribed verbatim. Due to young people's use of the discussion board within the focus group, a verbatim transcript of young people's typed answers was also included within the analysis. Within both transcripts, young people were given the same pseudonyms allocated to PPIE group members, during the reporting of the PPIE workshops. Although a lack of depth in focus group data hindered the performance of formal qualitative analysis, a helpful narrative summary of young people's experiences was produced.

5.2.5. Ethics

An extension of the previously attained favourable ethical review by the Health Research Authority's, London Bloomsbury board (IRAS #126868) was obtained in November 2021 to recruit participants for five PPIE workshops and subsequent PPIE evaluation focus group. A further extension of this ethical approval was sought in April 2022 to include up to five additional podcast development workshops with the PPIE group.

5.3. Research Outcomes – PPIE workshop sessions

5.3.1. Group members

Seven young people expressed an interest in taking part in the PPIE group; six of whom attended the introductory session and consented to join the PPIE group.

All PPIE group members were diagnosed with Crohn's Disease and consisted of more females (N=4) than males (N=2) with an average age of 14.83 years. Most young people had received their IBD diagnosis recently, with an average age at diagnosis of 13.33 years (Table 18). The sample were primarily prescribed azathioprine combined with another IBD medication, such as infliximab. Due to ill health, one CCTV group member was unable to attend the fifth PPIE workshop.

Table 11. Young people's demographic information

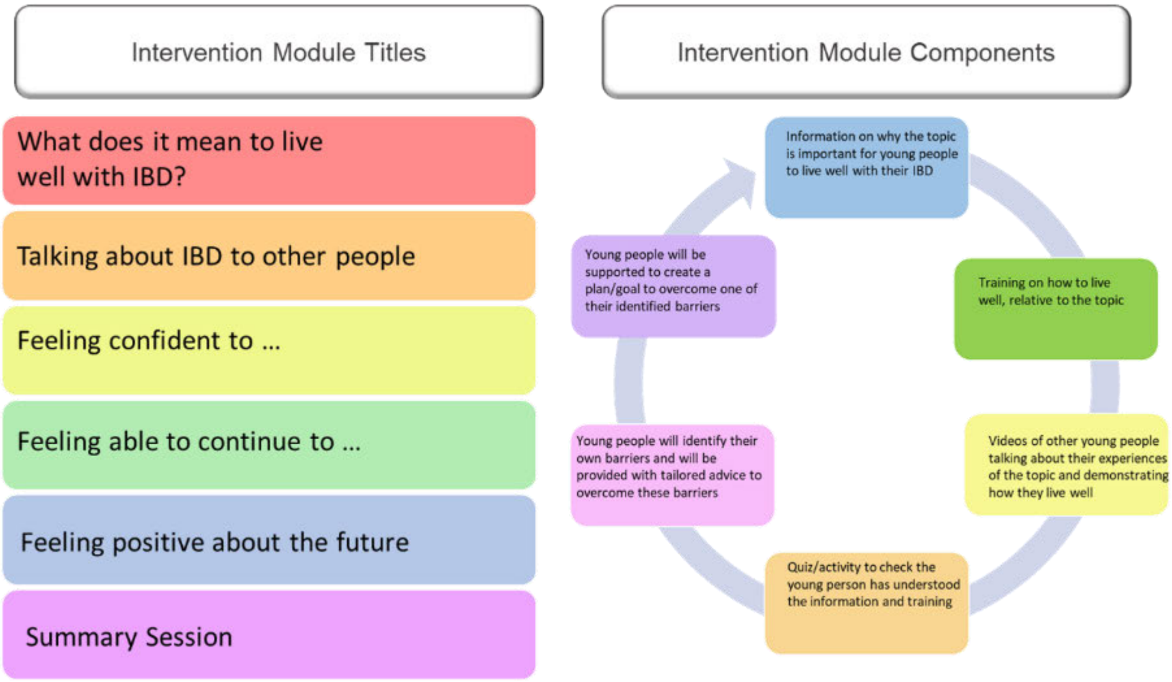
	PPIE group workshops (N=6)	*PPIE evaluation focus group (N=4)*
Age (Mean, SD)	14.83 (1.07)	14.5 (1.12)
Gender (N)		
Male	2	2
Female	4	2
Ethnicity (N)		
White British	6	4
Diagnosis		
Crohn's Disease	6	4
Age at Diagnosis (Mean, SD)	13.33 (1.89)	13.25 (2.05)
Medication (N)		
Azathioprine	4	4
Humira	1	
Infliximab	4	3
Pentasa	1	
Mebeverine	1	
Citalopram	1	

5.3.2. The introductory workshop

To meet the ethos of PPIE research, the introductory workshop aimed to share knowledge with young people, to inform them about the research. Steps were taken to reduce the power imbalance within future PPIE workshops, by removing the perception of the group facilitator as the expert as well as giving control to young people over how the group would run (e.g., platform, timings etc). During discussions of the formative exploratory research projects (Chapters two and three), young people were encouraged to ask questions and provide further insight into the research outcomes. Young people were also introduced to the newly developed intervention's outline (Chapter four) and were able to share their views on what this could mean for young people with IBD. Colourful diagrams were produced to differentiate between intervention modules and module components (Figure 13). The aims for the PPIE group's collaboration in the design of the intervention were also discussed. Young people were encouraged to ask questions about their potential involvement with the project. The session was then paused for 15-minutes to allow young people the opportunity to decide if they wished to join the PPIE group. Those who did not want to join were free to leave by closing their browser. However, all those who attended the introductory session chose to join the PPIE group.

During the introductory session, young people spontaneously began debating the best delivery method for the intervention. While all were enthusiastic over the online format, some thought it would be best delivered as a smartphone application, whilst others preferred a website format. Within later sessions, this was explored further, with a group consensus that the intervention should offer both a website and a WebbAPP (e.g., a smartphone application of a website's content). This would ensure the intervention delivery could be tailored to an individual's preference.

Figure 13. Plain English intervention diagrams used within the introductory session

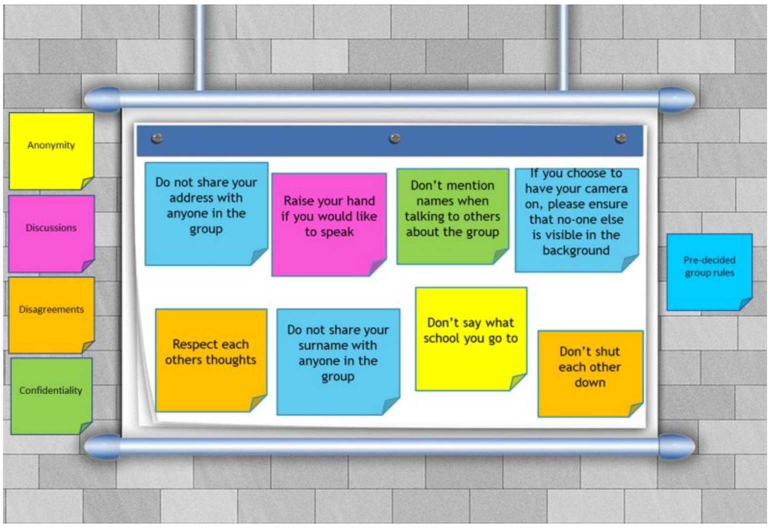


5.3.3. Forming the group's identity

Young people were able to take ownership over the group by developing the PPIE group's identity in a multitude of ways. First, young people were able to collectively decide which online platform would host the PPIE workshops. Initially the group opted to try different online platforms including MS Teams, Zoom and Google Hangouts, however, after using Zoom, the group signalled their preference for its continued use. The group had further autonomy over the date and time of each workshop to ensure it was accommodating of their commitments. While it had been intended the group sessions would be facilitated across eight weeks, a preference was expressed for workshops to be dispersed over ten weeks due to differences in regional school holidays.

The group were supported to form workshop rules surrounding group members' anonymity and confidentiality, and how to manage discussions and disagreements. Young people were able to use the online post-it note function on Google Jamboard to anonymously share their suggestions, before discussing these as a group and forming a collaborative set of rules (Figure 14).

Figure 14. PPIE group code of conduct



Do not share your address with anyone in the group

Raise your hand if you would like to speak

Don't mention names when talking to others about the group

If you choose to have your camera on, please ensure that no-one else is visible in the background

Respect each others thoughts

Do not share your surname with anyone in the group

Don't say what school you go to

Don't shut each other down

Young people developed the group's identity further by creating the group's name. The youth-led suggestion of "Crohn's and Colitis Teen Voice" group (CCTV group) was unanimously preferred by young people. One group member designed the group's logo using the Play-Doh in their activity pack (Image.2).

Image 2. Crohn's and Colitis Teen Voice (CCTV) group logo

The group facilitator included an icebreaker activity at the start of each workshop to help the group feel comfortable discussing their thoughts or preferences with each other. Most icebreakers included an art-based activity to promote creativity within group sessions. For example, young people were given three minutes to draw an image of their favourite film on a post-it note; each group member then displayed these images to the rest of the group who had to guess the film.

5.3.4. Intervention modules

The intervention was initially designed so that young people could select modules that are appropriate to their adherence needs. To ensure module topics were relevant to young people, the CCTV group developed module titles and descriptions. To explore young people’s understanding of the concepts of self-efficacy, resilience, and optimism, CCTV group members were each randomly allocated one of the following topics “feeling confident to…”, “feeling able to continue to…”, or “feeling positive about the future”. They were then asked to explain their interpretation of the topic using Play-Doh or Lego. Young people shared their creations with the group to create a topic definition which would be included within the intervention (Image.3).

Image 3. Grace and Chloe's understanding of resilience, and Eloise's understanding of optimism

When exploring confidence, Mark created a Lego model of a hospital and discussed how feeling well and controlling IBD symptoms improves young people's confidence. Liam's definition explored associations between happiness and self-efficacy, suggesting that when young people are happy with their abilities, they are more confident to adhere to their treatment. The group were in general agreement with these answers and felt they captured the different aspects of confidence. This led to the following youth-led topic definition:

> "Feeling confident to do things such as take your medication, or talk to others about your IBD, is important to help you live well with your IBD. Feeling confident to do things can encourage you to feel happy, and can help you manage your IBD and start to feel better"

Upon review, it was apparent that the group's definition was an appropriate plain English representation of self-efficacy, therefore no further revisions were required.

Young people's interpretations of the topic "feeling positive about the future" were inclusive of different elements of optimism. Cara created a heart because "loved ones and people around us help us through the tough times" by encouraging young people to remain optimistic. Eloise created multiple Play-Doh modules demonstrating their anticipated life achievements including a reduction of IBD symptoms, following manageable medication routines, and getting their dream job. Other group members discussed the importance of this topic, as it was disheartening to think about feeling unwell during adulthood. These factors were incorporated into the following group definition:

> “It may feel overwhelming to be diagnosed with IBD, and you may worry about your future. However, IBD does not have to limit what you are able to achieve in your life. In this topic you will explore how asking for support and living well with your IBD, can help you feel more positive about the future.”

Due to the group’s appropriate understanding, the topic title was demonstrated to be relevant and acceptable for the target population.

The final topic of resilience provided much thought-provoking discussion. Grace chose to list factors associated with continued adherence including medication taking, sleep behaviours, eating healthily as well as factors to promote psychological wellbeing. Chloe created a Lego car, describing it metaphorically as “being able to do stuff”. This reflected the idea that adherence allowed young people to have more life opportunities. The group generally understood the concept of resilience but required further information to form a definition. The group felt changing the title (from “Feeling able to…”) would provide others with a greater comprehension of the topic. Instead, they suggested the title of “Overcoming obstacles to…” In doing so the group developed the following definition:

> “Sometimes you will face challenges to following your treatment plan. When you feel able to overcome obstacles to look after your health and live well with your IBD, this can help you achieve everything you want to in your life”

It was clear that a title change was required to improve the acceptability of this topic, therefore such amendments were made.

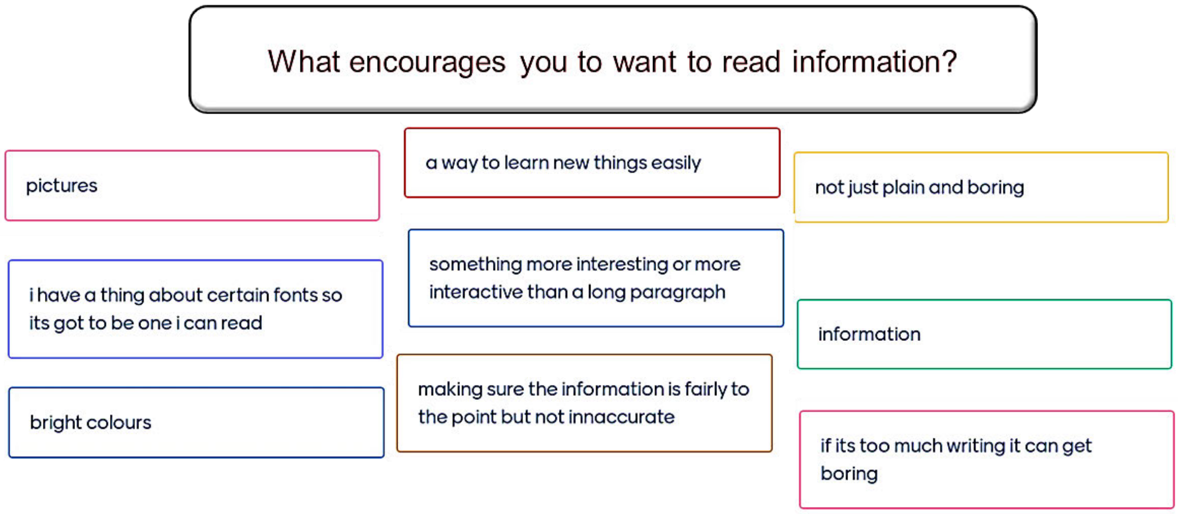
5.3.5. Module components

Education and training

The intervention’s provision of education and training is inclusive of six BCTs to target young people’s psychological capability, social opportunity, reflective and automatic motivation (Table 17). The CCTV group engaged in multiple tasks to produce user-centred decisions on the included educational and training material’s format, content, and aesthetic design.

Initially, young people were asked to contribute to an anonymous idea board via Mentimeter, to answer the question “What encourages young people to want to read information?” Answers could be categorised into two sections (Figure 15). First, young people wanted information presented in colourful interesting designs, inclusive of images. Second, concise, easily understood sections of information were preferred, to avoid boredom and confusion. Within group conversations, young people discussed their unanimous preference for a mixture of visual and written information within the intervention, as this hybrid of information formats would increase young people's engagement.

Figure 15. CCTV group anonymous responses to the question "What encourages you to want to read information?"



What encourages you to want to read information?

pictures

i have a thing about certain fonts so its got to be one i can read

bright colours

a way to learn new things easily

something more interesting or more interactive than a long paragraph

making sure the information is fairly to the point but not innaccurate

not just plain and boring

information

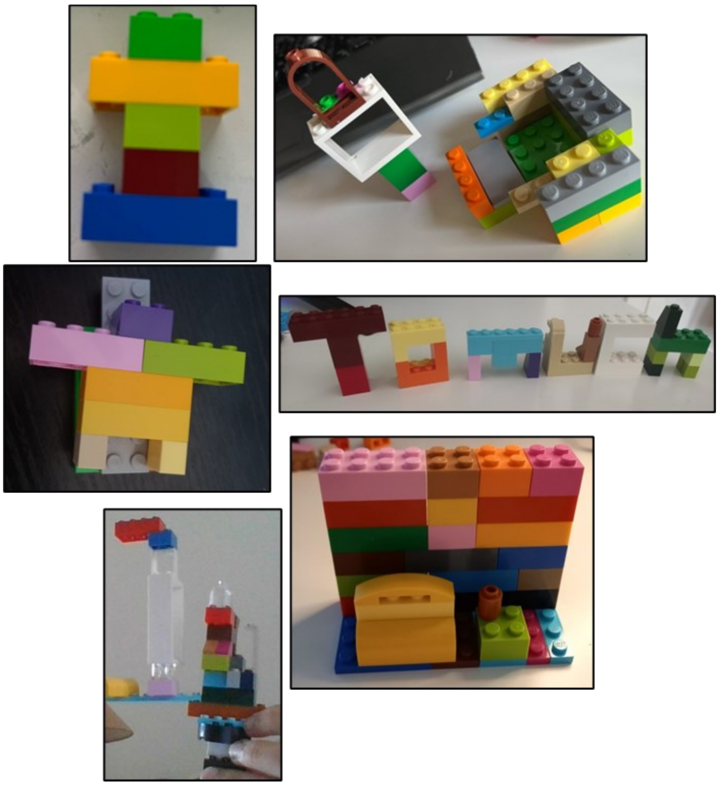
if its too much writing it can get boring

The need to avoid 'boring' content was frequently discussed by the CCTV group. To further understand young people's perceptions of boredom, the group were tasked to build a Lego model depicting their experiences of reading or watching boring information (Image.4). Two group members created people lying down to emphasise the exhausting nature of reading boring content. Grace created a rigid cubistic room to demonstrate the boredom caused by uninteresting repetitive information. Eloise explored the concept of passive attention during boring tasks, as young people are more likely to be distracted and pay attention to their surroundings when bored. Chloe created a moving structure whereby they had loosely clicked Lego bricks together in a fashion that meant when they moved their model Lego bricks fell off. Chloe descried their creation as:

> "It's just like a random collection of loads of different Lego bricks because sometimes it's just like too much information."

The visual representation of a disintegrating tower of Lego was a powerful metaphor to understand the challenge of retaining tedious pieces of information. The young people's interpretations of the created models provided a clear insight into the necessity of incorporating youth-led educational formats to prevent disengagement.

Image 4. CCTV group depictions of boredom using Lego



The CCTV group were also tasked to design potential layouts for education and training information using pens and papers in their activity pack. Each group member was randomly allocated one intervention topic and were provided with relevant information to be included within the module; such information was specifically designed to include relevant BCTs. Most young people used defined boxes or shapes within their design to display how information should be presented (Image.5). Videos were included within the CCTV group's designs to include a variety of information options to meet different learning styles. The content of each video differed depending on its educational aim. For example, healthcare professionals were considered best to provide training on how to take medication or describe healthy eating, whereas young people were perceived as best suited to sharing experiential information. Interactivity, such as clicking on images to reveal further information, was incorporated in the young people's designs to prevent boredom. Young people chose bold colours and indicated where colourful images should be included to disperse sections of text. Colour was further suggested as a helpful technique to differentiate between essential pieces of text or key words to signal the information's importance.

Image 5.CCTV group members suggested information layouts

The group reviewed each other’s ideas and concluded an interactive colourful layout, inclusive of written and verbal resources would support the user to absorb information at their own pace, making it the most acceptable and preferable format within the intervention.

Social support videos

Within the intervention’s design, support videos were included to provide young people with a sense of normality over their experiences, targeting young people’s social opportunity and reflective and automatic motivation. To achieve this, the video’s design was needed to be appropriate and relatable for young people. The provision of social support was favourably received by the CCTV group, who believed hearing others’ experiences would provide comfort and support the development of self-management skills. The group were asked to share their ideas on who should be included in the videos, the tone and content of video discussions, and possible filming locations. These thoughts were initially shared anonymously, on an idea board via Mentimeter, before being discussed collectively as a group.

Taking inspiration from the suggestions on the idea board, each young person was able to design three video concepts, with at least one being a video they would enjoy watching and another they would dislike watching. Using A5 card and felt tip pens from their activity pack, young people sketched their ideas and added notes about key features within the videos. Once the video concepts had been created, young people were asked to use the emoji stickers in their activity pack to rate their concept as if they were a young person watching the video for the first time (Image.6).

Image 6. A selection of CCTV group's favourable and disliked support video concepts

The group had very specific ideas about the videos' filming location. The importance of a relaxing environment that promoted discussion was highlighted. For example, settings that included comfortable seating, houseplants, and mindfulness related objects. Including humour within IBD discussions was perceived as essential to detract from the seriousness of living with IBD. Celebrities discussing their IBD was also viewed as a potentially effective behaviour change tool, as young people could view such individuals as role models. While videos of healthcare professionals had previously been identified as a useful educational resource, young people rated their inclusion within the support videos unfavourably.

Collectively, the group decided videos would be best if two young people were filmed discussing their experiences of the topic. Conversations were suggested to be honest and humorous, to promote a realistic but light-hearted understanding of others' experiences. All videos should be filmed in a location that is inviting, calming and promotes mindfulness. The CCTV group's decisions were suitable for the inclusion of relevant BCTs (Table 17).

Demonstration of knowledge activities

The CCTV group were randomly assigned an intervention module and tasked with developing a series of interactive games (e.g., quizzes and wordsearches) that would promote knowledge (targeting users' psychological capability), as well as being fun and engaging. Most young people preferred quiz-based activities, as these were perceived as the most acceptable and suitable option for the target population. However, there were variations in the preferred quiz format. Some found picture-based questions easier to use, while others preferred more detailed multiple-choice answers to allow them to test their knowledge. This led to a group consensus that each module should contain multiple different styled activities to match everyone's needs, including non-quiz-based activities.

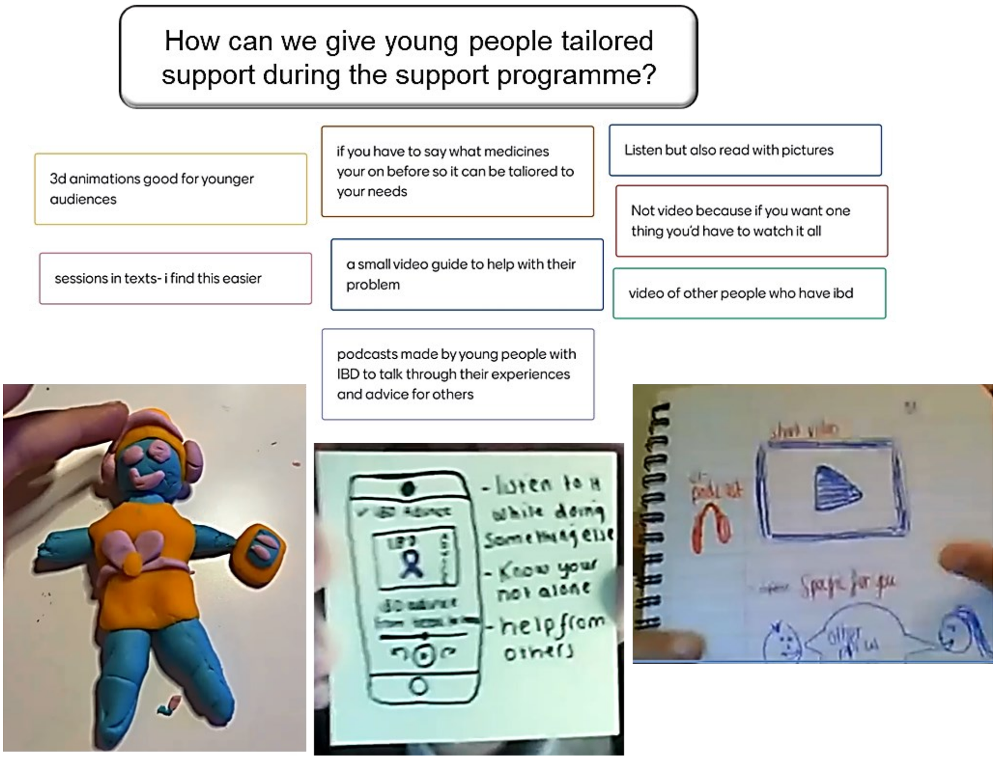
Tailored support

Receiving tailored support to overcome an adherence barrier is a crucial element of the intervention. It was important to determine how this concept should be explained within the intervention and identify the best format to offer such support. To explore young people's understanding of the concept, an anonymous word cloud was facilitated via Mentimeter, to answer the question "What does tailored support mean to you?" The group identified the individualised nature of tailored support and felt young people were familiar with the term through their interactions with healthcare professionals (Figure 16).

Figure 16. CCTV group interpretations of tailored support using an anonymous Word Cloud

The CCTV group then completed an anonymous idea board to gather their insight on how young people would like to receive tailored support during the intervention. A variety of options were suggested including written, visual, and audio support formats. Following a group discussion, each young person was asked to choose the most effective format and demonstrate the reasonings behind their decision using Play-Doh or pens and paper. Unexpectedly, there was a unanimous selection of a podcast format, inclusive of more than one young person discussing possible support options for a variety of IBD challenges (Figure 17). The CCTV group members discussed their current preferences for listening to podcasts as a resource to enhance their knowledge and wellbeing (Figure 17). The group felt the intervention podcasts would be more relatable if young people designed the podcast's contents so that it was "made by young people, so other young people can listen to it and like relate to it and know you are not alone" (Grace). The group also provided suggestions on how intervention users could tailor the podcast's content to meet their needs; "the podcast/video could have chapters so you could find what you're interested in" (Mark). Podcasts were further desirable as young people could listen to them at a time or location of their choosing; "You can listen to it anywhere, on the bus on the way to school" (Eloise).

Figure 17. Young people's suggestions for the provision of tailored support, with an overall preference for a podcast format



How can we give young people tailored support during the support programme?

3d animations good for younger audiences

if you have to say what medicines your on before so it can be taliored to your needs

Listen but also read with pictures

Not video because if you want one thing you'd have to watch it all

sessions in texts- i find this easier

a small video guide to help with their problem

video of other people who have ibd

podcasts made by young people with IBD to talk through their experiences and advice for others

- listen to it while doing something else
- Know your not alone
- help from others

Podcast development

The CCTV group were presented with the idea of extending PPIE group sessions to develop a prototype podcast. Following a group consensus for taking part in this development, approval was obtained to extend the number of CCTV workshops. The group were able to select suitable dates and times for the additional workshops. The first podcast workshop took place seven weeks after the CCTV group's fifth PPIE session, to accommodate young people's school exams. Three young people decided not to join the podcast development workshops, due to previous commitments.

Within the first podcast workshop, the remaining three CCTV group members identified eight barriers young people experience to feeling confident to take their medication, using the post-it note function on Google Jamboard. Each challenge was initially allocated to one group member who added additional post-it notes containing strategies to overcoming the barrier. Through group discussions, further support options were added until the group felt they had created a comprehensive overview of young people's adherence support needs.

Young people felt uncomfortable generating and reading a script during the podcast recording, instead preferring to allow the conversation to occur naturally, prompted by their list of adherence support options. Prior to the next session, the group's plan was reviewed by an IBD Nurse from a Specialist Children's Hospital, who checked the group's chosen support options were appropriate and suggested additional ideas the group may wish to consider.

During the second podcast development workshop, the group reviewed the IBD nurses' feedback and decided to incorporate the additional suggestions into their plan (Table 19). When recording the prototype podcast, discussions were light-hearted but supportive and inclusive of personal experiences, as well as encouragement to overcome adherence challenges. Without prompt, young people contributed equally to the conversation with no group member identifying as the leader.

Within the final meeting, young people reviewed the podcast audio. The group were pleased with the tonality of the podcast but were surprised to hear themselves casually discussing their IBD experiences. Eloise suggested intervention users may find it beneficial if they were aware of the podcast speaker's IBD diagnosis and prescribed medications. Following group agreement, additional audio was recorded and incorporated into the prototype podcast (Appendix.30). Overall, the group were proud of their creation and reflected on the benefit this would have for other young people with IBD.

Within the podcast's youth-led content, chosen support options were inclusive of the previously identified BCTs (Table 17). For example, suggesting the use of medication reminders and the group members' use of persuasive language when discussing how young people could overcome their adherence barriers. Therefore, following the success of the prototype podcast, it was decided this format should be included within the intervention.

Table 1912. The CCTV group's final podcast plan for the module "Feeling confident to take medication", inclusive of youth-led ideas and suggestions provided by an IBD nurse

Adherence Barrier	CCTV support suggestions	IBD Nurse suggestions
Feeling too unwell to take your medication	➢ Have a trusted family member do it for you ➢ Try to leave it a little bit until you feel a bit better to do it	➢ Use a phone reminder if you are going to wait a bit
Feeling worried about taking medication, including medication side effects	➢ Asking your doctor or IBD nurses about common side effects ➢ Knowing the probability of getting the side effect ➢ If you have any side effects asking your IBD team how best to treat them or lessen their effects ➢ Dealing with negative people who comment on side effects (e.g., steroid side effects)	
Feeling that your medication isn't working but still having to take it	➢ Tell your IBD team ➢ If you are taking it every day you may not notice the effects ➢ Understanding that it is helping ➢ Understanding that it takes time to work	➢ Emphasizing that some medications take a long time to work
Making sure you have your medication/not forgetting to get your prescription	➢ Always make sure to order more medication ➢ Tell your parents once you are a week away from running out of medication ➢ Set reminders for when it is going to run out and when you need to order more	
Forgetting to take your medication	➢ Set an alarm ➢ Put post-it notes in a common place that you see every day ➢ Ask someone who is not forgetful to remind you ➢ Creating a time and place to put and have your medication e.g., Next to your toothbrush	➢ Place medication next to a phone charger
Finding it difficult to create a medication routine	➢ Creating a time and place to put and have your medication e.g., Next to your toothbrush ➢ Setting reminders on your phone	➢ Place medication next to a phone charger or in a food cupboard

	➢ Trying to incorporate it into actions you already know	
Feeling like you do not know enough about your IBD and your IBD treatment	➢ Educating yourself though online resources ➢ Talking to other young people with IBD ➢ Asking your doctor or IBD nurses about your medication	➢ Talking to your IBD nurse without parents present ➢ Meeting other young people with IBD at charity or hospital events
Feeling embarrassed to take your medication around friends and family	➢ Go to a private room ➢ Hide it in a napkin/clothing ➢ Explain about your medication to your friends and family ➢ Own it! It's keeping you well don't listen to others' opinions	

Goal setting

Within each module young people are supported to develop user-centred action plans to overcome their biggest adherence challenge and thus improve their treatment adherence behaviours. It is essential this element provides clear and engaging advice to young people on how to create and implement their action plan; therefore, CCTV workshop activities were devised to achieve this.

In a sharing of knowledge exercise, discussions were held on how CCTV group members currently aim to overcome their adherence barriers and how the intervention will guide young people to develop action plans. CCTV group members liked the ability to set user-centred goals based on an individual's own assessment of their IBD needs, rather than being told what to do, resulting in Liam describing it as an "amazing idea". Further information was shared with the group about why the BCT's *1.1. Goal setting* and *12.5. Action planning*, would be implemented within each module; the group enjoyed the information and thought similar content should be included within the modules to allow intervention users to understand the evidence behind what they were being prompted to do. The group suggested using a combination of written and visual information to allow young people to gain further clarity on the action planning process. However, the terminology of "action planning" was less preferable to the group who felt "goal-setting" was a better reflection of the process. Therefore, to increase the acceptability of the intervention, the terminology of goal setting was embedded into the module components; additionally interactive multimedia information defining action planning and explaining how it can help overcome adherence barriers were included in the prototype.

When creating the aesthetic design of the goal setting process, young people suggested this should be akin to the educational information layout (Image.5), using clearly defined sections to allow young people to distinguish between different parts of their action plan. The CCTV group further suggested guidance should be provided to allow young people to foresee challenges to implementing their action plan, such as forgetfulness or “being too busy to do what you want to” (Cara), as an inability to complete goals would lead to disappointment and disengagement.

Therefore, rather than a single interactive textbox, multiple interactive “bubbles” were developed to divide the action planning process into clear sections. Additional information discussing potential implementation barriers and ways to overcome these, were added into the prototype, targeting young people’s automatic and reflective motivation to change their behaviours.

Reviewing goals

Seven days after an action plan’s formulation, young people will be prompted within the intervention to evaluate their behaviour change success; if issues to goal completion are recorded further support is offered. The module component’s aims were shared with the CCTV group, who all viewed the provision of additional guidance to achieve challenging goals as beneficial to promote continued engagement in young people; “I like how you can go back to it and if you are struggling you can find ways to help” (Grace). Through collaborative conversations, the group guided the content of the interventions goal review responses; “I have achieved my goal”, “I am still working towards my goal” and “I am struggling to achieve my goal”. The group suggested that all responses should be inclusive of motivational language and reward young people for their achievements and engagement with their action plan. The group suggested when young people were working towards or struggling to achieve their goal, responses should demonstrate an understanding of the difficulties of making behavioural changes, avoidant of patronising or overly empathetic language. Additional support option should be practical and easy to understand to allow young people to achieve their goal. All discussed factors were incorporated into youth-led responses for each goal review option (Figure 18).

Figure 18. Youth-led intervention goal review responses

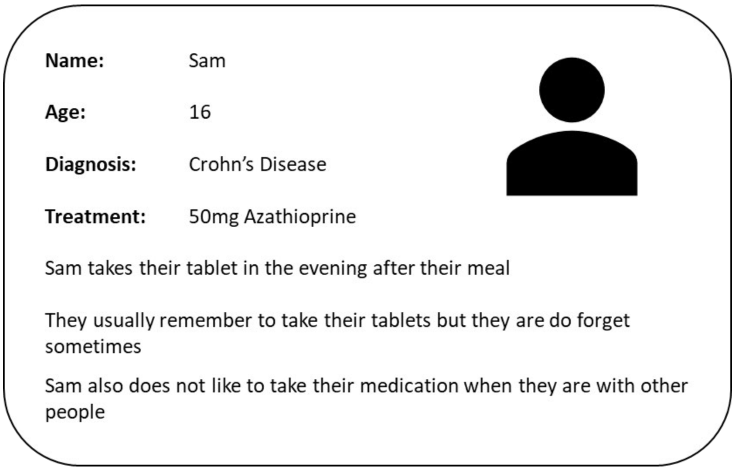
I have achieved my goal	Well done, keep up your hard work! How do you feel now you have achieved your goal?
I am still working towards completing my goal	Sometimes achieving our goals can take more than a few days. It can be helpful to review your progress and see how far you have already come in completing your goal. You can find helpful information on how to keep working toward your goal here
I am struggling to complete my goal	It's ok to say you are struggling to complete your goal. It can be helpful to review your progress and see how far you have already come to complete your goal. If you feel you have made no progress, it may be that your goal was too ambitious. Read more about how to make sure your goal is achievable here. You can find helpful information on how to keep working toward your goal here.

The inability to record a goal's success or begin a new module for at least seven days after a previous goals formation was perceived as acceptable by the CCTV group. A handful of group members had previously used Apps where they were awarded with digital icons when successfully completing an App's activity; young people suggested that this reward may be beneficial for the current intervention to further motivate young people to complete their action plans. To incorporate this into the intervention, a trophy symbol will be added alongside completed intervention modules.

5.4. Assessing acceptability of the intervention prototype

The prototype intervention module "feeling confident to take medication" was shared with the group in the fifth workshop. The CCTV group reported amazement over the extent their ideas had been translated into the intervention prototype, and the value the research had placed on their contributions. To demonstrate how young people would interact with the prototype, a short vignette of a young person with IBD, who was navigating their way through the intervention was provided (Figure 19). Young people were encouraged to share their thoughts on the acceptability of the prototype's content and design. To support the provision of feedback, young people used the "thumbs up" post-it notes and A6 card in their activity pack. The unique shape of the post-it notes allowed young people to rate elements of the prototype as likeable (thumbs up), partially liked (thumb placed horizontally) or disliked (thumbs down).

Figure 19. Vignette provided to CCTV group to demonstrate how young people would interact with the prototype intervention



Name:	Sam
Age:	16
Diagnosis:	Crohn's Disease
Treatment:	50mg Azathioprine

Sam takes their tablet in the evening after their meal

They usually remember to take their tablets but they are do forget sometimes

Sam also does not like to take their medication when they are with other people

The CCTV group felt the intervention was an “amazing programme” (Liam) which was highly acceptable for the target population. The tailored approach was perceived as a good way to ensure the relevance of the intervention for a wide range of young people; “I really like how it can be specific to each person using it” (Grace). Following the CCTV group’s feedback on the benefits of using a personalised approach, confidence rulers, a technique used to assess an individual’s motivation to change their behaviour, have been incorporated into the intervention. At the start of each intervention module, young people will be able to assess their current module relevant abilities as well as how much they want to change their behaviour. Intervention users will be presented with the same confidence rulers after achieving their module specific action plan. Both sets of measures will then be shown to young people with the aim of providing a further sense of achievement and enhancing young people’s reflective motivation to improve their self-management adherence behaviours.

Education

Overall, the intervention’s layout and use of colour was reviewed positively by the group. Young people liked seeing how their created layouts had been combined to form colourful interactive sections of information and felt other young people would enjoy this; “I like the way everything is laid out and how colourful everything is” (Cara). The language used across the intervention elements was favourably received; the group perceived the co-developed topic names and descriptions were “very well thought out and well worded” (Grace), and believed other young people would understand the topic’s relevance for living well with IBD. The group liked the decision to alter the colour of words which the intervention could provide an instant definition for when clicked on, and thus increase young people’s psychological capability: “It’s great I really like the information that pops up when you hover over words” (Mark). Young people also praised the tonality of the language used throughout the intervention as “it won’t spook you like google does” (Eloise); thus, indicating BCTs *15.1. Verbal persuasion about capability* and *11.2. Reduce negative emotions* were implemented appropriately within the intervention materials.

Social support videos

Young people felt the plan to film short videos of other young people discussing their IBD, were beneficial for the target population; and demonstrated an understanding of the implementation of BCTs *3.1. Social support (Unspecified)* and *11.2. Reduce negative emotions*. The CCTV group believed young people would like the “chilled out” (Liam) atmosphere of the videos. Other group members commented on the importance of the video discussions being youth-led to give those with IBD a platform to share their experiences; “it’s great how the information comes from young people who have experience in the medication” (Cara).

Demonstration of knowledge activities

During the showcasing of the intervention prototype, young people engaged with a variety of developed interactive knowledge demonstration activities, including quizzes, wordsearches and matching-pair activities. Overall quiz-based activities were favoured amongst the group, although young people remained in agreement that a variety of tasks should be included in the intervention to meet other young people’s preferences; “I think having the range is great so it doesn’t get boring” (Liam). To further accommodate the group’s ideas, additional styles of multiple-choice questions have been developed to increase the variety of question types available during the intervention.

Tailored support

Unfortunately, the final CCTV workshop occurred prior to the podcast development sessions, therefore a still image was used to symbolise where the podcast would sit within the prototype module. The group were excited about the prospect of incorporating a podcast into the intervention and felt other young people would see this as an appropriate delivery method for tailored support. The rationale behind the use of a podcast were like those discussed during CCTV workshops, whereby podcasts were an easy-to-use accessible format of disseminating support information; “it’s useful to listen to something you want to know about and it’s easy to find rather than having to search through paragraphs” (Grace). This feedback adds further validation over an online delivery method for the intervention, as young people can access the content at a time and place that suits their needs.

Setting and reviewing goals

The interactivity within the action planning module component was perceived to increase young people’s engagement in behaviour change processes. When formulating action plans, using interactive sections of text to facilitate the BCT’s *1.4. Action planning*; *1.2. Problem solving*; and *1.1. Goal setting (behaviour)*, were evaluated favourably by the group. The CCTV group believed the prototype’s function of allowing the opportunity to review and edit action plans before confirming these, would increase young people’s motivation to complete their goal, due to the sufficient time provided to ensure the feasibility of action plans before committing to achieving them. However, one group member was concerned that some young people may lose motivation to set goals during the support programme; “I think with the goal thing it might be hard to set like motivation and stuff” (Eloise). Some group members discussed how their engagement with a popular educational App was encouraged due to the Apps use of so-called “streaks” whereby the user’s days of continued engagement were counted within the App and displayed as a “streak.” Not using the App would “break” the streak and return the day counter to zero and was perceived to undo an individual’s hard work. While this is an interesting concept, it seemed apparent this would be more suited for daily goals. However, as the group felt this technique would be beneficial for young people’s automatic motivation, a similar self-implemented method could be suggested as a possible means to overcome certain adherence barriers within the podcast discussions.

Creative Evaluation

Upon reviewing the evaluation cards (Image.7), all intervention components were rated as preferable apart from one young person rating the knowledge demonstration activities as partially liked, due to a strong preference for quiz style questions. This nevertheless, provided reassurance that the prototype intervention was acceptable and relevant for the target population.

Image 7. Examples of the CCTV group completed intervention evaluation cards

To conclude young people's evaluation of the prototype intervention, the group were presented with ten images (Image.8), specifically chosen to elicit imaginative interpretation. The group were asked to select an image they thought best described the intervention and anonymously provide an explanation for their choice via Mentimeter. Each young person chose a separate image to describe the intervention (Image.8); however, there were commonalities in their reasonings. First, answers were inclusive of personal growth elicited in young people who partake in the intervention. One young person chose a scene of Mount Fuji to depict how the intervention can support young people to grow through "the ups and downs" (Anonymous), thus reflecting both the complexities of living with IBD and the need for a tailored intervention to meet young people's needs. Growth was also referred to in the development of knowledge; this again was reassuring as it was identified during the exploratory qualitative interviews that young people perceived they were ill informed about their IBD (Chapter 3) and thus suggests the intervention's appropriate benefit to young people's Psychological Capability.

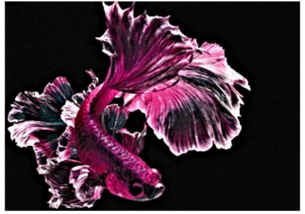
Two young people chose images that reflected their own experiences of joining the CCTV group; a colourful array of wool was chosen to highlight the creativity utilised by the group during the intervention's co-development. Another group member chose the image of an adult and infant elephant, due to its colourful depiction of "a journey/how it has improved overtime. Its like a reflection of the work we have done” (Anonymous); this powerful metaphor displays how one group member felt they have impacted the landscape for young people living with IBD.

Throughout the CCTV workshops, young people emphasised how humour and positivity should be fostered in young people to maintain an optimistic outlook; therefore, the selection of an image containing a rainbow due to its display of hope provided confirmation that young people felt the intervention effectively disseminated this message.

Image 8. CCTV groups perceptions of the intervention

1

2

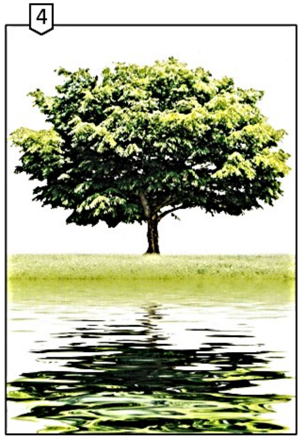


3

3. it shows growth and ups and downs

4 - shows a growth on your knowledge

4



5

6 - because the group is very creative

6

7

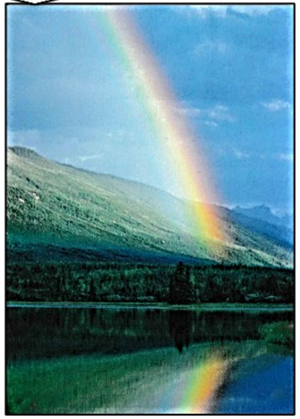
8

i think picture 8 because its colourful and shows a journey/ how it has improved overtime. its like a reflection of the work we have done

9

10 as there is hope for the future

10



5.5. Young people’s experiences of joining the CCTV group

To understand CCTV group members experiences of joining PPIE research and completing arts-based tasks in an online setting, an evaluative online focus group was facilitated via Zoom, two weeks after the group reviewed the intervention prototype, but prior to the development of a prototype podcast. Four CCTV group members took part in the PPIE evaluation focus group, participants were either prescribed azathioprine as a monotherapy routine or in collaboration with infliximab infusions (Table 18).

Within the focus group, young people chose to verbally share their views as well as provide their thoughts in the discussion board. Young people’s experiences were summarised to explore what young people had enjoyed about joining the CCTV group as well as what could be improved in future PPIE projects[2].

Young people enjoyed taking part in PPIE research

The CCTV group reflected positively about their overall experiences of taking part in PPIE research, reporting “its been really fun” (Mark, typed). The group were keen to learn about the process of designing interventions, and found behavioural science “interesting” (Chloe, typed). PPIE research was of further interest to the group, who found the idea of their contributions being of equal importance of the research teams as novel; “the fact that you would do this just seems interesting” (Eloise, verbal). Within the first session, young people appreciated the opportunity to make decisions about the group, including the group’s name and rules, as this promoted a sense of ownership over the PPIE group; “I liked the fact that we could all discuss like our own rules… everyone got to like have a bit of input and say like what we should do” (Eloise, verbal).

The workshop icebreakers were reviewed favourably; as they were “easy to get involved” (Chloe, typed) with and “quite fun” (Mark, verbal). Additionally, the use of arts-based thought-provoking methodologies or so-called “hands on activities” (Mark, typed) were enjoyed by the group, who viewed the ability to complete creative tasks as something which “kept things interesting” (Chloe, typed). When exploring the acceptability of the methods chosen; the group expressed their enjoyment over the use of Lego and Play-Doh, as these provided a useful medium for young people’s creative expressions.

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[2] All included quotes are reported verbatim, inclusive of incorrect spelling and grammar within typed responses.

> “I just really love Play-Doh. And you can make whatever you want out of Play-Doh really to be honest…You can mould it to whatever shape you want” (Eloise, verbal)

Young people received an altruistic benefit from joining the PPIE group

Most young people had wanted to join the PPIE project due to altruistic reasonings, specifically the opportunity to use their insight and experiences to help other young people living with IBD. The group received self-gratification from their involvement in the project and viewed volunteering their time to co-develop the intervention as “it helps people, it’s just like a good thing to do” (Chloe, verbal). The group felt a sense of pride over their involvement in the project and awaited the chance to share their contribution with others; Eloise elaborated on the anticipated praise they would receive from peers due to their input into the development of the intervention.

> “If it comes out like soon, maybe next year or something, I could tell like all my friends and they’ll probably be really happy with it. Like I know a few people that I’ve met at hospital that are like really young and I think they would like really appreciate it. And knowing that like I were a part of it as well” (Eloise, verbal)

PPIE workshops were a chance to connect with other young people with IBD

The group sessions were a chance for young people to develop their own IBD knowledge, this was often an unexpected benefit of joining the group as “the aspects of learning new things is amazing” (Liam, typed). Non-task-oriented conversations were common within the CCTV workshops and allowed young people to discuss their own personal IBD experiences within the safety of the group’s confidentiality and anonymity rules. Such discussions created a source of social support for the group, particularly for group members who had not yet met other young people with IBD. The organic nature of these conversations beneficially provided young people with control over what they disclosed within the discussions, as they were not being asked to explicitly share information about their IBD. Through the group conversations and creative tasks, young people felt more able to discuss their IBD with others, including potentially embarrassing information.

> “Well, it’s kind of freeing to talk about it just a bit more openly. It’s just quite a nice thing to do. You become more comfortable with it in yourself” (Mark, verbal)

Conducting PPIE workshops online reduces accessibility barriers

The online group format facilitated young people’s ability to join the project as “you dint have to give up whole evening w travel” (Chloe, typed); others commented they would not have joined the PPIE group if it had been facilitated face-to-face “due to the travel” (Liam, typed). CCTV group members further preferred the online format as it provided them with control over their right to anonymity and confidentiality. The group liked the ability to choose whether to turn their cameras and microphones on during group discussions; for Eloise, this was very important, as they were undergoing a course of steroids which had left them feeling self-conscious.

> “I think it’s been good because you can decide whether or not you want to like show your face or like let people hear you and stuff, so it’s kind of like up to you, whereas in face-to-face like you’re going to see everyone and hear everyone” (Eloise, verbal)

Young people were hesitant to join future PPIE groups

For some group members the benefit of taking part in PPIE research meant they were more likely to volunteer their time and use their experiences as a means of “helping for something important” (Chloe, typed). Young people were aware their ability to join future PPIE groups was limited due to the time commitments of such projects; “It’s just the time like when i get a job and that” (Liam, typed). However, the benefits of helping others resulted in the consideration to join PPIE groups in the distant future; “I don't think id do another just yet but maybe in future”(Chloe, typed). The time-consuming experiences of PPIE projects were reinforced by the inconvenient timing of the CCTV workshops and the challenges of attending group meetings alongside family routines; “The timing of the sessions have been sometimes a bit weird, like it’s a bit of a kind of a grey area between like before or after dinnertime” (Mark, verbal). Some young people thought they would have benefited from “slightly shorter sessions” (Chloe, typed) to allow their involvement in the group to be more cohesive with their lifestyle. To overcome this change young people suggested reducing the amount of rest breaks within each session or starting the group workshops earlier in the evening, to best fit their daily routines; “Well for me I’d like it maybe earlier, like just after school or maybe even later in the day” (Mark, verbal). Young people viewed future PPIE group session facilitated over the weekend as both unpreferable and unacceptable in comparison to sessions held on weeknights. Young people felt inspired by the creativity used within the intervention co-design process and suggested additional strategies to elicit engagement in future PPIE groups.

5.6. Reflecting on the co-development process

The formation of a PPIE group of young people (aged 13-17) with IBD has been essential in the development of a new treatment adherence intervention. The CCTV group generated a plethora of relevant and insightful ideas into the intervention's co-development. The group workshops included a vibrant mix of discussions and arts-based tasks to allow young people to express their thoughts and opinions. Working collaboratively with the CCTV group, while allowing for user-centred decision making, resulted in the design of an intervention prototype which is both acceptable and engaging for the target population. The outcomes of CCTV workshops were often inspiring, and led to the development of intervention components that were novel in their delivery of intervention functions and BCTs (e.g., podcasts to disseminate tailored support). The breadth of innovative suggestions clearly demonstrates the benefit of co-developing interventions with PPIE groups.

When reflecting on the PPIE workshops, significant changes were observed in group members' confidence and communication skills. Initially, the group were hesitant to unmute their microphones during group discussions and communicated their thoughts and ideas through the discussion board. However, with time and rapport building, more young people chose to verbally discuss their ideas within the sessions. It was evident that young people wanted time to discuss their IBD with other group members; therefore, adequate space was provided for young people to have these discussions throughout the group workshops. Within these conversations young people shared information about their IBD and were able to seek peer reassurance and support. When evaluating the intervention prototype, and their involvement in the CCTV group, young people were able to comment on their growth and felt they were better able to discuss their IBD. This not only supports my own observations of the changes in the group but highlights the potential benefits young people can experience through joining PPIE research projects, as identified previously (Flotten et al., 2020).

Unexpectedly, conversations within the PPIE evaluation focus group were minimal. Most young people chose to discuss their views within the discussion board, rather than engaging in a verbal conversation with either myself or their fellow CCTV group members. This was a stark contrast to the CCTV workshop discussions. It is possible that young people viewed the focus group as a formal piece of research and therefore no longer perceived themselves to be research partners. Whilst there was not a conscious effort to alter the group dynamics within the focus group, this highlights the importance of PPIE group members' role perceptions within the context of the research project (Locock & Boaz, 2019).

Through sharing research skills and knowledge, the group members were able to learn and be enthused about the practical application of health psychology research. Young people often asked further questions about behaviour change and the rationale behind the intervention's use of BCTs. The willingness for this project to place young people's views at the centre of an intervention's design was further inspirational for the group and provided group members with a sense of pride over their contributions. Within the group activities, young people were able to demonstrate their comprehension of behavioural constructs, their ability to problem solve and to work collaboratively as a team to develop a cohesive idea. Unexpectedly, when making collective decisions, the group required little intervention from myself within the decision discussions. Whilst this could reflect the group's intellectual abilities, or prior interest in Science Technology Engineering and Maths (STEM) subjects, it remains clear that through the provision of age-appropriate resources young people can make user-centred decisions that can actively improve interventions for the target population.

This Chapter has outlined how a variety of arts-based methods, including Lego and Play-Doh model making and online idea boards, can inspire creativity within intervention co-design processes. Young people often created intricate metaphors when explaining their creations, generating striking visual concepts. Previously, Fargas-Malet et al. (2010) suggested teenagers may perceive themselves as too grown up for such arts-based methods, however the CCTV group actively engaged with the workshop activities and reported their enjoyment of Lego and Play-Doh tasks. Additionally, hands on methods such as model building and drawing are typically conducted within face-to-face groups (Bowen et al., 2013; Vusio et al., 2021). This project has shown the feasibility of conducting these methods within online workshops, further extending the possibility to include arts-based mediums in research projects.

The facilitation of the CCTV group was not without application issues. First, it was initially challenging for group members to send photographs of their workshop creations to myself. To overcome this, a photograph icon appeared on the screen during the workshop's arts-based tasks, to encourage group members to share images with myself. Whilst this was beneficial for most group members, this did not completely overcome the barrier; future online PPIE group facilitators may wish to explore more creative or engaging methods to encourage young people to provide researchers with photographs of their creations.

Second, young people's right to confidentiality and anonymity were highly important for young people's comfort during the CCTV workshops; however, young people's reluctance to turn their camera on throughout the workshops prevented myself from gaining important visual engagement information. For example, it was hard to gauge who had completed the task or who was waiting for a pause in the conversation to discuss their views. To accommodate this, young people were given adequate opportunity to share their thoughts, and were encouraged to let myself know when they had finished the task. Additionally, the group co-facilitator monitored the discussion board throughout the workshops, to ensure everyone who wished to contribute to the conversation was able to.

When thinking about taking part in future PPIE groups, there was variance in the CCTV group's views; despite enjoying being part of the CCTV group, some were hesitant in joining future PPIE projects due to the time commitment. The time pressure experienced by the CCTV group may have arisen from the timing of the PPIE workshops in two ways. Despite the dates and timings of the group sessions being chosen by young people at the start of the CCTV group's formation as time progressed, these decisions became unpractical for the group. Future PPIE group facilitators should therefore regularly confirm the suitability of the next proposed meeting amongst group members. Additionally, around two thirds of the group were revising for their GCSE's whilst taking part in the CCTV group; therefore, the facilitation of workshops between March-May could have added to the perceived time pressures of joining PPIE research.

Unfortunately, the group lacked a greater diversity of demographic factors, for example all CCTV members were diagnosed with Crohn's Disease and identified as White British. Future PPIE groups may wish to use different recruitment strategies to ensure a wider variety of young people are included.

5.7. Conclusion

This Chapter has discussed the co-development of a novel evidence-based theory-driven user-centred treatment adherence intervention. Young people were given autonomy to make user-centred decisions on the intervention's components functionality and aesthetic design. Upon reviewing the prototype, young people found this to be an acceptable and engaging intervention for young people with IBD. The prototype remains grounded in behaviour change theory and implements a variety of BCTs to support treatment adherence behaviour change amongst young people. To further assess the practicality of the intervention, the following Chapter will discuss parental evaluations of the intervention, prior to the finalisation of the prototypes design.

Chapter six: Further refinements of a novel evidence-based theory-driven intervention to improve treatment adherence in young people with Inflammatory Bowel Disease (IBD)

6.1. Introduction

As detailed in the previous Chapters, parents and caregivers hold a significant role in the management of young people's health. They also provide support and encouragement for young people to participate in health interventions (Reed-Knight et al., 2014). Previously, consulting parents on the content of adolescent health behaviour interventions, co-developed by young people with chronic conditions, provided a beneficial insight into the potential effectiveness of the intervention (Boote et al., 2016; Bray et al., 2022).

Due to their unique insight, parents may be able to identify potential barriers in the newly developed intervention's application, that were not identified or discussed within the CCTV group's evaluation, detailed in Chapter five. Therefore, parents were consulted on the intervention's design and content to assess the intervention's practicality for young people with IBD. This Chapter presents a qualitative analysis of parents' feedback on the prototype intervention. Qualitative findings from this Chapter informed a final set of refinements of the intervention to support young people with IBD adhere to their treatment plan.

6.1.1. Research Aim

To explore the views of parents of young people with IBD on a prototype intervention designed to improve treatment adherence in young people with IBD; specifically with reference to practicality and relevance of the intervention.

6.2. Method

6.2.1. Design

A qualitative design was adopted to explore parents' views. A semi-structured, online focus group was conducted with parents of young people (aged 13-18) with IBD, to assess the practicality of the newly developed treatment adherence intervention for young people with

IBD. Topics explored how participants' experiences of parenting a child with IBD informed their views on the prototype intervention.

6.2.2. Sample and Recruitment

Parents of young people who joined the previously reported Crohn's and Colitis Teen Voice (CCTV) group (Chapter five) who had consented to being contacted about future research, were invited to take part in the research. Furthermore, a Consultant Gastroenterologist at a Specialist Children's Hospital used purposive sampling to recruit parents of young people (aged 13-18) with IBD. Opportunistic and snowballing sampling was also used to recruit parents/carers of young people (aged 13-18) with IBD, through adverts placed on Crohn's and Colitis UK's social media channels.

All interested parties were sent a letter of invitation containing a QR code link to a relevant online information sheet (Appendix.31). Parents who were interested in participating in the study were invited to contact a member of the research team, who would answer their questions before obtaining consent (Appendix.32).

Recruitment for this study was closed prematurely. Following a social media advert stating participants would receive a voucher for participating in the research, four parents contacted the research team requesting information about the research. After receiving a letter of invitation and online information sheet, all four parents agreed to participate in the research and completed relevant consent and demographic forms (Appendix.32 and Appendix.33). However, information provided about the participant's child's health within each demographic form did not accurately represent an authentic IBD treatment plan; additionally, all parents were White males, aged between 29-31 years and were parents of White males, between the ages of 14-16 years. Upon further exploration, the IP addresses of each potential participant were identical, suggesting the same individual was completing each form. To preserve the confidentiality of other parents who had already consented to join the focus group, as well as the integrity of the research, a decision was made (in consultation with the research team) to invite the four parents to a separate focus group on an alternative date. None responded to this request. To further preserve the research's integrity, it was deemed advisable to close recruitment at an earlier date than anticipated. This resulted in the final sample consisting of three parents whose children had joined the previously discussed CCTV group.

6.2.3. Data collection

A single in-depth semi-structured online focus group was conducted with parents of young people with IBD, over the online meeting platform Zoom. Synchronous online focus groups (e.g., online verbal communications) are a useful method of data collection because they can increase accessibility of the research to potential participants (Keemink et al., 2022; Stewart & Shamdasani., 2017). Participants were encouraged to join the focus group in a quiet location where disruption would be minimised.

Within the focus group, participants were invited to interact with the intervention prototype and ask questions about its functionality. To assist with the delivery of the prototype's content, an MSc student who had previously co-facilitated the CCTV workshops (Chapter five), demonstrated how a young person would interact with the intervention. Parents were encouraged to share their views on practicality and relevance of the intervention for young people with IBD (Appendix.34). The group were asked to provide opinions on time commitment for young people to participate in the intervention, as well as the practicalities of interactive activities and materials. Parents were also asked to suggest revisions for increasing user-engagement, as well as provide feedback on the potential for impact on young people's adherence behaviours. Discussions explored how participants' experiences of parenting a child with IBD related to their assessment of the practicality of the intervention.

The focus group lasted approximately 90 minutes. Each participant completed a short demographic questionnaire (Appendix.33), enabling findings to be interpreted in context. As a token of thanks, parents were compensated for their participation with an online £15 gift voucher.

6.2.4. Data Analysis

The focus group was audio-recorded and transcribed verbatim. Data was analysed using thematic analysis, a method of developing, analysing, and interpreting patterns within a data set (Braun & Clarke, 2006). Thematic analysis is an appropriate qualitative analysis method for applied health research, allowing researchers a rich insight into the experiences of patients and their families (Braun & Clarke, 2014). Data analysis was carried out in accordance with the six stages of thematic analysis as outlined by Braun & Clarke (2006), detailed below.

Stage one: Familiarisation. During this initial stage, I began to immerse myself within the dataset by re-reading the transcript and re-listening to the audio recording, making note of initial ideas or concepts in the margin of the transcript.

Stage two: Coding. I labelled points of interest within the data with a code name. Following inductive coding of the transcript, I grouped similar codes together in a meaningful way. In line with Braun & Clarke's (2006) recommendation, were applicable, I included codes within multiple code groups, to demonstrate contradictions within the data.

Stage three: Generating initial themes. I reviewed and refined each group of codes to develop potential themes and sub-themes which could provide a broad explanation for the data. To achieve this, I revisited my initial thoughts within my reflective diary and the interview transcripts. I created a miscellaneous category for any codes that did not appear to fit in any of the potential themes or sub-themes. Doing so prevented the eradication of information at this point, ensuring no relevant data was omitted. As themes were generated by my own insight and knowledge, I kept a detailed log in my reflective journal, tracking my analytical thoughts.

Stage four: Developing and reviewing themes. I assessed the previously generated themes and subthemes to check their fit with the initial intensions of the coded extracts as well as the entire dataset. Each theme was reviewed and revised to ensure they adequately explained the data in a comprehensive manner. Within this stage, I spent time familiarising myself with the themes and the data-driven story displayed when the themes were combined.

Stage five: Defining and naming themes. To gain a further understanding of how each theme's narrative fell within the wider story of the entire data, I created detailed definitions of each theme. Definitions were inclusive of the key feature of each theme. I also allocated easily understandable, concise, and evocative titles to each theme. The naming of themes was an evolving process, with themes names changing to help convey the narrative of the data's story.

Stage six: Writing up. When reporting my analysis, I selected insightful and relevant extracts of data to provide a compelling narrative for the qualitative analysis. At times, this was challenging, due to the variety of relevant participant quotes.

To ensure rigour, I kept a research journal to record personal reflections on the analysis as it progressed (Braun & Clarke, 2014; Braun & Clarke, 2022), as well as to record emerging understandings of the data to discuss within supervisory meetings and demonstrate a clear logic of enquiry.

6.2.5. Ethics

An extension of the previously attained favourable ethical review by the NHS's REC London Bloomsbury board (IRAS #126868) was obtained in November 2021, to involve parents in the intervention's co-development. All participants provided informed consent before participating in the focus group.

6.3. Results

6.3.1. Participants

Three parents of young people with IBD were recruited and took part in a single focus group (Table 20). The sample included mothers, with an average age of 50.67 years. Participants reported their children were currently between the ages of 14-16 years and had received their IBD diagnosis between the ages of 10-15 years. All young people were diagnosed with Crohn's Disease and prescribed azathioprine either as a monotherapy routine (N=1) or in combination with infliximab (N=2).

Table 13. Participant characteristics

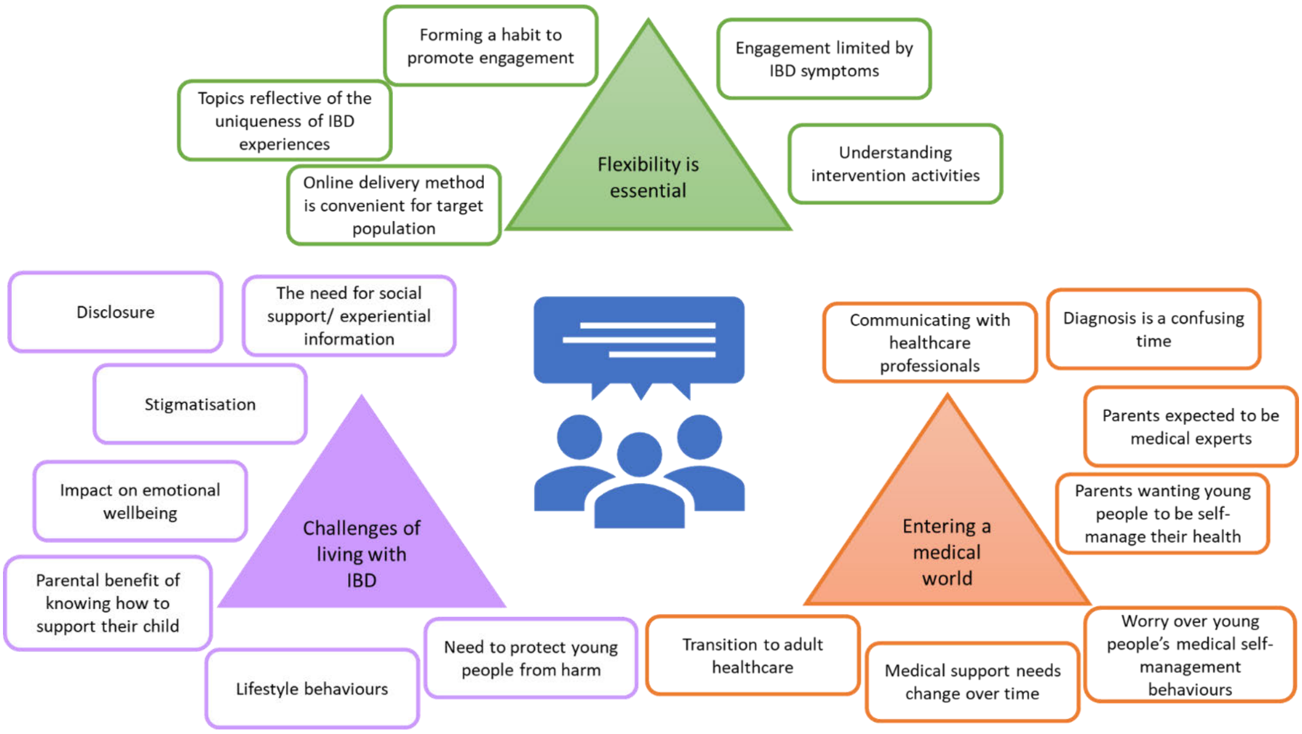
	(N=3)
Age (Mean, SD)	50.67 (0.47)
Gender (N= female)	3
Ethnicity (N=)	
White British	3
Child's Current Age (Mean, SD)	15 (0.82)
Child's Gender (N= female)	3
Child's Ethnicity	
White British	3
Child's Diagnosis (N=)	
Crohn's Disease	3
Child's Age at Diagnosis (Mean, SD)	12.68 (2.06)
Medication (N=)	
Azathioprine	3
Infliximab	2

6.3.2. Findings

A thematic analysis identified three themes across the dataset which explored parents' evaluations of the practicality of the prototype intervention, as well as their experiences of parenting a child with IBD. The themes were: Flexibility is essential; Challenges of living with

IBD; Entering a medical world. A thematic map was created to visually display the topics discussed within each theme (Figure 20).

Figure 20. Thematic map



[3]

Flexibility is essential

IBD was presented as a unique set of symptoms, treatment routines and experiences by parents within the group; “That’s the thing about Crohn’s isn’t it, that it seems to affect everybody so uniquely, you know” (Dina). Ability to tailor the intervention’s content to a young person’s own personal IBD treatment plan and circumstances was therefore received favourably by the group. Parents felt the intervention’s design encompassed the individual experience of living with IBD, because it avoided what has been previously termed the ‘righting reflex’, that is, the desire of health professionals to fix problems rather than support patients to generate their own solutions (Salvo & Cannon-Breland, 2015); “It’s not a diagnosis and then here’s the solution” (Dina). Rather, living with IBD was understood to be

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[3] Figure 20, details how the codes identified within the thematic analysis were combined to form the themes presented within this chapter.

a constant process of trial and error to identify the most effective solutions for an individual's problems as they arise. Due to the differences in IBD experiences, parents praised the inclusion of young people within the intervention's development, because this was thought to strengthen the relevance and suitability of the intervention for young people with IBD. While participants shared their insights into the functionality of the intervention, they also reflected on how adults may not always fully understand young people's needs. They all agreed that effective and acceptable interventions were best developed through working collaboratively with young people.

> "I mean it's crucial it's got to work for them…we could all come up with brilliant ideas but I mean we're all kind of second guessing what our children would want to do and also, they're all quite different, even the three children in the group" (Victoria)

Young people were reported to spend a significant amount of time on their phones, and parents welcomed the intervention as a positive use for their child's online screentime. Due to familiarity with technology-based resources, parents felt young people would be more motivated to engage with a web-based intervention independently, without the need for parental monitoring. The portable nature of a mobile/web-based resource was thought to have added benefits of flexibility in terms of access to the intervention at a time or place that was convenient to their lifestyle, such as outside of school hours or while spending prolonged periods of time managing their IBD symptoms. From the parent perspective, the self-led nature of the intervention enabled access to information when young people required it, rather than waiting for their next medical appointment or searching the internet.

> "[my child] spends obviously a lot of time on the toilet so if it was an App, it's what they do on the toilet int it? D'you know what I mean? It helps pass the time" (Steph)

Young people were often prescribed complex medication routines, which were frequently changed to meet their health needs. Parents thought their child would define their prescribed medication, as those taken frequently within the home and suggested young people may not consider treatments such as intravenous (IV) infusions as a prescribed medication; "[The IV infusions] just happen every eight weeks and [my child] probably forgets about them in-between" (Victoria). Parents believed this miscomprehension could limit young people's effective engagement with the intervention materials, as they may be less likely to report some aspects of their treatment routine. Additionally, within the prototype, parents were concerned that their children would struggle to complete a single question asking about their confidence to adhere to their entire medication treatment routine, due to young people's differing levels of confidence to adhere to different medications. Nevertheless, the interactive nature of the intervention tasks was preferred by the group, who felt young people would enjoy completing the activities, even if they did not fully understand the questions. In general, interactive activities that avoided the need to write extensive information were viewed as more practical. As Victoria suggested, “the biggest challenge for a 16-year-old boy would be getting [them] to write anything” (Victoria). Tasks that explicitly required a large amount of effort, or those which did not capture the complexities of living with IBD were therefore seen as likely to encourage disengagement.

> “with that confidence to take medication, um, if they’re taking more than one, like she’s had tablets, fine, absolutely no problem with tablets, she had a feeding tube, a bit weird, she had Infliximab infusions, that were okay, now she’s gone onto injections, absolute total meltdown…She couldn’t answer that one just on one ruler” (Steph)

Parents reviewed the time required to complete each module as practical for the target population. However, young people’s experience of IBD symptoms, inclusive of pain and fatigue, were considered likely to facilitate times when engaging with the intervention would be too tasking. Such experiences were further enhanced when young people’s health prevented school attendance, leaving them with large amounts of educational material to catch up on. Some parents felt after experiencing severe IBD symptoms, young people should be encouraged to spend their time doing things they enjoy, thus potentially limiting their free time to complete an intervention module. Flexibility with completing the intervention was welcomed by parents as it allowed young people to engage with its content during periods of wellness and not feel pressured to do so when experiencing IBD symptom flares.

> “I think just building as much flexibility as possible because it’s such a tough condition to live with really and sometimes just doing the basics in life are just enough” (Victoria)

Some parents felt the functionality of allowing young people to review their action plan’s success one week after setting their goal was too demanding and suggested young people should be able to set their own goal review timescales. However, parents were also conscious of the need to balance removing additional pressures on young people while maintaining consistent engagement with the intervention. Strategies to avoid disengagement were proposed to include use of prompts or “nudges”. Such approaches were believed to be an effective way of reminding young people to review their action plan and begin a new module. Parents shared their experiences of engagement techniques used within an educational App, whereby daily engagement was recorded numerically and seen as a measure of success. Steph suggested the nudges within the current intervention could mirror those of the discussed educational App’s, however Victoria felt the approach was too intensive for young people and added to the burden they already experienced trying to manage their condition amongst their other priorities. Overall, the group felt the most effective way of maintaining young people's engagement was to enhance the user-centred flexibility within the programme to encourage young people to create a feasible routine, whereby intervention users formed a habit of completing the intervention, at a timescale that met their needs.

> "It's creating habit isn't it, of getting into the App so you don't kind of forget about it and kind of customising it a bit to work with you" (Victoria)

The challenges of living with IBD

Within their daily lives, young people often faced hurtful comments and stigmatisation related to others' poor IBD knowledge. This resulted in feelings of distress and shame for young people. Parents welcomed support within the intervention to help young people deal with negative comments, in order to "be able to bat them off, you know…they're enough to contend with without having to deal with the comments" (Steph). IBD stigmatisation was described as detrimental to a young person's sense of self and encouraged the formation of negative body and illness perceptions. Taking steroids was linked to a greater encounter of hurtful remarks, due to visual changes in young people's appearance. Consequently, young people were often hesitant to disclose their IBD to others or reach out for peer support when it was needed; opting instead to disassociate themselves from their diagnosis.

> "[my child] doesn't want to associate in any way…you know, in any way admit to having it or to acknowledge having it, it just exists and [they] ignore it as much as possible" (Dina)

Parents aimed to provide a normalised view of living with IBD through encouraging young people to discuss their condition openly within the home; "I'm quite good on the poo chat and everything now. I say we talk shite every day. It's just the norm int it? Everything revolves around the toilet" (Steph). Whilst Steph's comments were factual and entwined with humour, the reference to their child's persistent use of the toilet may inadvertently be reinforcing the stigma that young people experienced within their daily lives. Most young people encountered hurtful comments within the school environment; Dina had further experienced problematic communication with school staff who did not understand her child's health needs; "they still won't let [my child] go to the toilet when [they] need to." While parents were grateful the intervention contained information to support young people to manage such cruel comments, parents wanted to actively tackle IBD stigmatisation and develop a culture of understanding and support within schools. The group felt the intervention could be inclusive of further interactive materials to help educate peers and school staff on the widespread effect IBD has on young people's lives.

> "I'm just thinking if they're sat at school…"Do you want to just have a go on this quiz bit for friends?" And they can pass it to their friends, you know, just to have a look and have a play and sort of say "oh I didn't realise that it affected your knee joints, I didn't realise it affected this" and just a bit more awareness int it?" (Steph)

Due to young people's resistance to discuss their IBD, worries arose over how willing young people would be to share their challenges with family members. Parents were concerned for example, that information provided by young people within the intervention regarding personal adherence barriers and action plans would not be automatically shared with a trusted adult. The thought of not knowing how to support their children cope with hardships was daunting for parents who expressed a need to protect their children from experiencing further difficulties; "if they are really, really struggling and they aren't telling the parents it's very hard for a parent to help if they don't know about it" (Steph). Such support was offered in the context of an additional means to enhance autonomous behaviours, rather than parents' intentions to inhibit young people's health management responsibilities. The group felt it was important young people understood they could still ask their parents for support to overcome challenges, while developing their independent self-management behaviours. Parenting a child with IBD often required problem solving to minimize disruption related to IBD; however, relevant support was often hard to find and only obtained through extensive online searches or following an adverse event. For example, Steph discussed how they were introduced to a special toilet pass to be used when watching theatrical performances, following an incident where their child had been refused access to the toilet. The sharing of such information was beneficial for the other focus group members as they were unaware such schemes existed. A lack of easily accessible information was frustrating for families, who wondered if the intervention could signpost parents and young people to appropriate resources to support families to live well with IBD.

> "Really practical stuff like that would be helpful. Anything that kind of makes it easier for them to be able to kind of manage their condition I think would be good and yeah, I think there's so much potential with it really" (Victoria)

The provision of social support for young people was valued by parents, who felt the acknowledgement and validation received during conversations with others living with IBD, benefited young people's emotional wellbeing. Yet, throughout their child's IBD journey, parents recalled the limited opportunities for their children to receive peer support. Furthermore, where opportunities did arise, many young people were described as hesitant to meet or discuss their health with others diagnosed with IBD, despite parental encouragement. However, Steph's child had actively engaged with a charity led support initiative and found this a useful resource to gain a greater understanding of their IBD and develop useful coping strategies. The other parents were positively surprised when their children had decided to join the intervention co-development workshops, as this was the first time their child had been willing to discuss their health needs and meet other young people with IBD. Parents noticed the benefits this had on their child's wellbeing and felt their children should continue to discuss their IBD experiences with others to reduce feelings of difference. The group suggested further social support could be included within the intervention to allow intervention users to interact with each other, for example within online discussion boards. Parents also felt it would be beneficial for the intervention to provide relevant links to social support groups to increase families' abilities to access this support; "because on a web all you've got to do then is click through rather than somebody putting another barrier in your way that oh go and look at this website" (Victoria). However, the group believed the facilitation of such interactions were important for its success, for example current charity initiatives which connect young people via email felt outdated and unfeasible, as young people rarely used email as a form of communication. The group believed the lack of appropriate peer support services encouraged their child to be over reliant on their parents and limited the development of key communication skills.

> "we never had the opportunity…to talk to anybody other than a doctor and the doctor said everything in a very factual "this is what you've got, this is what you've got to take and this is what will happen", whereas there was nothing about the emotions, the feelings and, you know, obviously [my child] only had me to talk to about it" (Dina)

Parents were worried about the impact living with IBD had on their child's emotional wellbeing and sought additional resources to help young people understand their emotions. To support young people to cope with their anxieties or physically painful IBD symptoms, parents felt it would be beneficial for the intervention to include relaxation or breathing exercises. The group further suggested the ability for young people to keep a log of their daily emotions within the intervention, for example selecting relevant emoji symbols, would beneficially improve young people's self-management skills through developing an understanding of when to ask for further wellbeing support, both at home and during medical appointments. Intervention users' ability to share visual representations of their emotions with caregivers was suggested to be important to allow parents to gain a further insight into their child's experiences and ensure young people were receiving appropriate support.

> "say you gathered over a period of time your little faces and then so it showed you back after a week or two weeks or whatever and you actually had quite a lot of sad faces and then it might say "do you want to send this to your nominated person?" and

> then so for example your mum might get a list and then suddenly mum says “oh my God, you’ve had a really bad week this week” and then that provokes that sort of conversation or whatever” (Dina)

Parenting a child with IBD was a frightening and intimidating experience; parents worried about the extent to which IBD would impact their child’s future. Parents believed it was their role to be a source of strength within the household, often to the detriment of their own wellbeing; “it’s just as a parent you have to be so strong and always with a smile and be positive and it’s hard” (Steph). The inclusion of resources for parents within the intervention, on how to support a child develop autonomous behaviours was welcomed. The group demonstrated a good understanding of the necessity for young people to self-manage their IBD, but often felt unsure over how to facilitate an environment to allow for this. Parents were keen to receive similar educational content to that of their child but requested that such content should be “something quick and easy” (Steph) to read, to fit into parents’ busy schedules. The group longed to hear about other families’ IBD journeys, to both normalise their own experiences and help prepare for future challenges. Social media groups were avoided by the group as the content and tonality of the discussions were often unhelpful and alarming. Gaining an understanding of how others coped with IBD challenges was therefore viewed as comforting, and likely to reduce feelings of loneliness for parents. The group proposed videos or personal testimonies from parents would be beneficial to include within the intervention’s parental resources.

> “I mean there’s a lot of information out there. I don’t feel like I struggle to get information…if you go onto kind of the different kind of charity websites you get the kind of perspective of people who’ve had the illness, not the kind of parent’s perspective” (Victoria)

Parents were aware that during adolescence, young people faced frequent lifestyle decisions that could impact their health and peer relationships. Victoria’s child for example, had recently encountered scenarios where they had been offered alcohol, yet had “already decided because of [their] condition [they] wasn’t going to drink.” Parents felt young people needed to be aware of the importance of lifestyle behaviours on their health outcomes and were therefore grateful the intervention was inclusive of adhering to lifestyle advice. Having an awareness of “how do you make those choices and what happens when you make the wrong choices” (Dina), were welcomed by parents to encourage young people to consider how they would behave in certain scenarios and negate peer pressures. Defining lifestyle behavioural intentions was perceived to help young people manage the burden of living with IBD and allow for the selection of appropriate coping strategies.

> “as you get older it’s not just going to be about your medication but it’s as you’re making your own choices, you know, what part is alcohol going to play in the life of somebody who’s got Crohn’s? Because they will all come face-to-face with alcohol, drugs and choices are going to be different when you have a condition that’s going to be affected by that…even food choices, you know, everyone else goes off and has a kebab or whatever, well are you going to be able to do that?” (Dina)

Entering a medical world

Receiving an IBD diagnosis was traumatic, and often left families emotionally scarred by their experiences. Parents felt they had been thrown into chaos and were assumed to spontaneously understand how to navigate their changing circumstances. Upon diagnosis, parents felt unaware of their child’s future health prospects and aims of their child’s treatment plan. Clinical appointments were therefore a source of education for parents as well as young people. When starting to adapt to the constraints IBD placed on family life, parents discussed their limited cognitive abilities to retain information as “your mind just goes to mush all of a sudden” (Steph). Due to the chaotic nature of receiving a diagnosis, parents felt families required time to adjust to living with IBD before accepting interventional support to develop appropriate adherence behaviours. Thus, suggesting the timing of when the intervention is introduced to families may be incremental for youth engagement and the success of the intervention.

> “when you do get newly diagnosed you’ve just, you’re like Alice in Wonderland, you’ve just gone down this rabbit hole and it’s just all medical terms, you don’t know who you’re supposed to be, you haven’t got an IBD nurse at that point, you’re all over the place” (Steph)

The expectation for parents to become proficient in medical terminology, was overwhelming with parents reporting “I didn’t do biology, I’m not medical in any shape or form” (Steph). However, understanding the medical aspects of IBD were important for families, as parents could translate this information for their child in a meaningful way outside of health appointments. Parents sought plain English terminologies to develop their IBD knowledge and to decipher the information provided by healthcare professionals. Online search engines were often used by parents to identify information about their child’s health to their own regret, as the information was often anxiety inducing or incomprehensible. Thus, parents welcomed the provision of instant definitions for medical terminologies. However, the group believed such definitions would be more beneficial if they were also placed within a separate glossary, which could be accessed outside of the intervention modules to help families understand medical jargon in a convenient manner. Parents further proposed this resource could be used to provide easily accessible definitions during consultations, allowing parents to “quickly check it in your meeting” (Dina) to prevent confusion.

> “I think the [healthcare professionals] we work with are really good at explaining things but they still lapse from time to time into kind of very clinical terminology. And then you get sent copies of the letters they send to the GP which are full of them and so it’s, yeah, something you can kind of look up…like one-line, two-line definition rather than the other things because that’s probably all the information you need sometimes” (Victoria)

Parents described how young people valued their healthcare professional’s trustworthy advice and expertise. As such, young people were suggested to be more willing to participate in the intervention if it was introduced to them by a healthcare professional and could “see how it fitted into [their] kind of programme of care” (Victoria). Viewing the intervention as an extension of the young person’s treatment plan was proposed as a way to increase the need to address adherence barriers within the intervention. Despite trusting their healthcare professional, parents felt their children were hesitant to discuss changes in their health and potentially embarrassing subject matters within health appointments. Instead, the group felt young people and healthcare professionals deferred to parents to relay important information. While parents were willing to supplement the health conversations, they were also aware of the benefits of their child independently communicating with healthcare professionals. Parents therefore encouraged their child to openly share information with their healthcare professionals, and prevent young people answering questions with limited or untrue information. Parents felt it was important for the intervention to include practical advice for young people to support their communication, such as writing a list of points to discuss prior to attending medical appointments.

> “[My child] if you’re not careful will just go “yeah, I’m fine” and [they’re] not but it’s just easier to say that” (Victoria)

As families continued their IBD journey, parents felt young people “need different information at different times” (Dina). Throughout adolescence young people experienced social and educational factors which often complicated treatment routines and proposed further worries about the future. Parents foresaw scenarios where intervention users would also need to “dip in and out” (Victoria) of previously completed modules, to gain additional guidance to support the maintenance of adherence behaviours. Having the ability to select from a variety of intervention topics were reviewed favourably as intervention users could develop their knowledge and skills to meet their current adherence needs. Within childhood and early adolescence, parents were mainly responsible for the management of their child's condition, including engaging with health professionals and organising treatment routines. However, some parents were aware this approach was unsustainable and wanted their child to start taking responsibility for their own health as young people would be "in situations where I'm, you know, mum isn't always there to come and help" (Dina). Some believed the dependency children placed on their parents was reinforced by the paediatric healthcare system, as it fostered an environment that allowed young people to remain reliant on their caregivers.

> "when you're trying to get them to be independent, the whole kind of paediatric system sort of makes them dependent because you have to go with them to everything" (Victoria)

Transitioning to adult healthcare was viewed as a significant moment in young people's IBD journey. Victoria was the only parent whose child had started the transition process, which she described as a challenging experience due to issues connecting "young people's teams and adult teams" and delays in their child accessing NHS prescription services. Parents of children yet to start the transition process were conscious of the vast amount of self-management responsibility young people required to prepare for adult healthcare. However, Steph felt young people were unable to independently manage their condition at such a young age without continued parental support "because they're still, they might think they're adults but, you know, they still need their mum don't they…you can't just suddenly become from a child then go straight to an adult."

Parents also reflected on how the intervention could help their child develop the skills needed to prepare for the stark changes in adult healthcare services; "I think that would be quite good having it for changing over to adult care because I think that's a whole new ballgame really" (Steph). Victoria believed the intervention topics mirrored the behaviours their child's healthcare professional had identified as essential to have acquired prior to moving to adult healthcare, thus confirming relevance of the intervention content.

The concept of young people having access to a source of support at a time when parents were encouraged to step back from the management of their child's health was valued by parents. Independently remembering to take medication on time, was believed to be young people's greatest adherence challenge, especially when trying to adapt to changes in daily routines. The inclusion of support for overcoming this barrier was perceived to be highly beneficial for young people. Parents highlighted the further importance of additional support during the healthcare transition period, as this was naturally a time of change for young people in regards to their education and friendships as well as forming their identity and developing an understanding of the world. The user-centred approach within the intervention was reviewed as relevant for young people with IBD, as it allowed intervention users to select treatment plan behaviours that matched young people's understanding of their own health needs.

> "it's good that that's built in because I think it's also a difficult time life-wise isn't it when you're sort of, you know, doing A-levels or going to college or starting jobs? So, there's a lot going on for them at that same time so it is good that it's built into this because it can be quite a daunting process" (Victoria)

6.3.3. Reflexivity

Prior to facilitating the focus group, I was apprehensive that my presence would have an impact on the group discussions. Parents were aware that I am a PhD researcher who had conducted research to inform the intervention's development, including facilitating the co-development workshops with their children. Therefore, it was likely this may have generated a power imbalance, whereby I was seen to have greater authority or be perceived as the expert. Additionally, due to their children participating in the CCTV workshops, I had already become familiar, particularly to parents who had provided their own email address as a means of correspondence for a CCTV group member. I was concerned that such familiarity would limit the feedback parents provided, as participants may have found it challenging to provide negative or constructive criticisms to someone, they were familiar with. I was further conscious that parents may have been unwilling to critique the prototype intervention due to their child's involvement in its development. To reduce these possibilities, I emphasised how the group's unique insights could greatly benefit the intervention's development; with no feedback being perceived as unwanted or unhelpful.

For continuity, I decided to showcase the same prototype module that had been reviewed by the CCTV group (Chapter five). In doing so, I was able to compare parents' views with those from young people to effectively revise the prototype intervention. For example, parents had greater ideas on how to expand the intervention to be inclusive of young people with IBD's wider needs beyond treatment adherence. Parents commented on young people and their family's need for a single resource inclusive of a range of practical support, to improve young people's quality of life. In addition to medication taking, parents suggested the intervention could include educational resources for schools and peer groups, as well as information on relevant nationwide schemes to increase young people's access to enjoyable activities. Young people's perceived need for such an extensive array of resources were not discussed by the CCTV group, who remained focused on ways to engage young people to improve their treatment adherence both within the co-development workshops and during the group's assessment of the prototype intervention. When contemplating these differences, I was reminded of my personal health needs when managing my own chronic condition during childhood, in comparison to my recent diagnosis. During my youth I was very much focused on feeling better and being able to be with my friends, similar to the young people in the CCTV group. However, following my current health issues as an adult, I am contemplating more practical factors, such as how I can have suitable access to public spaces. Furthermore, when discussing this with my supervisor, the parental need to care and provide for one's child is likely to be providing parents with a detailed overview of the barriers and deficits in relevant support for young people with IBD. When assessing the practicalities of including parents suggested revisions in the intervention, this was at times challenging. I found myself conflicted between my awareness of the realistic parameters of the intervention, while sympathising with parents' clear need for additional resources, such as a space to discuss their IBD experiences with other parents to increase their social support.

When analysing the generated data, I was further conscious of how my own involvement in the intervention's co-development would impact the analysis process. Therefore, within my reflective diary, I recorded my initial interpretations and included possible rationale for these thoughts, e.g., outcomes from the formative exploratory qualitative research or similarities or contrasts between the views of the current focus group and young people within the CCTV group.

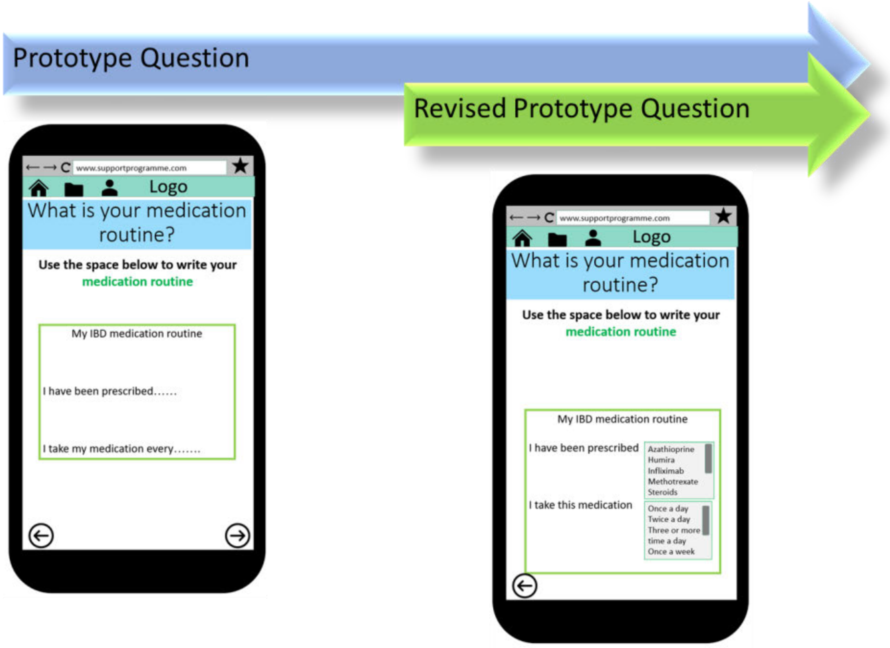
6.3.4. Final revisions to the prototype

To enhance the practicality of the intervention for the target population, parents suggested a series of revisions and extensions. Each suggestion was carefully considered, keeping in mind the resource limitations summarised in Chapter four.

Revisions to the intervention's interactivity and engagement

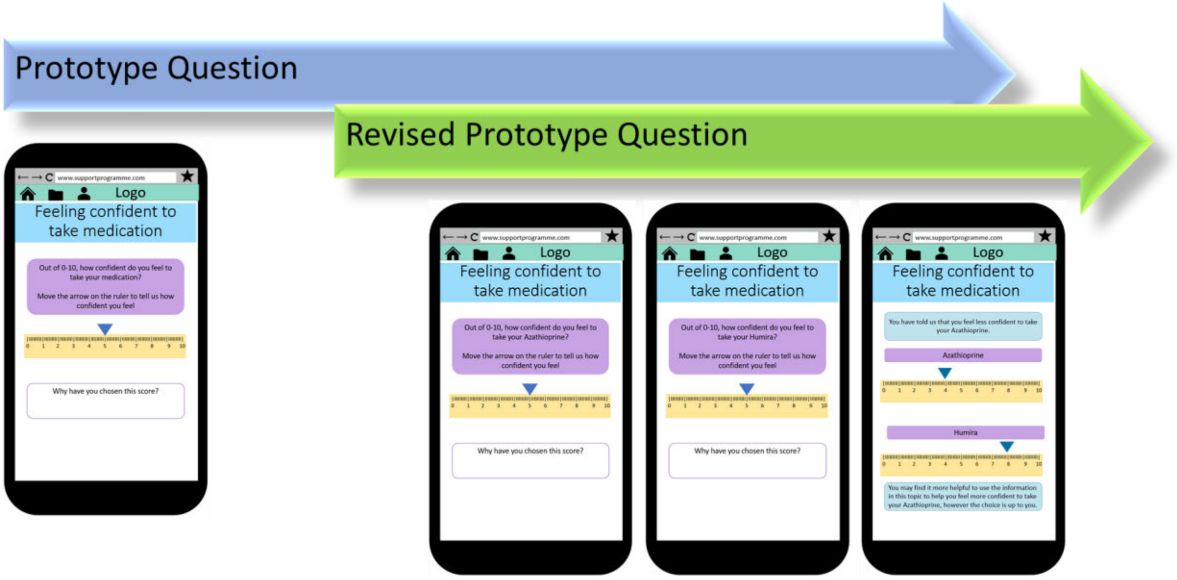
Initially, the prototype included multiple activities where young people could input information regarding their treatment plan. While young people reviewed this as acceptable, parents were concerned the requirement for young people to write vast amounts of information may make such questions susceptible to disengagement. Therefore, each activity was reviewed and where applicable, questions were adapted to include a dropdown list of possible answers for intervention users to select from (Appendix.35). For example, when defining medication routines, young people can now select relevant medications and medication doses from a prepared comprehensive list, rather than being required to write lengthy descriptions for each medication (Figure 21).

Figure 21. Prototype revision to remove excessive amounts of written information



Parents highlighted the complicated nature of asking young people to complete generalised questions about IBD treatment plans. As such, these questions failed to capture differences in young people's medication taking experiences. Equally questions generalising lifestyle behaviours into one subject matter were seen as likely to encounter difficulties. Specificity of questions was therefore enhanced, to remove ambiguous questions regarding young people's treatment plan adherence behaviours (Appendix.35). For example, young people who are prescribed azathioprine and humira will now be asked how confident they feel to take each of these medications in separate questions (Figure.23). This revision further allowed young people to be provided with an indication of which element of their treatment plan behaviours they may wish to tailor the content of the intervention module to. For example, if young people provided a lower confidence rating for azathioprine in comparison to humira, the intervention will now suggest the individual may gain a greater benefit if they chose to increase their confidence to take azathioprine. To ensure the maintenance of user-centred control and flexibility within the intervention, young people will still have the final choice over which of their adherence barriers to target within each intervention module (Appendix.35).

Figure 22. Prototype revision to provide additional clarity and guidance



Out of 0-10, how confident do you feel to take your medication?

Move the arrow on the ruler to tell us how confident you feel

Why have you chosen this score?

Out of 0-10, how confident do you feel to take your Azathioprine?

Move the arrow on the ruler to tell us how confident you feel

Why have you chosen this score?

Out of 0-10, how confident do you feel to take your Humira?

Move the arrow on the ruler to tell us how confident you feel

Why have you chosen this score?

You have told us that you feel less confident to take your Azathioprine.

You may find it more helpful to use the information in this topic to help you feel more confident to take your Azathioprine, however the choice is up to you.

Providing immediate definitions of medical terminologies within the intervention was included to improve young people’s psychological capability. The group’s suggestion to extend this support by providing intervention users and their parents with a separate glossary of such definitions is likely to be a highly beneficial tool for families, therefore, this resource will be included within the intervention.

Both parents and young people (as discussed in Chapter five), independently identified the engagement strategies (e.g., nudges and engagement rewards), used within a popular educational App as potentially effective but demanding for the target population. The focus group discussions with parents provided support for the previously detailed conclusion to suggest such self-led techniques within the tailored support podcasts, to facilitate action plans regarding daily adherence behaviours, rather than being implemented as an engagement strategy across the intervention.

The group felt it would be beneficial to automatically send young people’s action plans to their caregiver, to enable parents to appropriately assist in an action plans completion. As the intervention aims to develop autonomy within young people, it is important intervention users develop the skills to independently discuss their health needs with their caregivers. To support this, the intervention provides resources and training for young people on the facilitation of such discussions. Furthermore, intervention users can retain a copy of their action plan and share it with caregivers or a trusted adult if they wish to (Appendix.35).

Revisions to the intervention's flexibility

Flexibility built into the intervention was praised by parents; but suggested this could be increased to strengthen the intervention's user-centred approach and accommodate the unpredictable nature of living with IBD. During periods of ill health, parents felt that a need to review action plans would place additional burden on young people. Based on this feedback, young people are now given the option to "silence" intervention reminders for a user-set period to allow sufficient time to recover from an IBD symptom flare. This information will be shared with young people during the introductory session, and will be easily accessible throughout the intervention (Appendix.35).

Revisions for future consideration

Within the group discussions, parents provided many suggestions on how the intervention could target young people's emotional wellbeing. Assisting young people to develop the skills to identify when to ask for support is an important element across the intervention topics. Young people keeping records of their emotions could assist young people within the tailored support options to communicate their wellbeing needs with others. Equally information on relaxation and breathing techniques could be suggested for those struggling with pain management or anxiety during relevant tailored support podcast discussions.

Each module further contains education and social support to help reduce feelings of difference. Facilitating social interaction between young people with IBD is impractical for the current intervention because hosting discussion boards or forums and/or providing relevant links to support services, would require one or more individuals to monitor these interventional elements, thus incurring a financial cost. Within the focus group discussion, it was apparent that parents sought experiential information from others to help process their own experiences. However, as the intervention only looks to provide parents with information on how to support young people during the intervention (at this time), the inclusion of such resources falls outside the limits of the current intervention. However, it is possible this could be included in future iterations.

The inclusion of resources for peers and school staff to increase others understanding and acceptance of IBD is further beyond the scope of the current intervention. However, by engaging with the intervention, it is anticipated young people will develop their health communication skills and thus feel more comfortable discussing their needs and coping with stigma.

6.4. Discussion

A thematic analysis of a single focus group with parents of young people with IBD has generated three themes exploring the practicality of a newly developed intervention to support treatment adherence in young people living with IBD. Findings suggested the intervention is practical and relevant for the target population. Flexibility within the intervention was suggested to empower young people to tailor the intervention to meet their needs and overcome their personal adherence barriers. Using an online format was reviewed favourably by parents, who felt young people would be comfortable engaging with online resources. Following parental feedback, refinements were made to the intervention to increase its usability. Additionally, the focus group discussion was inclusive of family's additional support needs beyond treatment plan adherence; while unfeasible to include within the current iteration, it provided useful insight into the needs of young people with IBD and their parents for future exploration.

In line with the INVOLVE (2012) guidance, this research included parents of young people with IBD as consultants within the intervention's co-development. Parents had the opportunity to explore how young people would interact with the intervention and provide feedback based on their experiences of parenting a child with IBD. Parents provided a range of positive and constructive comments regarding the intervention's design and implementation. The flexible nature of the intervention, allowing young people to make user-centred decisions to match their health needs, was welcomed by the group, who felt taking a personalized approach was appropriate for the management of IBD. Previously, tailored interventions have been defined as those aiming to address a person's individual characteristics, for example, their goals, needs or preferences (Beck et al., 2010) and have been found to be beneficial in an oral medication adherence intervention for young people with IBD (Maddux et al., 2017). Parents' favourable reviews of the intervention's tailored approach correlated with the views of young people with IBD (Chapter five), thus indicating its usability and relevance to the target population.

Variance in IBD-related topics were viewed as beneficial for the development of important self-management health behaviours in young people with IBD, including transition to adult healthcare. While parents in the current research held some concerns over their diminished presence in the management of their child's IBD, the group understood that developing autonomy was essential for a young person's development into adulthood. Parents were therefore torn between wanting to ensure their child was supported in their preparation for adulthood/care, while avoiding being overly involved. However, when young people had begun the transition process, service-level complications and delays were experienced as frustrating for parents who wanted to begin the transfer of health responsibilities. Shaw et al. (2021) proposed that while ‘overparenting’ should be viewed as a naturalistic reaction to prevent young people from experiencing harm, parental overinvolvement in young people’s health into late adolescence can inhibit the success of young people’s transition to adult healthcare. The current findings support this understanding of parental behaviours and further suggests that a lack of clarity over future health outcomes informs parental threat perceptions. Transitional uncertainty has been identified as a cause of anxiety and distress for parents (Heath et al., 2017), therefore, healthcare providers should be aware and accommodating of parental support needs during young people’s transition to adult healthcare.

The group believed IBD complexities (e.g., varied IBD medication routines) were likely to influence how young people interacted with the intervention activities. As treatment plans involving multiple medications are likely to incur a variety of adherence barriers (Greenley et al., 2010; Greenley et al., 2015), it is vital the current intervention can provide the support required to enhance young people’s adherence. Therefore, revisions were made across the intervention modules to remove ambiguous or challenging questions. Parents further highlighted how the overwhelming experience of IBD symptoms would limit young people’s engagement with the intervention, particularly when young people experienced the additional burden of catching up on missed educational activities. To remove additional burden young people would experience, greater flexibility was included to prevent feelings of failure or guilt over disengaging from the intervention during periods of stress or ill health.

Parents within the current focus group were conscious that young people’s enthusiasm and engagement may dwindle over time, and therefore suggested utilising additional engagement strategies within the intervention. Akin to their children in the CCTV group (Chapter five), parents discussed their own experiences with a popular educational App, which used daily prompts to encourage engagement with the Apps content, as well as numerically recording the days of engagement as “streaks”, often perceived to be an indication of success. As within the conversations amongst CCTV group members (Chapter five), there was a divide in opinion over the relevance of such strategies within the current intervention. While periodic prompts or reminders have the potential to increase eHealth intervention engagement (Neff & Fry, 2009), the frequency of reminders utilised by the discussed educational App, were viewed to increase the burden experienced by young people with IBD and were subsequently not incorporated into the intervention’s design.

Parents shared their experiences of how their child’s health needs had changed over time. At diagnosis, parents felt overwhelmed by the need to adopt IBD into family life and contemplated how this would impact their child’s future. While parents in the current study felt they were provided with large amounts of educational material around the time of their child’s diagnosis, they struggled to absorb the information’s content and wanted greater amounts of experiential information. However, a study of families IBD knowledge, found parents had greater health knowledge at diagnosis, but such parental knowledge declined over time (Appleton & Day, 2021). Within the current study it was identified that as families felt more familiar with the constraints of living with IBD and young people experienced changes in their adolescent development, families need for additional information and support was more apparent. Adolescence is a normal time of change for all young people as they develop their identity, often becoming susceptible to peer pressure and risk-taking behaviours (Pinzon et al., 2004). Lifestyle behaviours such as healthy eating and having good sleep hygiene are important in the management of IBD (Lamb et al., 2019; Rozich et al., 2020). Risky behaviours such as alcohol consumption or recreational drug use can alter the effectiveness of IBD medications (Lu & Markowitz, 2011), however young people with IBD are more likely to engage in these behaviours in comparison to healthy adolescents or those with other chronic health conditions (Brooks et al., 2016). Subsequently, parents viewed the inclusion of information and practical support regarding lifestyle behaviours as relevant for the current intervention’s target population.

The skills to independently manage IBD in adulthood, are developed gradually during adolescence (van Groningen et al., 2012). Hait et al. (2018) produced a timeline to identify key milestones in the development of self-management skills to facilitate a successful transition to adulthood. Within such guidelines, young people gaining an awareness of their IBD medication routine and being able to discuss the impact IBD placed on their life should be achieved within the ages of 11-13; with such skills incrementing in difficulty until the ages of 20-22, whereby young people can independently manage their health and know how to access relevant support (Hait et al., 2018). Within the current study, parents were aware of their ever-evolving role as their child developed autonomous self-management behaviours; therefore, the user-centred flexibility within the newly developed intervention was praised by families as it allowed young people to access support relevant to their adolescent development needs.

Experiencing IBD stigmatisation can cause additional health worries in young people (Roberts et al., 2021). Young people with IBD further experience poorer quality of life and are at greater risk of depression than other young people with chronic conditions such as juvenile rheumatic disease and cystic fibrosis (Halloran et al., 2020). The need for the current intervention to address young people’s emotional distress due to IBD stigmatisation were discussed in detail by parents, however, such support was not mentioned by young people in the CCTV group (Chapter five). Muller et al. (2009) compared quality of life measures of young people with IBD to parental proxy scores and concluded parents underestimated children's emotional and social quality of life. It is possible that such mismatched judgements were informing the current focus group's views; however, it is further probable members of the CCTV group chose not to disclose their emotional support needs within the intervention co-development workshops due to fear of judgement (Carter et al., 2020). While the constraints of the current intervention could not fully address parents' concerns regarding young people's emotional wellbeing, further interventions should be devised to target this explicitly.

Roberts et al. (2021) suggested challenges in communicating health needs may arise from experiencing IBD stigmatisation, subsequently resulting in feelings of "thwarted social belongingness" and symptoms of depression. It is therefore understandable parents in the current research were concerned over the reliance on young people to communicate their health needs and devised action plans with relevant others, to receive appropriate levels of support. However, the development of such communication skills with family members and health professionals may reduce young people's experience of IBD worries and symptoms (Varni et al., 2017). Subsequently it is valid the intervention looks to provide young people with the skills to initiate conversations about their health and effectively articulate their support needs with others.

It is known that parenting a child with IBD can cause anxiety and worry in parents, such stress is felt more acutely at point of diagnosis (Day et al., 2005; Rea et al., 2022). Due to the unpredictable nature of IBD, it has recently been suggested health professionals should provide both educational and relevant IBD resources to families to reduce the impact IBD has on family's emotional wellbeing (Thapwong et al., 2022). Mindfulness interventions have further been identified as a feasible way to reduce stress in parents of children with IBD (Oseran et al., 2021) The current research identified a variety of parental support needs, including a desire to obtain greater information on others lived experiences, in order to increase their IBD knowledge. However, available support options, such as social media groups, induced additional parental anxieties. While the current intervention is unable to provide support for parents, future research could look to develop resources which effectively meet parent's needs. At the Nationwide Children's Hospital in Ohio, an IBD parental mentoring scheme has been initiated, whereby parents of young people with IBD receive training to mentor other parents (Donegan et al., 2016). Within such training parents learn how to share relevant experiences and practical advice, as well as, how to track mentees' concerns and relay these to the IBD medical team (Donegan et al., 2016). Similar opportunities could be offered within the UK to meet the parental needs highlighted within the current research.

A desire to receive instant and relevant practical support was identified within the current focus group; parents felt disheartened by the extensive process of identifying ways to benefit their child's lives. Recently, key stakeholders have been involved in the rewriting of UK IBD standards, within which it outlines the need for healthcare professionals to signpost IBD patients to relevant information and support from patient organisations (Kapasi et al., 2020). The current research highlights that while families acknowledged they were signposted to some information; this was often difficult to access and did not always meet their needs. IBD health services and charities should therefore be aware of the hidden nature of available support and may wish to make organisational structure changes to ensure their services are clearly identifiable for families.

6.4.1. Strengths and limitations

To the authors knowledge, this is the first-time parents have been consulted on the development of a behaviour change treatment plan adherence intervention for young people with IBD. Parents are key stakeholders in the management of young people's health, therefore consulting with parents to refine a prototype intervention was an important step in its development.

The online nature of the research facilitated parental participation from across the UK. This allowed for the inclusion of regional differences in service provision for young people with IBD to further inform the interventions co-development, thus increasing its relevance at a national level. However, the project suffered from considerable recruitment issues; leading to a smaller sample of parents than initially intended. All focus group members' children had joined the CCTV co-development workshops (Chapter five), thus, participants shared similar values and experiences to those who had previously co-developed the intervention. The inclusion of a greater variety of parents may have provided further valuable insight into the practicality and relatability of the intervention.

Within the focus group, there were little variance in demographic information; all parents identified as mothers and White British. It has previously been noted that fathers of young people with IBD differ in their experiences of parental distress (Bramuzzo et al., 2020), therefore the inclusion of fathers is important for future research. Equally, all participants were parents of young people diagnosed with Crohn's Disease and prescribed azathioprine. Such limited demographic and IBD-related variables may limit the transferability of the focus group outcomes. Nevertheless, findings did resonate with themes from existing research which supports their importance and relevance to this population as a whole.

6.5. Conclusion

Parents of young people with IBD (aged 14-16) provided a wealth of personal insight into the practicality and relevance of the co-developed intervention for young people with IBD. The discussions took the approach of viewing IBD like a fingerprint due to young peoples individualised experiences and thus highlighted the need for a tailored intervention to match the uniqueness of living with IBD. The flexibility within the intervention and allowance for young people to make user-centred decisions were well received by parents, as it allowed intervention users to access tailored information and support alongside developing key self-management behaviours. The online delivery method was further relevant for the target population due to young people's established familiarity with technology. Parents also suggested valuable amendments to the intervention prototype to increase engagement with the intervention. This outcome has allowed for the final revisions of the prototype intervention and concludes the intervention's development within this body of research.

Chapter seven. Discussion

7.1. Introduction

This Chapter synthesises findings from the five studies presented in this thesis, integrating the views and experiences of young people, their families, and NHS staff to develop broader and deeper understandings of barriers to treatment adherence for young people with Inflammatory Bowel Disease (IBD), with the aim of co-developing an intervention to address such challenges. The Chapter starts by revisiting the aims and objectives of the research, this is followed by a summary of key findings across the thesis, including how empirical research has informed the development of A Self-led Self-management Intervention to Support Teenagers with IBD (ASSIST-IBD). The Chapter concludes with a discussion of implications for future research and practice.

7.2. Research aims and objectives

This thesis aimed to develop an acceptable and engaging behaviour change intervention to improve treatment adherence in young people (aged 13-18) with IBD. Within each stage of the research there were specific objectives to support the intervention's development (Figure.24).

Figure 23. Stages of research within the current thesis

Stage one: Exploratory Research

A systematic literature review was conducted to evaluate the success of reported treatment adherence interventions, for young people with IBD, as well as to identify behaviour change theory underpinning existing interventions and techniques used to change behaviour (Chapter two). Second, qualitative research explored the views and experiences of young people, parents, and healthcare professionals regarding the challenges of treatment plan adherence for young people with IBD (Chapter three). Interviews further aimed to identify what support young people with IBD need from an intervention to address their treatment adherence challenges.

Stage two: Intervention Design and Development

The Behaviour Change Wheel (BCW) approach (Michie et al., 2011) was used together with knowledge generated in the formative research to develop a novel treatment adherence intervention for young people with IBD (Chapter four). A Patient and Public Involvement and Engagement (PPIE) group of young people with IBD was then formed. This group supported translation of the theoretical intervention content into a working prototype (Chapter five).

Stage three: Intervention refinement

Views on acceptability and practicality of the intervention along with suggestions for refinement were gathered from young people in the final PPIE group workshop (Chapter five) and from parents via a focus group discussion (Chapter six). To elicit such views, a prototype intervention module was showcased to stakeholders and feedback obtained.

7.3. Key findings

The key findings from this research suggest that living with IBD is challenging for young people. Adherence to treatment consists of multiple complex behaviours, with various determining factors. Successful management of IBD requires young people to engage with professionals, as well as parents and peers.

A Self-led Self-management Intervention to Support Teenagers with IBD (ASSIST-IBD) aims to support young people to overcome their adherence barriers to effectively manage their own condition. Currently, ASSIST-IBD is the only intervention that targets a broad spectrum of adherence behaviours, including lifestyle changes, engaging in medical appointments and medication-taking.

The following summary highlights how key findings from across the thesis directly influenced intervention development.

7.3.1. Living with IBD

Throughout this research, families of young people with IBD have provided insight into their world; informing the contextual background for the intervention's development. Living with IBD meant experiencing debilitating and embarrassing symptoms of urgency, pain, and fatigue, all of which prevented young people from engaging in a full life (Chapters three, five and six). Embarrassment caused by living with IBD, has previously been shown to directly affect young people's friendships and indirectly impact young people's mental health (Qualter et al., 2021). Furthermore, limiting social activities due to IBD symptoms has been associated with feelings of isolation among adolescents (Barnard et al., 2016). Within Chapter three, young people discussed how their experiences of IBD symptoms induced feelings of low mood and encouraged their desire to ignore their health needs. This suggested a need for interventional resources to help young people develop relevant coping strategies and maintain self-management behaviours.

The pain and fatigue experienced by young people often prevented school attendance, however the culture within schools often came with the expectation of young people finding adequate time to catch up on missed education materials (Chapters three and six). In line with Moody et al.'s (1999) research, young people's school absences were often met with unsympathetic responses from school staff. Due to the significant burden of experiencing IBD symptoms, parents were cautious of young people's ability to engage in an intervention during periods of ill health (Chapter six). To reduce possible user disengagement, relevant amendments to the prototype ASSIST-IBD were made to increase the flexibility and relevance of the intervention for young people with IBD.

It is also important to acknowledge the impact of the Covid-19 pandemic which was happening while the research was carried out. Immediate and long-term disruptions caused by Covid-19 were therefore present throughout stakeholder accounts and may have directly influenced participants' reported experiences of living a restricted life. At the start of the pandemic, confusing guidance was produced as to whether young people with IBD were classed as clinically vulnerable. Such lack of clarity was anxiety-inducing for participants. The research in Chapter three was predominantly conducted when participants had been removed from their usual routines due to strict lockdown governance. In Chapters five and six, no participants were limited in their activities due to Covid-19 restrictions, however the chronic effects of the pandemic were evident. For example, young people voiced their concerns about the possible re-closure of public toilets.

7.3.2. Young people's adherence support needs

Within Chapters three and five, young people shared their desire for greater autonomous self-management behaviours to improve their adherence. This outlined the need for an intervention to target young people's treatment plan self-efficacy, resilience behaviours, optimism about the future and health communication skills. The need to enhance self-management was underpinned by the significant benefit these behaviours would have on young people's transition to adult healthcare (Paine et al., 2014). As highlighted in the systematic review (Chapter two), no such intervention has previously looked to explicitly target these behaviours to improve young people's adherence to their entire IBD treatment plan.

Self-efficacy

Enhancing young people's self-efficacy (Bandura, 1977) is recognised as important by healthcare professionals during the transition from paediatric to adult healthcare (Dur et al., 2014; Stone et al., 2022; Zijlstra et al., 2013). Within Chapter three, young people shared feelings of uncertainty over their ability to follow their treatment plan, with most young people not knowing how to obtain a prescription or book a medical appointment (Chapter three). While this has been noted in previous research (Krauthammer et al., 2020), young people within Chapter three outlined their desire to develop these skills required to manage their health autonomously. Furthermore, across the research young people reported feeling uncertain about their health knowledge, despite eloquently articulating their health needs (Chapters three and five). Previously, Fishman et al. (2011) suggested young people with IBD have good general IBD knowledge, but lack an understanding of adverse medication side-effects. Research detailed in Chapter three has provided a contextual understanding of Fishman et al.'s (2011) research, whereby caregivers intentionally protected their child from unpleasant information to prevent increased anxiety in young people. However, doing so unintentionally, negatively impacted young people's self-efficacy.

To shield their child from experiencing emotional distress, parents further sought to consciously remove health management responsibilities from their child and thus absorb the burden of living with IBD (Chapter three). However, this inadvertently restricted young people's development of key autonomous self-management behaviours. In line with Shaw et al.'s (2021) proposal, such parental behaviours were seemingly the result of wanting to protect children from the adverse consequence of living with a chronic health condition. However, parental hypervigilance encouraged rebellious volitional non-adherence behaviours in young people (Chapter three). Furthermore, parents often aimed to absorb the burden of their child's health condition at the detriment to their own wellbeing. In line with previous research, the analysis in Chapter three suggested parental anxiety was heightened when a young person began developing self-management behaviours, thus relying less on their caregiver (Greenley & Cunningham, 2008; Abraham & Khan, 2014). Nevertheless, some parents wanted to transfer the health management responsibilities to their child but felt hindered to do so. Healthcare barriers, such as delays in providing young people with access to an appropriate prescription ordering service, were perceived to encourage young people to continually rely on their parents (Chapter six).

Social media groups were described as a vital source of support for young people, who engaged with such groups to understand how other young people followed their treatment plan (Chapter three). These conversations developed young people's self-efficacy, as it reinforced the belief that they could perform similar behaviours (e.g., through vicarious experiences). Social media groups further enhanced young people's self-efficacy due to the supportive and encouraging tonality of the group conversations (e.g., through verbal persuasion about their capability).

During a behavioural analysis, detailed in Chapter four, deficits in young people's reflective motivation (e.g., their belief in their ability to perform the behaviour), indicated an intervention to improve young people's self-efficacy would be beneficial for the target population. Within the PPIE co-development workshops, young people felt this was a highly relevant subject matter to support young people's adherence behaviours (Chapter five).

Resilience

Encounters of fluctuating illness severity and the disappointment of treatment failures was extremely difficult for young people. In order to appropriately manage their IBD, young people were expected to adapt to their changing circumstances in order to perform sufficient treatment plan adherence behaviours; often involving the development of flexible and adaptive treatment routines. In Chapters three and five, young people discussed the challenges of remembering their treatment routine. Within the literature, forgetfulness is a frequently reported treatment adherence barrier for young people with IBD (Gray et al., 2012; Schurman et al., 2011). Despite this, forgetfulness is rarely targeted within adherence interventions for young people with IBD. Young people proposed a variety of helpful solutions to overcome forgetfulness, within the qualitative interviews and podcast development workshops, such as using visual or digital prompts (Chapters three and five). These practical adherence solutions demonstrated the potential to implement specific youth-led strategies to improve young people's adherence and therefore, were included in the current intervention.

Young people are further expected to be resilient when experiencing persistent IBD stigmatisation. Cruel comments were frequently encountered in public settings, such as the school environment, and directly impacted young people's self-image, confidence, and psychological wellbeing (Chapters three, five and six). Young people's experience of social stigmatisation, as discussed in Chapter three, were in line with Weiss et al.'s (2006), proposed definition, whereby health-related stigma was perceived as a social process, consisting of experienced or anticipated negative peer judgement, social exclusion, rejection, and health blame. Additionally, the current research has demonstrated how the fear of stigmatisation, directly impacted young people's adherence behaviours, highlighting the need for an intervention to support young people to cope with hurtful comments.

Resilience behaviours are associated with a greater ability to cope with adverse events in adult IBD patients, resulting in better health outcomes and a greater quality of life (Sehgal et al., 2021; Taylor et al., 2018). Therefore, resilience is an important life skill to develop during adolescence for young people's immediate adherence barriers as well as their future health (Ahola Kohut et al., 2021). During the intervention's development, as detailed in Chapter four, deficits in young people's psychological capability (i.e., psychological skills and strength to perform a behaviour), indicated an intervention to enhance resilience in the target population would be advantageous. The PPIE group acknowledged the relevance of this topic for young people with IBD, and commented on young people's need to persevere and overcome challenges in order to maintain their emotional wellbeing and adherence to their treatment plan (Chapter five).

Optimism

Young people discussed their inability to participate in life as they would wish and often experienced low mood (Chapters three and five). In line with previous research, young people discussed concerns over their health, physical appearance, and friendships

(Goodhand et al., 2011; Newton et al., 2019; Nicholas et al., 2007; Staples & Bravender, 2002). Those who were struggling to follow their treatment plan and manage their health were often pessimistic about the future, and worried about the impact IBD would have on their adult life (Chapter three). To enhance young people's emotional and social wellbeing, it has previously been suggested young people with IBD should be encouraged to identify enjoyable activities they can participate in, rather than focusing on those they cannot (Mackner & Crandall, 2006); although identifying such activities was challenging for young people in the current research (Chapter three). Nevertheless, some young people remained unwaveringly optimistic and were motivated by the idea that one day they would feel well (Chapter three). The PPIE group emphasised the need for intervention content to be positive and optimistic about the future (discussed in Chapter five). Across the literature it has been suggested doing so can help remove perceived life limitations to encourage young people to participate in a full life, and improve their health-related quality of life (Avvenuti et al., 2016; Roberts et al., 2021; Tomlinson et al., 2021; Wrosch & Scheier, 2003).

Additionally, young people actively sought a period of symptom remittance. Remission was viewed as a mechanism to allow young people and families to live a "normal life", free from IBD restrictions. An optimistic view of remission thus strengthened young people's beliefs in the importance of adherence behaviours (Chapter three and five). However, while it was promising to see the benefits of such optimism, remission was often viewed as a permanent, rather than temporary, state. As previously identified, families viewed remissions to be devoid of all IBD symptoms and were therefore disheartened when they continued to experience IBD symptoms while in remission (Kitchen et al., 2020). Therefore, caution should be placed on the language used around remission, as it is possible that future periods of ill health can have a negative impact on young people's illness and treatment perceptions. Within ASSIST-IBD, honest information is provided about remission, allowing young people to understand remission is an impermanent state, which may continue to be inclusive of IBD symptoms. Thus, improving young people's health knowledge and creating realistic future health expectations.

The current research was suggestive that while some young people held a positive view of the future, most felt their IBD significantly limited their life. Within the intervention design process, reported in Chapter four, targeting young people's reflective motivation, (e.g., their belief that performing the behaviour will lead to a positive outcome) was assessed as beneficial for the target population's treatment adherence. The PPIE group felt support for young people with IBD often focused on the negative aspects of a chronic health diagnosis, and wanted ASSIST-IBD to capture the humorous moments of living with IBD, such as young people's experiences and behaviours of awakening from anaesthetic (Chapter five).

The inclusion of interventional materials to help young people feel positive about their future was welcomed by the PPIE group, who foresaw this having a great benefit for young people living with IBD.

Disclosing IBD to peers

The fear of stigmatisation resulted in most young people avoiding disclosure of their IBD at all costs. Rather, young people found innovative ways to hide IBD symptoms and treatment routines from their friends, to maintain anonymity over their health (Chapter three, five and six). Rather than a stable construct, Muse et al. (2021) suggested living with IBD meant navigating a fluctuating spectrum of “otherness” whereby individuals experience both exclusion and integration across different social contexts. Such altering states of social belongingness and separation were discussed by families in Chapters three and six. Parents therefore aimed to create an accepting home environment whereby their child felt comfortable discussing their health. To minimise the risk of stigmatisation, young people often selected a few trusted friends to whom they disclosed their condition. Such practices have been noted previously (Barnard et al., 2016). To fully demonstrate the complexities of the verbal disclosure decision-making process, Barnard et al. (2016) produced a comprehensive flow chart, detailing the importance of factors such as illness severity, risk of stigmatisation and trustworthiness of peers. The findings detailed in Chapters three and five expand Barnard et al.’s (2016) conclusions, by demonstrating such decisions are applied when performing treatment adherence behaviours in public more generally. Despite the perceived risks, when young people shared their health needs with peers, they were often met with support and understanding, with friends providing an additional source of support during ill health. This is reflected in Chapter three and the wider literature (Carter et al., 2020; Rouncefield-Swales et al., 2020).

Carter et al. (2020) noted that young people would benefit from training or education on how to disclose their health needs with others. Outcomes of the current research are in agreement with this and have further identified relevant mechanisms within the disclosure process to target. Within Chapter four, it was deemed unfeasible to change peer groups’ behaviours and/or understanding of IBD within the current intervention, however to overcome the deficit in young people’s social opportunity to perform treatment adherence behaviours, it was decided young people needed support to understand how to articulate their health needs and cope with overwhelming IBD stigmatisation. This is directly addressed within one intervention module, as well as being discussed across the intervention.

Communicating with healthcare professionals

Having good communication with healthcare professionals is important for the management of IBD, including preparing for transition to adult healthcare (McCartney, 2011). However, previous research has indicated young people's limited ability to do so (van Groningen et al., 2012). The current research identified that discussing IBD within health appointments was often challenging for young people, due to experiences outside of the hospital environment (Chapter three). Young people therefore, relied on their parents to relay relevant information to healthcare professionals. Open conversations within health appointments were necessary to facilitate the co-creation of appropriate, personalised treatment plans for young people with IBD. Healthcare professionals, therefore, took the time to engage patients within appointments by directing their questions specifically to the young person (Chapter three). Shared decision-making when formulating a young person's treatment plan was preferable to strengthen young people's treatment adherence and allowed young people to feel important and valued in decisions surrounding their health (Chapter three). However, at times, the shared decision-making process was overwhelming for families, who felt ill-informed to make such decisions. Both young people and parents believed the educational materials within ASSIST-IBD would support families to navigate medical conversations (Chapters five and six).

Paediatric gastroenterology medical professionals were the first healthcare professionals to validate a child's ill health and provide clarity and solutions to the young person's adverse experiences. This set the foundation of a trusting relationship. When young people engaged in their health appointments, a meaningful trusting relationship was formed between the young person and their healthcare professional. Parents felt healthcare professionals were vital for young people's adherence behaviours, as their children were more willing to engage with their treatment plan, as well as with a behaviour change intervention, if introduced by a healthcare professional (Chapters three and six). Therefore, increasing young people's capability and willingness to engage in medical appointments may have long-term benefits for young people's treatment adherence and overall health, particularly during their transition to adult healthcare services. Within qualitative interviews and the BCW intervention design process (Chapters three and four), poor health communication skills were identified as a significant barrier to treatment adherence. Subsequently, interventional materials aiming to improve young people's knowledge on how to communicate their health needs (e.g., psychological capability) as well as young people's intentions (e.g., reflective motivation) and desires (e.g., automatic motivation) to engage in medical appointments, were included within the intervention. Parents thought it was appropriate to develop young people's health communication skills within an intervention, to impart relevant techniques to facilitate such conversations (Chapter six).

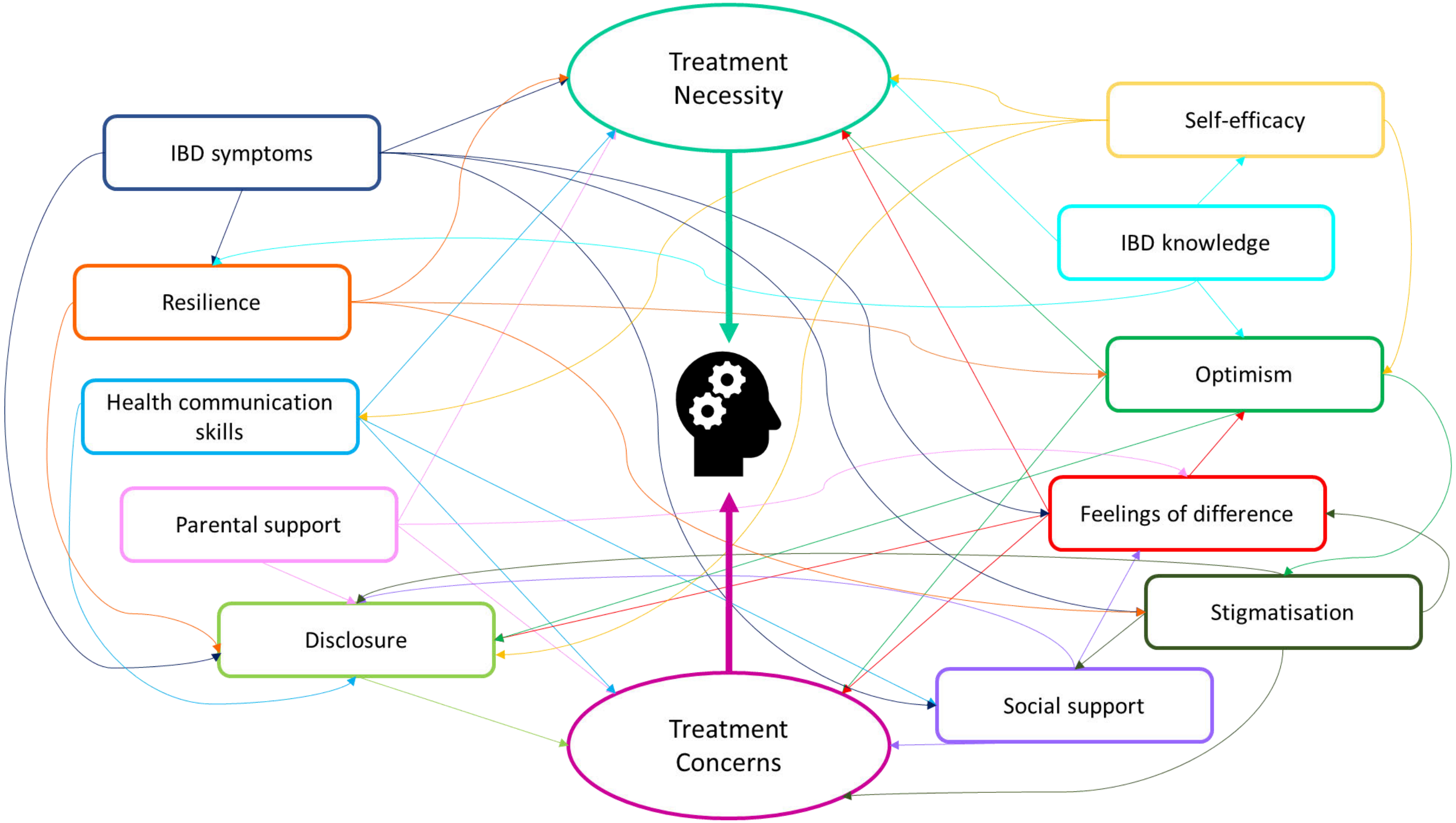
7.3.3. Treatment perceptions

Across the thesis, young people's treatment beliefs have been shown to vastly impact their treatment adherence. Treatment perceptions were not unanimous amongst young people, rather they were formulated due to an individual's personal experiences and views. However, there were commonalities in identified factors that contributed to these decisions. For example, the risk of disclosure or stigmatisation, the threat treatments posed to a young person's sense of self, young people's health knowledge and communication skills and young people's sense of resilience, self-efficacy, and optimism.

Treatment beliefs have previously been identified as an important and modifiable factor for IBD medication adherence behaviours (Hall et al., 2007; Jackson et al., 2010; Moshkovska et al., 2009). The Extended Common Sense-Self Regulation Model (Extended CS-SRM) (Leventhal et al., 2016), details how the perceptual need and concern over treatments informs how an individual appraises the illness threat and their subsequent adherence behaviours (Chapter one). Findings of the current research confirms relevance of the Extended CS-SRM when aiming to understand young people's adherence. In general, the desire to be well, emphasised young people's need to adhere to their treatment plan, often requiring them to remain optimistic and resilient. Furthermore, young people's concerns over the risks of social disclosure when following their treatment plan hindered the performance of adherence behaviours (as detailed in Chapters three, five and six). Equally, some young people's uncertainty of their medication's safety and side effects further limited young people's adherence behaviours (as discussed in Chapters three and five). However, as such information was often withheld by parents, medication side-effects appeared to be of a lesser concern to young people than the risk of social stigmatisation (Chapter three).

The current research further adds to the Extended CS-SRM's notions of treatment beliefs, by suggesting such views are formed within a spectrum of complex decisions as displayed in Figure.25. Young people's treatment beliefs were based on situational factors as well as individual traits, and thus were often modified to reflect the environment the adherence behaviour was performed within. Identified significant factors often influenced each other, creating a complex network of adherence causal mechanisms in the formation of treatment beliefs. This highlights the importance of taking a user-centred, tailored approach when developing interventions for this population, to ensure the provision of relevant education, and social and practical support to overcome young people’s adherence barriers.

Figure 24. Causal mechanisms that influence treatment perceptions in young people with IBD



7.4. Intervention development

ASSIST-IBD is a novel intervention for young people with IBD, due to its inclusivity of a range of treatment behaviours, as well as its ability to support young people's adherence for all forms of IBD medications. A systematic review (detailed in Chapter two), concluded the existing behaviour change adherence interventions for young people with IBD (aged 13-18) only target oral medication adherence, neglecting the variance in commonly prescribed IBD medications and complexity of behaviours included in IBD treatment plans. Additionally, an understanding of the theory informing the design of previous interventions for young people with IBD, as well as the clear reporting of an intervention's content, mechanisms for behaviour change, and method of delivery, were often absent in the publication of such interventions. The systematic review highlighted a noticeable absence of intervention development frameworks, such as the BCW, to effectively communicate an intervention's design (Hoffmann et al., 2014; Michie et al., 2011). Thus, clarity within the reporting of the development of ASSIST-IBD, including a clear rationale for the utilisation of behaviour change theories and techniques, provides a novel contribution to literature.

ASSIST-IBD includes ten modules to improve young people's treatment adherence, comprising a variety of self-management behaviours. Each behaviour was specifically chosen to assist in the maintenance of treatment adherence, long-term. Within each module there are seven interactive elements, which target four relevant constructs of the Capability, Opportunity, Motivation, Behaviour (COM-B) model (Michie et al., 2011): psychological capability, social opportunity, automatic motivation, and reflective motivation. Clear reporting of the intervention's targeted COM-B behaviour constructs will provide a deeper understanding of the mechanisms related to the success of the intervention, within future research assessing the feasibility and effectiveness of ASSIST-IBD. To prevent feelings of guilt or shame, the intervention's content avoids blaming language for non-adherence, rather it acknowledges the challenges of adhering to IBD treatment plans and provides encouragement for young people to believe in their ability to overcome barriers.

A key feature of ASSIST-IBD is its focus on empowering young people to tailor each element of the intervention's content to their personal treatment adherence needs. The provision of support to personal adherence goals has previously resulted in greater levels of oral medication adherence in young people with IBD (Maddux et al., 2017). However, the extent to which Maddux et al.'s (2017) intervention was tailored to young people's needs is unclear. Tailored interventions have also been shown to be effective in improving self-management behaviours in other paediatric health conditions such as asthma and diabetes (Franklin et al., 2008; Joseph et al., 2013). The outcome of each ASSIST-IBD module is for a young person to set an action plan to address their most significant (module-relevant) treatment adherence barrier. Within podcasts, written and recorded by young people with IBD, intervention users can receive suggestions on how to overcome their adherence barriers (Chapter five). Young people are further guided to form their behaviour change action plan and set implementation intentions within the programme's interactive materials. The PPIE group were impressed by the freedom and flexibility intervention users would have in making decisions on how best to overcome their personal challenges. This, they believed, is a crucial element of the intervention, and as such was assessed as highly acceptable and relevant for young people with IBD (Chapter five).

Tailored web-based interventions are an effective and preferred intervention delivery method for multiple health conditions and behaviours (Lustria et al., 2013; Ramsay et al., 2020). Through facilitating ASSIST-IBD on a digital platform, participants will be able to access the intervention's content at a convenient time and location, thus enhancing the flexibility of the intervention. For young people and parents, such flexibility was essential to increase relevance for the target population, as discussed in Chapters five and six. To the author's knowledge, this is the first treatment adherence intervention for young people with IBD to offer such flexibility.

After conducting a behavioural analysis using the COM-B model, the need to further support young people's social opportunity to perform a behaviour became apparent. To accommodate this need, separate online information resources will be provided to caregivers which discuss the importance of their child developing autonomy in their self-management behaviours for each intervention topic (Appendix.36). Parents felt the provision of such resources would be beneficial, as they would be comforted in knowing what was expected of their child during their engagement with the intervention; however, such information should be succinct to accommodate parents' demanding needs of looking after their child's health while maintaining their normal parental role (Chapter six).

7.4.1. Intervention acceptability and refinement

Young people with IBD (Chapter five) reviewed ASSIST-IBD as highly acceptable and relevant for the target population. In Chapter five, young people positively reviewed the intervention's aesthetic design, use of clear and concise welcoming language, and interactive engagement strategies. Furthermore, the inclusion of intervention components designed by young people with IBD were suggested to increase the relatability of the intervention to the target population. Within Chapters five and six, young people and parents reviewed ASSIST-IBD as a practical intervention to address young people with IBD's treatment adherence behaviours. Parents praised the inclusion of a variety of topics within ASSIST-IBD, especially information on lifestyle advice, as parents felt this was often overlooked within current support for young people's treatment adherence (Chapter six). Parents further noted the longitudinal benefits of supporting young people to develop self-management behaviours during adolescence, as these would likely improve health outcomes throughout adulthood (Chapter six).

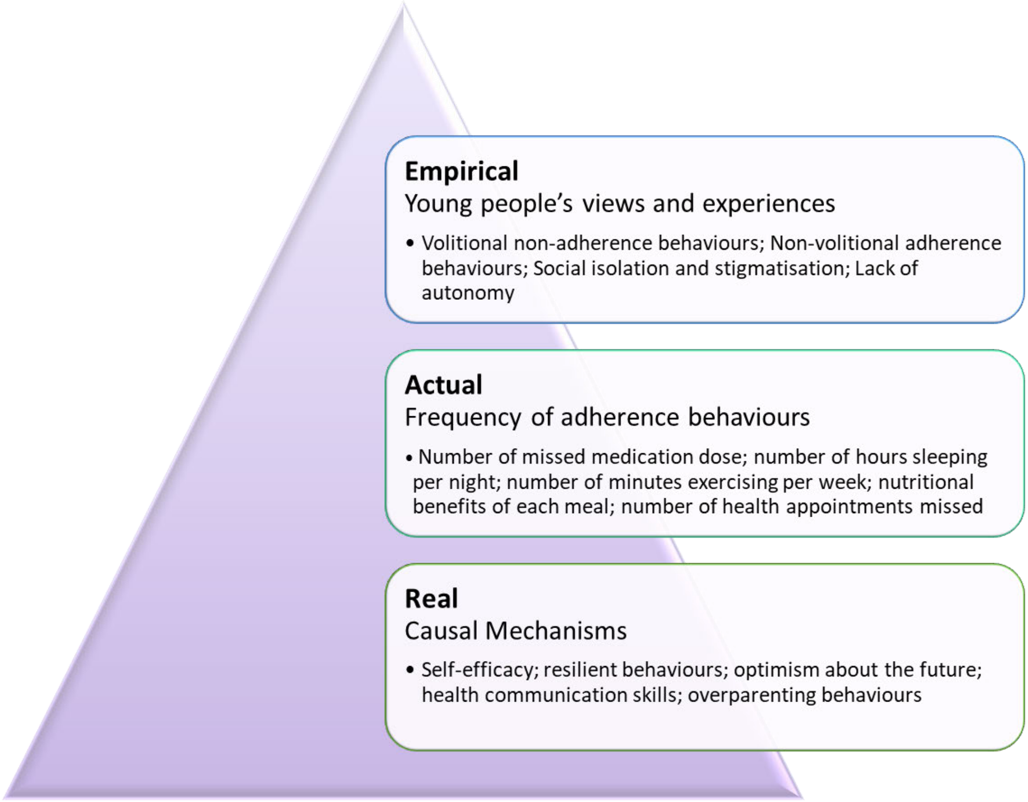
Young people and parents liked the intervention's tailored focus to allow young people to gain greater autonomy over their IBD health management skills and make user-centred decisions, as well as being accommodating of the uniqueness in IBD experiences (Chapters five and six). Both young people and parents viewed the intervention's use of an online delivery method was further relevant and practical for the target population due to young people's established reliance on technology. Furthermore, young people believed the intervention's interactivity would increase an intervention user's engagement in behaviour change processes (Chapter five). Parents' valuable insight led to multiple suggestions to further increase young people's engagement within ASSIST-IBD, such as increasing the use of simple interactive activities (Chapter six).

7.5. Methodological Reflections

Throughout this research, a pragmatic approach has been taken to allow for the identification of methodologies that best suit the research objectives. This has included a range of qualitative and arts-based research methodologies and co-production techniques. Pragmatism further influenced intervention design decision-making through use of the APEASE criteria outlined by Michie et al. (2014), discussed in Chapter four.

The philosophical framework of critical realism has allowed for a deeper understanding of the causal mechanisms that influence the health behaviours of young people with IBD and resulted in the development of appropriate interventional materials that address such causal mechanisms. Critical realism has previously been shown to be an appropriate philosophical framework for health sciences, and can help capture the unseen causes of health behaviours (Alderson, 2021; Bhaskar, 1979). It is possible previous interventions (identified in Chapter two) aim to change behaviours within the "empirical" or "actual" layers of reality and are therefore not addressing the unseen causes of adherence. Explorations of young people's "real" level of reality within this thesis has highlighted a complex set of beliefs that motivate adherent and non-adherent behaviours, see Figure.26. Therefore, taking a critical realist position has informed the development of a novel, appropriate treatment plan adherence intervention for young people with IBD.

Figure 25. Critical realistic approach to young people with IBD's adherence behaviours



Qualitative research methodologies

Qualitative research methods within this thesis were highly beneficial for the investigation of the causal mechanisms of young people's adherence behaviours. Due to the large sample of participants in Chapter three, a thematic framework analysis, provided a beneficial means to compare participants experiences and generate relevant themes (Gale et al., 2013; Ritchie & Spencer, 1994). Within the parent focus group (Chapter six), thematic analysis was used to generate patterns within parents' views on the practicality of ASSIST-IBD for young people with IBD (Braun & Clarke, 2006). A similar thematic analysis was intended for data generated during a focus group of PPIE group members, to understand young people's experiences of taking part in such projects. However, due to a lack of participant discussions within the focus group, a formal analysis was not possible and a narrative summary was provided (Chapter five).

Due to limitations imposed by the Covid-19 pandemic, all qualitative research was conducted remotely either using online meeting platforms (such as Zoom) or over the telephone. While online interviews and focus groups are known to be a valuable method of data collection (Keemink et al., 2022; Shapka et al., 2016; Stewart & Shamdasani, 2017), one potential concern of such methods is the lack of pre-interview rapport-building conversations (Jowett et al., 2011; Shapka et al., 2016). To limit the impact this may have on the research, time was provided to have informal rapport-building discussions with participants about their interests. To further build the rapport and encourage an easy flow of conversation, the language used within the research projects was carefully selected to provide an age-appropriate understanding of the research and research questions. Despite the potential limitations, the use of online methodologies has beneficially allowed for the inclusion of participants from across the UK, and thus captures a range of IBD experiences from within different geographical locations and NHS trusts.

While the diversity of participants in Chapter three allowed the inclusion of a variety of demographic and IBD condition factors within the sample, such as age, gender, IBD diagnosis and severity, this was not replicated in Chapters five and six. Furthermore, there was an overall lack of ethnic diversity across participants, with most identifying as White British, as highlighted in Chapters three, five and six. Within a recent review of UK IBD incidences, patients of Indian ethnicity had a greater disease severity than White Europeans (Misra et al., 2019), suggesting research with a predominantly White British sample may not capture experiences from those more severely affected by their IBD.

Co-development techniques

The formation of an online PPIE group of young people, Crohn’s and Colitis Teen Voice (CCTV) group, allowed for the successful co-development of ASSIST-IBD’s content and design, as discussed in Chapter five. While the CCTV group is aligned with the INVOLVE (2012) guidance for collaborative involvement, user-centred decisions were encouraged throughout the workshops to allow the developed intervention to be relevant and acceptable for the target population. Across the CCTV workshops young people proposed many ideas for the content and design of the intervention, that were unlikely to have been conceptualised by myself or the supervisory team, for example, the use of podcasts to deliver tailored support to overcome intervention user’s adherence barriers. Equally, the CCTV group identified elements of the conceptualised intervention that were unlikely to be engaging for young people with IBD, for example some proposed knowledge demonstration activities were perceived to be boring. Within the prototype podcast workshops, the group required little support to identify a range of potential adherence barriers and relevant helpful solutions to overcome each challenge. Therefore, the intervention co-development workshop outcomes, outlined in Chapter five, are a strong advocate for the inclusion of PPIE groups within the development of behaviour change interventions.

Young people also experienced a wealth of personal benefits to joining the CCTV group, as detailed in Chapter five. The CCTV group members discussed receiving an altruistic benefit from co-developing the intervention, as they were able to use their own experiences to help others, and were proud of their contributions. For most group members, the PPIE workshops were the first time they had disclosed their IBD in a public setting and were initially hesitant to discuss their personal experiences, however throughout the course of the workshops I was able to observe the group grow in confidence and discuss their health concerns with other group members. The online PPIE workshops aimed to develop young people's transferrable skills such as teamwork, joint decision making and analytical thinking; furthermore, young people were able to develop their interest in behavioural science and Science, Technology, Engineering and Maths (STEM) subjects. While it is acknowledged the self-selected sample were more likely to be inclusive of young people with a greater interest in developing interventions and those who have a higher level of education, the group's enthusiasm for such subject matters was evident throughout the sessions.

When conducting the CCTV workshops, it was essential to ensure that group members felt equal in power and value to myself and the workshop co-facilitator; it has previously been suggested that this is not consistently achieved within PPIE research (Osborne et al., 2016). Within the current workshops, multiple techniques were incorporated to address this including: informing the group on the rationale for developing a new intervention, as well as the outcome of research conducted prior to the CCTV group's involvement; providing the group with autonomy over the group's identity, such as the group's name and rules of conduct; reiterating the benefit and values of young people's input on the interventions development; and the use of ice-breaker activities to facilitate social bonding and encourage young people's creativity. Within the CCTV group's evaluation of taking part in PPIE research, young people reported feeling valued within the co-development process. However, a lack of communication over the time pressure young people experienced in joining the workshops indicated the power dynamic may not have been fully addressed. Furthermore, young people within the CCTV group's evaluation stated they would have been unlikely to join the PPIE group had it been conducted in person, due to the requirements to travel to and from the workshops, as documented in Chapter five. Suggesting that while

PPIE has vast benefits for an intervention's design and provides PPIE members with personal growth, researchers should be aware of the potential burden for young people to join such groups.

Within a focus group setting, parents were consulted and provided additional feedback on the co-developed intervention prototype (as reported in Chapter six). The group were able to employ their experiences of parenting a child with IBD to make valuable suggestions which were not considered by the CCTV group, (e.g., the amount of time taken to complete some activities), and therefore provides support for the inclusion of multiple forms of PPIE methodologies within intervention co-development research.

Using the BCW approach

The BCW approach (Michie et al., 2011) provided a successful framework for the current intervention's design, allowing for the consolidation of knowledge collated across Chapters two and three and assisted in making informed decisions about the selection of appropriate intervention components. Therefore, unlike previous interventions for young people with IBD, the reporting of ASSIST-IBD demonstrates a clear rationale for the inclusion of each intervention component (Chapter four). At the end of the BCW process, a detailed intervention outline was produced and used to create the intervention's content, thus providing support for the use of the BCW for complex interventions.

Arts-based methodologies

Arts-based research methods were included across this research as they provide participants with the opportunity to express their thoughts and experiences in a different way, void of the imposed sense of how a question should be answered (Caldirou-Bessette et al., 2020; Fargas-Malet et al., 2010; Punch, 2002; Tumanyan & Huuki, 2020). Within Chapter three a creative mapping task was used with participants, which led to the development of a list of emerging priorities for the intervention target population. Each online PPIE workshop, discussed in Chapter five, included a novel combination of group discussions and arts-based tasks. The use of non-digital arts-based methods encouraged the CCTV group to construct intricate metaphors for their artistic outputs, particularly when describing abstract constructs such as resilience and optimism. Previously, arts-based methods have been found to be an effective tool when co-developing interventions with young people, however online PPIE groups have previously only used digital creative techniques (Bray et al., 2022; Bowen et al., 2013; Kirtland et al., 2019; Langley et al., 2020; Walker et al., 2009; Wolstenholme et al., 2019). There were however unresolved barriers in PPIE group members sending images of their creative outputs to myself, which hindered the visual reporting of some creations within this thesis; future research should look to employ more engaging ways of obtaining such information from young people. However, this research's successful use of digital and non-digital arts-based methods within an online PPIE group, makes a novel contribution to the current literature, expanding researchers understanding of the potential to conduct art-based research within an online setting.

7.6. Covid context

The Covid-19 pandemic resulted in unexpected recruitment delays which significantly impacted the research's timeline. First, during the start of the pandemic, the research's partner NHS site paused the research project until Autumn 2020, which significantly hindered the research discussed in Chapter three. Second, recruiting families to participate in this body of research was challenging as families were already managing the increased burden of changes to work and school routines due to the Covid-19 pandemic. Furthermore, recruiting healthcare professionals was extremely difficult due to their current stressors of adapting to working within Covid-19 restrictions. Subsequently the recruitment of participants for the research detailed in Chapter three took fifteen months to reach target participation numbers.

Covid-19 also had a direct effect on the participants eligible to take part in this programme of research. Due to the inability to conduct in-person research, all participant involvement was facilitated online or over the telephone, this meant those who did not have access to these means could not be reached within the current research. Additionally, recruiting participants through social media posts, left the research susceptible to inauthentic participants, as discussed in Chapter six. Due to the current economic climate, special consideration should be placed on recruitment adverts detailing the use of a financial token of thanks for participants' time.

7.7. Reflections and personal development

While I have thoroughly enjoyed my PhD experience, it is hard to reflect on the past few years without discussing the adversity this research project and I, personally, have faced.

As detailed, delays in recruitment and ethical review have been significant and had a vast impact on the research timelines. At times an inability to progress my research felt deflating. However, overcoming such barriers left me feeling grateful for the ability to facilitate each piece of research and encouraged me to not take such opportunities for granted.

Furthermore, I have experienced multiple changes to my supervisory team, with supervisors leaving the university and the untimely passing of Prof Helen Pattison. I had previously worked alongside Prof Pattison prior to my PhD and was able to gain much benefit from her wealth of expertise. The news of her sudden retirement due to ill health and subsequent death, was extremely sad and required the appointment of a new supervisor. While efforts were made to reduce the impact on my research, this was still a stressful period as I navigated my own emotions while dealing with uncertainty in my supervisory team.

Throughout my PhD, I have also experienced multiple adverse events within my personal life which likely impacted data collection and analysis, including being diagnosed with a long-term health condition in the Spring of 2021. I therefore found myself managing my own personal feelings of difference and health uncertainty alongside those of my participants. While I acknowledge my health needs are significantly different to those of my participants, I feel I was able to gain a unique understanding of the complexities of dealing with personal adversity and adapting to change, as well as dealing with a range of healthcare teams and undergoing many medical tests in order to obtain a diagnosis. Akin to the experiences discussed by participants, I too found myself anxious about the future, and wondering how I would be able to live my “normal” life.

However, facing such adversity has allowed my further development as a researcher. As a self-proclaimed perfectionist, at the start of this project, I was hesitant to ask for help or support, as I did not want my supervisors to view me as incompetent. However, as time progressed, I understood the value of asking for guidance, and how this can help researchers expand their knowledge base and develop personal growth when faced with challenges.

Within this research, it has also been important for myself to note how my personal experiences of ill health during childhood are likely to have influenced my data collection and analysis. As young people discussed their experiences of living with health limitations, I felt I could relate to their experiences of managing debilitating symptoms and feeling different to peers. At times I was often surprised at how similar my experiences were to my participants, despite there being key differences in mine and my participants’ diagnosis and required adherence behaviours. The most resounding similarity was the challenges of living with an invisible illness, and the misconception that looking well does not equate to good health.

Within each stage of this research, I have found myself drifting in and out of my personal reflections of living with ill health and the experiences of my participants (Finlay, 2006). Often the familiarity of participants' experiences invoked feelings of empathy towards families. Furthermore, the sensitive information shared by young people and parents about their experiences of social exclusion and IBD stigmatisation were often challenging to hear. As I could understand young people's emotional turmoil over living with a health condition, it was hard to hear how my participants experienced further cruelty from other people. I was therefore conscious of the empathetic tone of my analysis of young people's adherence barriers. Conversations within my supervisory team and notes in my reflective journal assisted me to work with my own experiences and emotions to explore the deeper mechanisms driving young people's treatment beliefs and adherence behaviours.

Despite the similarities in health experiences, young people's experiences of adolescence were significantly different to my own. This was mainly due to their internet exposure and their online behaviours. As someone who personally has limited social media engagement, my participants' experience of discussing their health in online social media groups felt concerning at times, especially as the advice given within such unregulated groups were seen as highly trustworthy. Equally, young people's understanding of emotional wellbeing encouraged online help seeking behaviours, such as identifying relevant podcasts to promote mindfulness. Prior to this research project, I had viewed listening to podcasts as an enjoyable activity whilst commuting to work, and it had not crossed my mind that young people would be engaging in podcasts in a similar manner to help further their knowledge and improve their wellbeing. This research has therefore emphasised the importance of PPIE research to me, and spending the time to truly explore the experiences and needs of those who applied research aims to support.

Throughout this body of work, I have been able to utilise analytical methods I had not yet experienced within my research career, as well as pursue my passion for applied behaviour change research and the implementation of arts-based methodologies. This challenged me to develop new skills within my time as a PhD researcher, for example conducting a framework analysis, which will be beneficial for my future career. Furthermore, within this PhD research, I have had the chance to understand and develop my philosophical viewpoints, which has subsequently provided a greater context to my analytical interpretations. Additionally, the research conducted in Chapter five, allowed me to develop the skills required to use arts-based methodologies, including online digital tools and model building with Lego and Playdoh. I have also expanded my ability to communicate research outcomes to a wide variety of audiences including families, academic colleagues, healthcare professionals, IBD charities, and conference audiences. Furthermore, I have gained a deeper understanding of the value of public engagement with research, and the importance of selecting appropriate language to allow research projects to be understood by different audiences. For example, it was essential the content of the PPIE workshops disseminated information about psychological constructs and BCTs in plain English. This was initially difficult, as the familiar language used within academic settings was inappropriate for the workshops, and I found myself questioning the possibility of communicating such concepts in an age-appropriate manner. However, as the workshops progressed, my ability to alter my use of language became easier and the results were rewarding, as I observed the group's enthusiasm to learn about behavioural science.

One of my biggest personal developments as a researcher is my new found confidence with conducting online research. While I understand the benefits of conducting interviews online, and have done so in previous research projects, I have always felt more comfortable meeting with participants face-to-face. Due to Covid-19 restrictions, the requirement to conduct research online aided myself to become more familiar with the process and find ways to develop an effective rapport with participants both before and within the interviews, as discussed previously. I also found myself becoming more relaxed when faced with technological issues that may occur when conducting online research, such as participants struggling to connect to the online meeting platform; rather than allowing such situations to provoke anxiety over the potential impact this could have on the interview.

7.8. Recommendations for future research

The research discussed across this thesis contains many recommendations for future research to expand on the key findings from Chapters two to six.

Testing the feasibility and effectiveness of ASSIST-IBD.

Future research is needed to expand on the current project outcomes by conducting additional PPIE workshops with young people with IBD and parents of young people with IBD, to co-develop the ASSIST-IBD prototype materials onto digital platforms such as a website and WebApp. Once the interventional materials have been translated, a feasibility study of ASSIST-IBD will be needed. This will lay the foundation for a definitive randomised control trial to assess the effectiveness of ASSIST-IBD.

Defining adherence behaviours

The lived experiences of young people with IBD and their families highlighted a need for future research to include behaviours beyond medication-taking when exploring young people's treatment adherence. Furthermore, viewing adherence behaviours through the lens of critical realism will allow for the further exploration of causal mechanisms which influence young people's treatment adherence behaviours.

Developing effective interventions to reduce IBD stigmatisation

Stigmatisation was a prominent causal mechanism of treatment non-adherent behaviours. Additional research is needed to further understand IBD social stigmatisation and identify relevant interventions to reduce such stigmatisation, specifically within school settings.

Utilising targeted recruitment processes

The general lack of diversity amongst participants across this research is likely to have influenced the projects' findings. Future research should look to address this issue by using a more targeted recruitment process, to ensure a diverse representation of IBD characteristics and participant demographic factors are included within paediatric IBD research projects.

Understanding parental support needs

Within Chapters three and six, parents self-identified a need for practical, emotional, and social support at significant moments of change, such as at diagnosis or during a child's transition to adult healthcare services. It is acknowledged that ASSIST-IBD is currently unable to meet these parental support needs. Additional research should therefore explore parents' support needs in greater detail and aim to develop relevant interventions to improve parents' quality of life. As parents are instrumental to children and adolescent's treatment adherence, such interventions are likely to positively impact on young people's treatment adherence behaviours.

Including young people

When conducting PPIE research with young people, researchers may assume taking a consultation approach is more appropriate; however, as detailed in Chapter five, great benefits were obtained from including young people as collaborators. Young people were invested in the intervention design process, and were curious to learn more about behavioural science; this is suggestive of the potential to collaborate with young people within earlier stages of an intervention's development, such as when completing a behavioural analysis within the BCW approach (Michie et al., 2011). Therefore, researchers should not underestimate young people's abilities to understand complex theories of behaviour change and provide PPIE groups with autonomy over an intervention's development.

Clear reporting of future behaviour change interventions

Previously reported interventions lack relevant information about the intervention's design and content (as discussed in Chapter two). The current body of research has transparently detailed the rationale, design, content, and refinement of a novel treatment adherence intervention for young people with IBD. Future research should also employ a similar systematic approach when developing new interventions, and provide clarity of this process within published intervention protocols or research articles.

7.9. Recommendations for practice

Once feasibility and effectiveness of ASSIST-IBD have been established, the intervention is likely to have multiple clinical benefits for young people. These might include improvements in IBD symptoms, reduced need for escalation in therapy, reduced unplanned hospital admissions and surgical procedures, and a reduction in healthcare costs. Within the ages of 13-18 years, young people are required to develop greater autonomy within their health self-management and become responsible for their adherence behaviours. This research has identified several barriers to the development of these behaviours, which could have significant clinical consequences and hinder young people's transition to adult healthcare. Understanding the causal mechanisms of a patient's treatment adherence within consultations may assist patients to generate their own adherence solutions with the support of their healthcare professional. Previously developed tools such as Ready Steady Go (Transition & Patient Empowerment, Innovation, Education and Research Collaboration Network, 2022), can support clinicians to gain a deeper understanding of young people's adherence needs during the transition process.

The current research identified families' and healthcare professionals' experiences of positive adherence outcomes when young people are engaged in shared decision-making. While this is part of the NHS ethos and vision (The NHS Constitution for England, 2021), practitioners may wish to explore new methods of increasing young people's engagement within the shared decision-making process, in order to ensure young people's treatment plans are accommodating of their adherence support needs.

The intervention's content targets relevant self-management behaviours, as well as self-efficacy, resilience, and optimism, which will potentially lead to lasting benefits throughout adulthood. The online nature of ASSIST-IBD means such beneficial support can be offered in a sustainable, cost-effective manner, as young people can independently engage with the intervention materials at their own pace outside of medical appointments. ASSIST-IBD also supports young people to develop their health communication skills, enabling them to communicate their health needs with others, resulting in greater health benefits for young people with IBD. It is further plausible that support offered in ASSIST-IBD could be translated to other paediatric health conditions, such as diabetes and asthma, suggesting ASSIST-IBD could become the foundation of further adherence interventions for young people with other chronic conditions.

Within this research, families detailed UK-wide delays in accessing relevant support for their child. This resulted in young people often being referred to gastroenterological services at a point of health crisis. Therefore, further research may support the identification of new methods to streamline the care pathways of young people who present with gastroenterology symptoms within primary care.

Families shared the complicated nature of identifying relevant support for young people with IBD (Chapters three, five and six). In order to minimise the distress experienced by young people and parents, relevant IBD health services and charities could further look to restructure how they provide support to families, to ensure such resources are easily identifiable and relevant for family's needs. Doing so may reduce families' anxiety and improve families' quality of life.

7.10. Conclusions

The use of qualitative and arts-based research methodologies has created a deeper exploration of the challenges young people face to adhere to their IBD treatment plan. Young people were often confronted with the conflicting need to avoid feelings of difference, whilst wanting to autonomously perform treatment plan adherence. This research is indicative of the essential need to not only identify the causal mechanisms of young people's adherence behaviours, but to expand the inclusivity of definitions of treatment adherence behaviours to comprise of behaviours beyond medication taking. Through gaining a greater understanding of the experiences and treatment adherence needs of young people with IBD, this research has developed ASSIST-IBD; a novel, user-centred evidence-based, theory-driven behavioural intervention for young people with IBD. The intervention's design was guided through the systematic process of the BCW (Michie et al., 2011). A PPIE group of young people with IBD co-developed the interventions content through interactive online workshops. Not only were the outcomes of such workshops inspiring and not conceptualised within the prior intervention development research, but the variety of arts-based methods used to support the generation of these outcomes were novel in their method of delivery. Young people within the PPIE group and parents of young people with IBD, assessed the intervention prototype to be both acceptable and relevant for young people with IBD.

ASSIST-IBD aims to empower young people to take responsibility for their health and make user-centred plans to improve their adherence behaviours based on their self-assessed needs. Overall, the intervention aims to improve young people's treatment plan self-efficacy, enhance resilience behaviours to overcome adherence barriers, foster optimism about the future, and develop appropriate health communication skills. ASSIST-IBD is the first treatment adherence intervention to be inclusive of a variety of treatment plan behaviours and therefore makes a novel contribution to the current literature. Furthermore, the transparent use of behaviour change theory and BCTs provides a clear rationale for the intervention's potential to improve young people's treatment adherence behaviours. Additional research should be conducted to assess the feasibility and effectiveness of ASSIST-IBD to improve young people with IBD's treatment plan adherence behaviours.

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Appendix

Appendix.1. Full list of search terms used

(child* OR “young person” OR adolescent* OR teenager* OR parent* OR family OR paediatric OR mother OR father) AND (intervention OR “behaviour* change” OR RCT OR “randomised control trial”) AND (“inflammatory bowel disease” OR IBD OR “Crohn’s Disease” OR “Ulcerative Colitis”) AND (“treatment adherence” OR “medication adherence” OR “non-adherence” OR “medication compliance” OR diet OR exercise OR “lifestyle change*”)

Appendix.2. Systematic review data extraction form

Overview of the paper

Date of data extraction:	Name of reviewer:	
Paper title:		
First Author:	Year/volume/pages:	
Comments (incl links to other studies/papers):		
Aim of intervention (Aim to change which behaviour/s)		
Study design		
Participant group – Recruitment	**General**	

	Inclusion	
	Exclusion	
Country:		
Feasibility trial? Yes No Pilot study? Yes No		

Intervention details

Where is the intervention described?	
1. All in this paper	
2. All described elsewhere	
3. Additional information described elsewhere	
4. Based on another study, described elsewhere	
(If 2, 3 or 4 please state reference for the paper referred to	
Intervention Characteristics	Please tick
Primary outcome of intervention:	
1. Medication Adherence	
2. Appointment attendance	
3. Physical Activity	
4. Diet	
5. Other, specify	
Setting:	
0. Hospital / Clinic	
1. GP Surgery	
2. Community Centre	
3. By post	
4. By telephone	
5. Participants home	
6. Online/email	
7. Other (Please specify)	
8. Not stated	

Delivered by:	
0. Researcher	
1. Student	
2. Nurse	
3. Physiotherapists	
4. GP	
5. Consultant	
6. Psychologist	
7. Other (Please specify)	
8. Not stated	
Delivery mode:	
Intervention type :	
0. Group intervention	
1. Individual intervention	
2. Family intervention	

Study definition of adherent behaviours	

Intervention group 1

Definition and description (e.g. treatment group):

Definition	
Were specific conditions required to enter intervention	
Brief description of required participation	

Intervention group 2 (where applicable)

Definition and description (e.g. treatment group):

Definition	
Were specific conditions required to enter intervention	
Brief description of required participation	

Control Group

Definition and description (e.g. treatment group):

Definition	
Were specific conditions required to enter intervention	
Brief description of required participation	

Intervention at a glance

Behaviour target for intervention (type/frequency):	
Duration of intervention:	
Number of intervention contact sessions:	

Adherence measure (e.g. taking medication	
Measurement tool	
Type of measure (circle) Subjective Objective	
Time point of main analysis (i.e. time between baseline measure and post-intervention measure)	

Outline of the Intervention – Group 1 (Number of contact sessions, assessment time points)

Time point	Contact / Activity

Outline of the Intervention – Group 2 (Number of contact sessions, assessment time points)

Time point	Contact / Activity

Outline of the Intervention -Control group (Number of contact sessions, assessment time points)

Time point	Contact / Activity

Other outcomes reported	Tick	Summary
Psychological variables (Anxiety/depression)		
Weight/height		
Coping skills		
Health related quality of life		
Disease severity		
Other		
Fidelity - Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them		
Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned		

Participants

Participants	Intervention group 1	Intervention group 2	Control group	Overall
No. of participants				
Mean age (SD)				
Gender split (M/F)				
Type of IBD health condition				
Disease Severity				
Type of IBD medication				
Ethnicity:				
Education status				

Any involvement with parents/carers?

Parent participants	Intervention group 1	Intervention group 2	Control group	Overall
No. of participants				
Mean age (SD				
Gender split (M/F)				
Ethnicity:				
Relationship status				
Household income Median				

ADHERENCE BEHAVIOUR DATA

Data analysed:				**Adherence measures**			
Reliability of measure:							
Statistical techniques used:							
Time point 1:					**Between group differences**		
Behaviour			WHOLE sample only? %	Control (Mean and SD)	Effect size	P-Value	Test statistic
Pill count							
Electronic monitoring							
Parent report							
Young person report							
	Time point 2:						
Behaviour		Whole sample only %	Group 2 (Mean and SD)	Control (Mean and SD)	Effect size	P-Value	Test statistic

Pill count							
Electronic monitoring							
Parent report							
Young person report							
	Time point 3:						
Behaviour		Group 1 (Mean and SD)	Group 2 (Mean and SD)	Control (Mean and SD)	Effect size	P-Value	Test statistic
	Time point 4:						
Behaviour		Control Group (Mean and SD)	Group 1 (Mean and SD)	Group 2 (Mean and SD)	Effect size	P-Value	Test statistic
Effect size							

Over time change	P-Value		*all non significant		
	Test statistic				

Other results

Repeated measures ANOVA to examine treatment effects on each adherence measures

Measure		Treatment % change from baseline-post	Usual care % change from baseline-post	P
Pill count				
Pill count				
Electronic monitoring				
Parent report				
Parent report				
Young person report				
Young person report				

Behavioural Change Techniques

Behavioural Change Techniques used	Control	Intervention Group 1	Intervention Group 2
Section1. Goals and planning			
1.1 Goal-setting (behaviour)			
1.2. Problem-solving			
1.3 Goal-setting (outcome)			
1.4 Action planning			
1.5 Review behaviour goal(s)			
1.6 Discrepancy between current behaviour and goal			
1.7 Review outcome goal(s)			
1.8 Behavioural contract			
1.9 Commitment			
Section 2. Feedback and monitoring			
2.1 Monitoring of behaviour by others without feedback			
2.2 Feedback on behaviour			
2.3 Self-monitoring of behaviour			
2.4 Self-monitoring of outcome(s) of behaviour			
2.5 Monitoring of outcome(s) of behaviour without feedback			
2.6 Biofeedback			
2.7 Feedback on outcome(s) of behaviour			
Section 3. Social support			
3.1 Social support (unspecified)			

3.2 Social support (practical)			
3.3 Social support (emotional)			
Section 4. Shaping knowledge			
4.1 Instruction on how to perform the behaviour			
4.2 Information about the antecedents			
4.3 Re-attribution			
4.4 Behavioural experiments			
Section 5. Natural consequences			
5.1 Information about health consequences			
5.2 Salience of consequences			
5.3 Information about social and environmental consequences			
5.4 Monitoring of emotional consequences			
5.5 Anticipated regret			
5.6 Information about emotional consequences			
Section 6. Comparison of behaviour			
6.1 Demonstration of the behaviour			
6.2 Social comparison			
6.3 Information about others' approval			
Section 7. Associations			
7.1 Prompts/cues			
7.2 Cue signalling reward			
7.3 Reduce prompts/cues			
7.4 Remove access to the reward			
7.5 Remove aversive stimulus			
7.6 Satisfaction			
7.7 Exposure			
7.8 Associative learning			

Section 8. Repetition and substitution			
8.1 Behavioural practice/rehearsal			
8.2 Behavioural substitution			
8.3 Habit formation			
8.4 Habit reversal			
8.5 Over-correction			
8.6 Generalisation of target behaviour			
8.7 Graded tasks			
Section 9. Comparison of outcomes			
9.1 Credible source			
9.2 Pros and cons			
9.3 Comparative imagining of future outcomes			
Section 10. Reward and threat			
10.1 Material incentive (Behaviour)			
10.2 Material reward (Behaviour)			
10.3 Non-specific reward			
10.4 Social reward			
10.5 Social incentive			
10.6 Non-specific incentive			
10.7 Self-incentive			
10.8 Incentive (outcome)			
10.9 Self-reward			
10.10 Reward (outcome)			
10.11 Future Punishment			
Section 11. Regulation			
11.1 Pharmacological support			
11.2 Reduce negative emotions			

11.3 Conserving mental resources			
11.4 Paradoxical instructions			
Section 12. Antecedents			
12.1 Restructuring the physical environment			
12.2 Restructuring the social environment			
12.3 Avoidance / reducing exposure to cues for the behaviour			
12.4 Distraction			
12.5 Adding objects to the environment			
12.6 Body changes			
Section 13. Identity			
13.1 Identification of self as role model			
13.2 Framing/reframing			
13.3 Incompatible beliefs			
13.4 Valued self-identity			
13.5 Identity associated with changed behaviour			
Section 14. Scheduled consequences			
14.1 Behaviour cost			
14.2 Punishment			
14.3 Remove reward			
14.4 Reward approximation			
14.5 Rewarding completion			
14.6 Situation-specific reward			
14.7 Reward incompatible behaviour			
14.8 Reward alternative behaviour			
14.9 Reduce reward frequency			
14.10 Remove punishment			
Section 15. Self-belief			

15.1 Verbal persuasion about capability			
15.2 Mental rehearsal of successful performance			
15.3 Focus on past success			
15.4 Self-talk			
Section 16. Convert learning			
16.1 Imaginary punishment			
16.2 Imaginary reward			
16.3 Vicarious consequences			

Behavioural Change theory

#	Item	Description	Yes No Don't know	List with location	
1	*Theory/model of behaviour mentioned*	Models/theories that specify relations among variables, in order to *explain* or *predict* behaviour (e.g., TPB, SCT, HBM) are mentioned, even if the intervention is not based on this theory			
5	*Theory/ predictors used to select/develop intervention techniques*	The intervention is explicitly based on a theory or predictor or combination of theories or predictors		**Theory**	**Predictor**
7	*All intervention techniques are explicitly linked to at least one theory-relevant construct/ predictor*	Each intervention technique is explicitly linked to at least one theory-relevant construct/predictor.[1]		**Construct (list links)**	**Predictor (list links)**

8	*<u>At least one</u>, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/ predictor*	At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/ predictor.[2]		**Construct (list links)**	**Predictor (list links)**
9	*Group of techniques are linked to a group of constructs/ predictors*	A cluster of techniques is linked to a cluster of constructs/ predictors.[3]		**List clusters of techniques/constructs**	**List clusters of techniques/predictors**
10	*All theory-relevant constructs/predictors are explicitly linked to at least one intervention technique*	Every theoretical construct within a stated theory, or every stated predictor (item 5), is linked to at least one intervention technique.[4]		**Construct (list links)**	**Predictor (list links)**
11	*At least one, but not all, of the theory relevant constructs/predictors are explicitly linked to at least one intervention technique*	At least one, but not all, of the theoretical constructs within a stated theory or at least one, but not all, of the stated predictors (item 5) are linked to at least one intervention technique.[5]		**Construct (list links)**	**Predictor (list links)**
12	*Theory-relevant constructs/ predictors are measured*	a) At least one construct of theory (or predictor) mentioned in relation to the intervention is measured POST-INTERVENTION. b) At least one construct of theory (or predictor) mentioned in relation to the intervention is		**Construct**	**Predictor**
13	*Quality of Measures*	All of the measures of theory relevant constructs/predictors		**Construct**	**Predictor**

		had some evidence for their reliability b) At least one, but not all, of the measures of theory relevant constructs/predictors had some evidence for their reliability c) All of the measures of theory relevant constructs/predictors have been previously validated d) At least one, but not all, of the measures of theory relevant constructs/predictors have been previously validated e) The behaviour measure had some evidence for its reliability f) The behaviour measure has been previously validated			
14	*Randomizaton of participants to condition*	a) Do the authors claim randomization? b) Is a method of random allocation to condition described (e.g., random number generator; coin toss) c) Was the success of randomization tested? d) Was the randomization successful (or baseline differences between intervention and control group statistically controlled)?			
15	*Changes in measured theory-relevant constructs/predictor*	The intervention leads to sig. change in at least one theory-relevant construct/predictor (vs control group) in favour of the intervention.		**Construct**	**Predictor**

16	*Mediational analysis of construct/s / predictors*	In addition to 14, do the following effects emerge?: a) Mediator predicts DV? (or change in mediator leads to change in DV) b) Mediator predicts DV (when controlling for IV)? c) Intervention does not predict DV (when controlling for mediator)? d) Mediated effect statistically significant?		**Construct**	**Predictor**
17	*Results discussed in relation to theory*	Results are discussed in terms of the theoretical basis of the intervention			
18	*Appropriate support for theory*	Support for the theory is based on appropriate mediation OR refutation of the theory is based on obtaining appropriate null effects (i.e. changing behaviour without changing the theory-relevant constructs).			
19	*Results used to refine theory*	The authors attempt to refine the theory upon which the intervention was based by either: a) adding or removing constructs to the theory, or b) specifying that the interrelationships between the theoretical constructs should be changed and spelling out which relationships should be changed		a) Constructs added or removed from theory:	b) Interrelationships between the theoretical constructs to be changed:

Appendix.3. Study information pack for young people aged 13-15 years recruited though a Specialist Children's hospital

Aston University

Illustration removed for copyright restrictions

CROHN'S & COLITIS UK

Supporting young people to live well with Inflammatory Bowel Disease

Dear Parent/Caregiver,

Researchers at [redacted] and Aston University are conducting research about what it is like for young people (aged 13-18) to live with Inflammatory Bowel Disease (IBD).

They would like to find out what makes it easy or difficult for young people to manage their IBD as well as ideas on how best to support young people to live well with IBD.

As a parent of a young person (aged 13-15) who has been diagnosed with IBD, I am writing to yourself to invite your child to take part in this project.

I enclose an information sheet with more details. Please note that none of your personal details have been passed to the research team or shared with Aston University and your participation in this study is voluntary.

If your child is interested in taking part, or would like more information about the study, please contact one of the research team directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,

Ms Cassie Screti, Dr Lou Atkinson, Dr Gemma Heath, and Dr Rachel Shaw

Supporting young people to live well with Inflammatory Bowel Disease

Participant Information Sheet- Parent of a young person (aged 13-15)

Invitation

We would like to invite your child to take part in a research study, exploring how young people experience living with inflammatory bowel disease (IBD) and having to manage their condition. This study is being carried out by researchers from Aston University and the Gastroenterology department at [redacted] as part of Miss Cassie Screti's PhD thesis, and is part funded by Crohn's and Colitis UK.

Before you decide if you are happy for your child to participate in this study, please take time to read the following information and, if you wish, discuss it with others such as your family or friends.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

What is the purpose of the study?

We would like to find out about why young people may struggle to adhere to their treatment routine for their IBD. We would like to learn more about:

- Your child's views and experiences of living with IBD
- The challenges young people face, particularly with medication of lifestyle changes.
- Your child's thoughts on how other young people can be supported to follow their treatment routine

This information will help to inform the development of a new intervention to improve treatment adherence in young people (aged 13-18) with IBD.

Why has my child been invited?

Your child has been invited to take part in this study because your child is a young person (aged 13-18) who has been diagnosed with IBD and are under the care of the Gastroenterology clinic at [redacted] or because you or your child has contacted the research team about taking part in this study.

What will happen to my child if they take part?

A researcher will talk your child through the study and answer their questions. If you and your child are happy for your child to join the study, the researcher will ask you to fill out a Consent form and your child to complete an assent form.

Your child can then choose if they would prefer to participate in a focus group with other young people with IBD, or be interviewed by a researcher. During the focus group/interview, with your permission, a researcher will audio record this conversation. The conversation is recorded so that the researcher can listen back to everything your child has said and type it up. Your child's name will be removed after the focus group/interview is typed so no one will know it was your child.

The researcher will talk to your child about their experiences of living with IBD and managing their condition. Your child will be asked how other young people could be supported to ensure they are managing with condition correctly.

Focus Group

- The focus group last around 90 minutes, depending on how much the group has to say.
- The focus group will be held at [redacted] or Aston University

Individual interview

- The interview will last around 60 minutes, depending on how much your child has to say.
- Interviews will be held at [redacted] Aston University or a location of your child's choosing. Interviews can also be conducted over the phone or via skype.

How will the conversation during the interview be recorded and the information my child provides be managed?

With your permission we will audio record the focus group/interview and take notes. The recording will be typed into a document (transcribed) by a transcriber approved by Aston University. This process will involve removing any information which could be used to identify individuals e.g. names, locations etc.

The audio recording from your child's interview or focus group will be transcribed within 24 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your child's data cannot be withdrawn.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything your child has told us that is included in the reporting of the study will be anonymous.

Your child is free not to answer any questions that are asked, without giving a reason.

Does my child have to take part?

No. It is up to you and your child to decide whether or not your child wishes to take part.

If your child does decide to participate, your child will be asked to sign and date a consent form. Your child will still be free to withdraw from the study at any time without giving a reason.

Will my child's taking part in this study be kept confidential?

Yes. A code will be attached to all the data your child provides to maintain confidentiality.

Your child's personal data (name and contact details) will only be used if the researchers need to contact your child to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

What are the possible benefits of taking part?

While there are no direct benefits to your child of taking part in this study, the data gained will inform the design of a new behaviour change intervention, aiming to improve young people's treatment adherence.

What are the possible risks and burdens of taking part?

If you and your child decide to take part in this research, you may experience a small burden due to the time taken out of your day to travel to and from your child's interview or focus group location. This may also require you to travel to [redacted] in addition to your child's scheduled appointments. Efforts will be made to lessen this burden by arranging a convenient time and place for your child's interview to be held.

We do not expect there to be any risks to your child in taking part in this study. However, in the unlikely event that your child becomes upset during the research, the focus group/interview will be terminated and the research team will be able to guide your child towards sources of support.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your child's identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in Miss Cassie Screti's PhD Thesis.

Expenses and payments

A small token of thanks, in the form of a £20 shopping voucher, will be given to each participant who takes part in this research.

Who is funding the research?

The study is being funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

What if I have a concern about my child's participation in the study?

If you have any concerns about your child's participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 4869.

Further information

To speak to an independent advisor, you can contact: [redacted]

Research Team

Researcher:

Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath@wlv.ac.uk	Tel: 0190 232 2362
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details.

- Yours and your child's name
- A brief history of your child's medical condition
- Your contact details, such as an email address or telephone number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 0121 204 3000

Supporting young people to live well with Inflammatory Bowel Disease

Participant Information Sheet- Young person (aged 13-15)

We would like to ask for your help with our research project.

We would like to talk to you about what it is like to live with Inflammatory Bowel Disease (IBD), including Crohn's Disease and Ulcerative Colitis, and what makes it easy or difficult to manage your condition.

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information and discuss it with friends, family or us if you wish.

This research is being carried out by researchers from Aston University with the Doctor from the Gastroenterology clinic at [redacted] If you would like more information please contact Cassie or Lou who are leading the project. Their emails and phone numbers can be found at the end of this information sheet.

What is this project about?

We would like to find out about what makes it easy or difficult to live with IBD. We would like to learn more about:

- How do you feel about having IBD?
- What challenges you might face, particularly with medication or lifestyle changes?
- How you think other young people can be supported to follow their treatment routine

Why have I been invited?

You have been invited to take part in this study because you are a young person who has been diagnosed with IBD and under the care of the Gastroenterology clinic at [redacted] or because you contacted the research team as you are a young person with IBD, who is interested in taking part in this study.

Do I have to take part?

No, it is your choice. If you decide to take part, you are free to change your mind without giving a reason and free to skip difficult questions. If you decide to stop taking part, just let the researchers know and they will stop the meeting. Nothing will happen to you if you decide not to participate. The care you receive from [redacted] will not be affected if you decide not to take part.

What will happen to me if I take part?

A researcher will talk you through the study and answer your questions. If you are happy to join the study, the researcher will ask you to sign a form to say you are happy to take part. Then we will need to ask a parent or carer to give us permission to let you take part in the study by filling out a consent form.

During the interview, with your permission, Cassie will audio record your conversation. The conversation is recorded so that Cassie can listen back to everything you have said and type it up. Your name will be removed after the interview is typed so no one will know it was you.

Cassie will talk to you about your experiences of living with IBD and managing your condition. You will be asked how other young people could be supported to ensure they are managing their condition correctly.

<u>Individual interview</u>

- The interview will last around 60 minutes, depending on how much you have to say.
- Interviews will be held at [redacted] Aston University or a location of your choosing. Interviews can also be conducted over the phone or via skype.

What are the possible risks or benefits of taking part?

If you decide to take part in this research, you may experience a small burden due to the time taken out of your day to travel to and from the interview or focus group location. This may also require you to travel to [redacted] in addition to your scheduled appointments. Efforts will be made to lessen this burden by arranging a convenient time and place for your interview to be held.

We do not expect there to be any risks to you in taking part in this study. In the unlikely event that you become upset during the focus group/interview, Cassie will stop the interview and audio recording and support you. A contact number for support will be offered. Some people like taking part as the findings could help other young people and families going through a similar experience.

Will other people know that I have taken part in the project?

No. Only the research team will know that you have taken part. Your name and other personal information will be removed from the typed-up interview so no one will know that it is you. The only time when we would need to tell someone else is if you tell us something that suggests a risk of harm to yourself or others. The research team will ensure that all information is kept securely and confidentially at Aston University. Only the research team will be able to access the interviews.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

We will send you a summary of the findings of the research in words you can understand.

The results of the study will also be used in Cassie's PhD Project.

Expenses and payments

A small token of thanks, in the form of a £20 shopping voucher, will be given to you if you if you take part.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

Who is organising the research?

The research is organised by Aston University in collaboration with Crohn's and Colitis UK.

Who can I contact if I have any questions or worries?

If you have any concerns about anything to do with this study, please speak to the research team and we will do our best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 4869.

Further information

To speak to an independent advisor, you can contact: [redacted]

What do I do now?

If you would like to take part in the research, or would like further information, please contact Cassie, or you can ask your parent to contact Cassie, whose details can be found below.

Research Team

Researcher:

Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath@wlv.ac.uk	Tel: 0190 232 2362
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank You.
We look forward to hearing from you.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details.

- Your name, we will ensure the pseudonym given to you is different to that of your own.
- A brief history of your medical condition
- Your parents contact details, such as an email address or telephone number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 0121 204 3000

Appendix.4. Study information pack for young people aged 16-18 years recruited though a Specialist Children's hospital

Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease

Dear ,

Researchers at [redacted] and Aston University are conducting research about what it is like for young people (aged 13-18) to live with Inflammatory Bowel Disease (IBD).

They would like to find out what makes it easy or difficult for young people to manage their IBD as well as ideas on how best to support young people to live well with IBD.

As a young person (aged 16-18) who has been diagnosed with IBD, I am writing to yourself to invite your child to take part in this project.

I enclose an information sheet with more details. Please note that none of your personal details have been passed to the research team or shared with Aston University and your participation in this study is voluntary.

If your child is interested in taking part, or would like more information about the study, please contact one of the research team directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,

Ms Cassie Screti, Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw and Dr Rafeeq Muhammed

Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease

Participant Information Sheet- Young people (16-18 years)

Invitation

We would like to talk to you about what it is like to live with Inflammatory Bowel Disease (IBD) and what makes it easy or difficult to manage your condition.

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information and discuss it with friends, family or us if you wish.

This research is being carried out by researchers from Aston University with the Doctors from the Gastroenterology clinic at [redacted] as part of Miss Cassie Screti's PhD thesis, and is part funded by Crohn's and Colitis UK. If you would like more information please contact Cassie or Lou who are leading the project. Their emails and phone numbers can be found at the end of this information sheet.

What is the purpose of the study?

We would like to understand what makes it easy or difficult to live with IBD. We would like to learn more about:

- How do you feel about having IBD?
- What challenges you might face, particularly with medication or lifestyle changes?
- How you think other young people can be supported to follow their treatment routine

This information will help to inform the development of a new intervention to improve treatment adherence in young people (aged 13-18) with IBD.

Why have I been invited?

You have been invited to take part in this study because you are a young person who has been diagnosed with IBD and under the care of the Gastroenterology clinic at [redacted] or because you contacted the research team as you are a young person with IBD, who is interested in taking part in this study.

What will happen to me if I take part?

A researcher will talk you through the study and answer your questions. If you are happy to join the study, the researcher will ask you to fill out a Consent form.

You will then be able to choose if you would like to take part in an interview with Cassie. During the interview, with your permission, Cassie will audio record your conversation. The conversation is recorded so that the researcher can listen back to everything you have said and type it up. Your name will be removed after the focus group/interview is typed so no one will know it was you.

The researcher will talk to you about your experiences of living with IBD and managing your condition. You will be asked how other young people could be supported to ensure they are managing their condition correctly.

Individual interview

- The interview will last around 60 minutes, depending on how much you have to say.
- Interviews will be held at [redacted] Aston University or a location of your choosing. Interviews can also be conducted over the phone or via skype.

How will the conversation during the interview be recorded and the information I provide managed?

With your permission we will audio record the focus group/interviews and take notes. The recording will be typed into a document (transcribed) by a transcriber approved by Aston University. This process will involve removing any information which could be used to identify individuals e.g. names, locations etc.

The audio recording from your interview or focus group will be transcribed within 24 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your data cannot be withdrawn.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything you have told us that is included in the reporting of the study will be anonymous.

You are free not to answer any questions that are asked, without giving a reason.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part. Nothing will happen to you if you decide not to participate. The care you receive from [redacted] will not be affected if you decide not to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You will still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform the design of a new behaviour change intervention, aiming to improve young people's treatment adherence.

What are the possible risks and burdens of taking part?

If you decide to take part in this research, you may experience a small burden due to the time taken out of your day to travel to and from your interview or focus group location. This may also require you to travel to [redacted] in addition to your scheduled appointments. Efforts will be made to lessen this burden by arranging a convenient time and place for your interview to be held.

We do not expect there to be any risks to you in taking part in this study. However, in the unlikely event that you become upset during the focus group/interview, Cassie will stop the interview and audio recording and support you. A contact number for support will be offered.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in Miss Cassie Screti's PhD Thesis.

Expenses and payments

A small token of thanks, in the form of a £20 shopping voucher, will be given to each participant who take part in this research.

Who is funding the research?

The study is being funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 4869.

Further information

To speak to an independent advisor, you can contact: [redacted]

Research Team

Researcher:

Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath@wlv.ac.uk	Tel: 0190 232 2362
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details.

- Your name
- A brief history of your medical condition
- Your parents contact details, such as an email address or telephone number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 0121 204 3000

Appendix.5. Study information pack for parents recruited though a Specialist Children’s hospital

Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease

Dear ,

Researchers at Aston University and the Gastroenterology team at [redacted] are conducting research about how young people (aged 13-18) experience living with Intolerable Bowel Disease (IBD) and having to manage their condition.

They would like to find out about your experiences of parenting a young person with IBD, as well as your views on how young people with IBD can be supported to live well.

As the parent of a young person (aged 13-18) with IBD, I am writing to ask if you would be willing to take part in this study. Taking part would involve you talking to a researcher in an individual interview or in a group discussion with other parents of children with IBD.

We are able to hold interviews at your home or at [redacted] and group discussions at [redacted]. It is up to you how much you say, but interviews usually last for around one hour. You will receive a £20 voucher for taking part.

Findings will help us to improve the support offered for young people to help them to take their medications and to live well with IBD.

I enclose an information sheet with more details. Please note that none of your or your child’s personal details have been passed to Aston University. Participation in this study is voluntary and non-participation will not affect your child’s care in any way.

If you are interested in taking part or would like more information about the study, please contact the lead researcher directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,

Aston University

Illustration removed for copyright restrictions

CROHN'S & COLITIS UK

Supporting young people to live well with Inflammatory Bowel Disease

Parent/or Guardian Participant Information Sheet

Invitation

Researchers at Aston University and members of the Gastroenterology team at [redacted] [redacted] are conducting a study about how young people (aged 13-18) experience living with IBD and having to manage their condition. They would like to find out about your experiences of parenting a young person with IBD, as well as your beliefs about the most effective strategies to support treatment adherence.

Before you decide if you would like to participate, please take time to read the following information and, if you wish, discuss it with others such as your friends or family.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

What is the purpose of the study?

The purpose of this study is to understand the challenges of living with IBD for young people and families and what kinds of support would be useful to young people and families to help them live well with IBD. Through gathering detailed information from young people, parents/or guardians and health professionals, we will be able to identify the information and support needs of young people with IBD to help them adhere to their treatment regimes. This information will help to inform the development of a new programme of support to improve the health and well-being of young people with IBD.

Why have I been invited?

You are being invited to take part in this study because you have been identified by the Gastroenterology team at [redacted] as a parent/or guardian of a young person (aged 13-18), who has been diagnosed with IBD, or because you have identified yourself as a parent/or guardian of a young person (aged 13-18), who has been diagnosed with IBD.

What will happen to me if I take part?

If you are happy to join the study, you will be invited to take part in an individual interview with a researcher. It is up to you which you choose. During the focus group/interview, the researcher will talk to you about your experiences of parenting a young person with IBD. The researcher will audio record your conversation so that she can listen back to everything you have said and type it up. Your name will be removed after the interview is typed so no one will know it was you.

Individual interview

- The interview will last around 60 minutes, depending on how much you have to say.
- Interviews can take place at your home (or another quiet location); or at [redacted] or at Aston University. Alternatively, your interview can be conducted over the telephone or via skype.

During the focus group/interview you can choose to skip any questions that you find difficult. At any point during the focus group/interview you can choose to stop and withdraw from the study. After the focus group/interview, demographic information will be collected; this information will be used to explore the range of participants that have taken part.

How will the conversation during the interview be recorded and the information I provide managed?

With your permission we will audio record the focus group/interview and take notes. The recording will be typed into a document (transcribed), by the student researcher. This process will involve removing any information which could be used to identify you e.g. names, locations etc.

The audio recording from your interview or focus group will be transcribed within 24 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your data cannot be withdrawn.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything you have told us that is included in the reporting of the study will be anonymous.

You are free not to answer any questions that are asked, without giving a reason.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You will still be free to withdraw from the study at any time without giving a reason. If you decide not to take part in the study, this will not affect your child’s care.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

Confidentiality may need to be broken in cases where sensitive information is disclosed that could reveal potential harm to yourself or another person, which will be discussed with the research participants and escalated to the researcher's supervisor. Should there be any concerns over the welfare of any child, the interview will be stopped and [redacted] protocol for information sharing will be implemented.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform the design of a new behaviour change intervention, aiming to improve young people's treatment adherence.

What are the possible risks and burdens of taking part?

If you decide to take part in this research, you may experience a small burden due to the time taken out of your day to travel to and from your interview or focus group location. This may also require you to travel to [redacted] in addition to your child's scheduled appointments. Efforts will be made to lessen this burden by arranging a convenient time and place for the interview to be held.

We do not expect there to be any risks to you in taking part in this study. However, in the unlikely event that you become upset during the research, you will have the option to stop the interview/focus group and the research team will support you.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

A summary of the study results will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in Ms Cassie Screti's PhD Thesis.

Expenses and payments

As a thank you for their time, a £20 shopping voucher will be given to each person who takes part in the research.

Who is funding the research?

The study is funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 4869.

Further information

To speak to an independent advisor, you can contact: [redacted] [redacted]

Research Team

Researcher:

Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath@wlv.ac.uk	Tel: 0190 232 2362
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details.

- Your name
- A brief history of your child's medical condition
- Your contact details, such as an email address or telephone number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 0121 204 3000

Appendix.6. Study information pack for healthcare professionals recruited though a Specialist Children's hospital

Supporting young people to live well with Inflammatory Bowel Disease

Dear Health Care Professional,

Researchers at Aston University are conducting a study about how young people (aged 13-18) experience living with IBD and managing their condition. They would like to find out about your experiences of working with young people with IBD, as well as your views on what support young people need to improve their treatment adherence.

As you are a professional who works with young people with IBD, I am writing to ask if you would be willing to take part in this study. The outcomes of the study will be written up as part of Ms Cassie Screti's PhD thesis and may also be published in scientific journals.

I enclose an information sheet with more details. Please note that none of your personal details have been passed to the research team or shared with Aston University and your participation in this study is voluntary.

If you are interested in taking part or would like more information about the study, please contact one of the research team directly:

Researcher: Ms Cassie Screti, Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,

Ms Cassie Screti, Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw and Dr Rafeeq Muhammed

Supporting young people to live well with Inflammatory Bowel Disease

Participant Information Sheet

Invitation

We would like to invite you to take part in a research study, exploring reasons why young people with inflammatory bowel disease (IBD) do not adhere to their prescribed treatment. This study is being carried out by researchers from Aston University as part of Miss Cassie Screti's PhD thesis, and is part funded by Crohn's and Colitis UK.

Before you decide if you would like to participate, please take time to read the following information and, if you wish, discuss it with others such as your family, friends or colleagues.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

What is the purpose of the study?

The purpose of this study is to understand the challenges of living with Inflammatory Bowel Disease (IBD) for young people and families, and what service users would want or need from an intervention to help them address these challenges. Through gathering detailed information from health care professionals, who work with this population, we will be able to identify the information and support needs of young people with IBD to help them adhere to their treatment regimes. This information will help to inform the development of a new intervention to improve treatment adherence in young people (aged 13-18) with IBD.

Why have I been invited?

You are being invited to take part in this study because you have been identified by Dr [redacted] a consultant paediatric gastroenterologist, as a health professional who is employed by [redacted] as working with young people (aged 13-18) with IBD.

What will happen to me if I take part?

You will be invited to an interview with a researcher who will ask you some questions about your experiences of working with young people with IBD. The interview will last approximately 1 hour but may be longer if conversation develops. Interviews can be conducted at your place of work or at another agreed location, whichever is best for you. You can choose to skip any questions that you find difficult. At any point during the interview you can choose to stop and withdraw from the study. After the interview, we will ask you to provide some demographic information. This information will be used to explore the range of participants that have taken part.

How will the conversation during the interview be recorded and the information I provide managed?

With your permission we will audio record the interview and take notes. The recording will be typed into a document (transcribed), by the student researcher. This process will involve removing any information which could be used to identify individuals e.g. names, locations etc.

The audio recording from your interview will be transcribed within 24 hours of the interview being conducted. Once the audio recording has been transcribed and anonymised, your data cannot be withdrawn. Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything you have told us that is included in the reporting of the study will be anonymous.

You are free not to answer any questions that are asked, without giving a reason.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You will still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

Confidentiality may need to be broken in cases where sensitive information is disclosed that could reveal professional misconduct, which will be discussed with the research participants and escalated to the researcher’s supervisor. Should you say something during your interview that causes the research team to have concerns in relation to the welfare of a child you care for, the interview will be stopped and [redacted] protocol for information sharing will be implemented.

As well as your own confidentiality, it is important that you do not disclose the identity of specific patients to the researcher during your interview.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform the design of a new behaviour change intervention, aiming to improve young people's treatment adherence.

What are the possible risks and burdens of taking part?

If you decide to take part in this research, you may experience a small burden due to the interview taking time out of your day. Efforts will be made to lessen this burden by arranging a convenient time and place for the interview to be held.

We do not expect there to be any risks to you in taking part in this study. However, in the unlikely event that you become upset during the interview, the interview will be terminated and the research team will be able to guide you towards sources of support.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in Miss Cassie Screti's PhD Thesis.

Expenses and payments

There will be no expenses and payments made to participants.

Who is funding the research?

The study is being funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 4869.

Research Team

Researcher:

Ms Cassie Screti Email: screticc@aston.ac.uk Tel: 0121 204 4541

Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath@wlv.ac.uk	Tel: 0190 232 2362
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details.

- Your name
- Your contact details, such as an email address or telephone number.
- Information about your employment

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 0121 204 3000

Appendix.7. Study information pack for young people aged 13-15 years recruited though IBD charities

Aston University

CROHN'S & COLITIS UK

cicra better lives for children with crohns and colitis

Supporting young people to live well with Inflammatory Bowel Disease

Dear Parent,

Researchers at Aston University are conducting research about what it is like for young people (aged 13-18) to live with Inflammatory Bowel Disease (IBD).

They would like to find out what makes it easy or difficult for young people to manage their IBD as well as ideas on how best to support young people to live well with IBD.

As a parent of a young person (aged 13-15) who has been diagnosed with IBD, I am writing to yourself to invite your child to take part in this project.

I enclose an information sheet with more details. Please note that your participation in this study is voluntary.

If your child is interested in taking part, or would like more information about the study, please contact one of the research team directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,

Supporting young people to live well with Inflammatory Bowel Disease

Participant Information Sheet- Parent of a young person (aged 13-15)

Invitation

We would like to invite your child to take part in a research study, exploring how young people experience living with inflammatory bowel disease (IBD) and having to manage their condition. This study is being carried out by researchers from Aston University, as part of Miss Cassie Screti's PhD thesis, and is part funded by Crohn's and Colitis UK.

Before you decide if you are happy for your child to participate in this study, please take time to read the following information and, if you wish, discuss it with others such as your family or friends.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

What is the purpose of the study?

We would like to find out about why young people may struggle to adhere to their treatment routine for their IBD. We would like to learn more about:

- Your child's views and experiences of living with IBD
- The challenges young people face, particularly with medication of lifestyle changes.
- Your child's thoughts on how other young people can be supported to follow their treatment routine

This information will help to inform the development of a new intervention to improve treatment adherence in young people (aged 13-18) with IBD.

Why has my child been invited?

Your child has been invited to take part in this study because your child is a young person (aged 13-18) who has been diagnosed with IBD and, either yourself or your child has contacted the research team about taking part in this study.

What will happen to my child if they take part?

A researcher will talk your child through the study and answer their questions. If you and your child are happy for your child to join the study, the researcher will ask you to fill out a Consent form and your child to complete an assent form. Both of these forms will be sent via email, and will need to be completed and emailed to the researcher before your child's interview.

Your child will then be interviewed by a researcher. The interview will last around 60 minutes, depending on how much your child has to say. Interviews can be conducted over the telephone or via video call (e.g. using Skype, Zoom, FaceTime), depending on your child's preference.

During the interview, with your permission, a researcher will audio record this conversation. The conversation is recorded so that the researcher can listen back to everything your child has said and type it up. Your child's name will be removed after the interview is typed so no one will know it was your child.

The researcher will talk to your child about their experiences of living with IBD and managing their condition. Your child will be asked how other young people could be supported to ensure they are managing with condition correctly.

Prior to their interview, your child will have the option to collect images representing barriers young people with IBD face to live well. These images can include photographs taken by your child, or images found online. If your child chooses to do this, they will be asked to share these images with the researcher during their interview.

recorded and the information my child provides be managed?

With your permission we will audio record the interview and take notes. The recording will be typed into a document (transcribed) by a transcriber approved by Aston University. This process will involve removing any information which could be used to identify individuals e.g. names, locations etc.

The audio recording from your child's interview will be transcribed within 24 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your child's data cannot be withdrawn.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything your child has told us that is included in the reporting of the study will be anonymous.

Your child is free not to answer any questions that are asked, without giving a reason.

Does my child have to take part?

No. It is up to you and your child to decide whether or not your child wishes to take part.

If your child does decide to participate, your child will be asked to sign and date a consent form. Your child will still be free to withdraw from the study at any time without giving a reason.

Will my child’s taking part in this study be kept confidential?

Yes. A code will be attached to all the data your child provides to maintain confidentiality.

Your child’s personal data (name and contact details) will only be used if the researchers need to contact your child to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

What are the possible benefits of taking part?

While there are no direct benefits to your child of taking part in this study, the data gained will inform the design of a new behaviour change intervention, aiming to improve young people’s treatment adherence.

What are the possible risks and burdens of taking part?

If you and your child decide to take part in this research, you may experience a small burden due to the time taken out of your day to complete the interview. Efforts will be made to lessen this burden by arranging a convenient time for your interview to be held.

We do not expect there to be any risks to your child in taking part in this study. However, in the unlikely event that your child becomes upset during the research, the interview will be terminated and the research team will be able to guide your child towards sources of support.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your child’s identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in Miss Cassie Screti’s PhD Thesis.

Expenses and payments

A small token of thanks, in the form of a £10 shopping voucher, will be given to each participant who takes part in this research.

Who is funding the research?

The study is being funded by Crohn’s and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was has been reviewed and received a favourable ethical opinion from the School of Life and Health Sciences Ethics Committee at Aston University.

What if I have a concern about my child's participation in the study?

If you have any concerns about your child's participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 4869.

Further information and Support

If you have any further questions about the study, please contact the research team whose contact details can be found at the end of this information sheet.

If you wish to access further support, you can contact: Crohn's and Colitis UK https://www.crohnsandcolitis.org.uk/ Tel: 0300 222 5700.

Research Team

Researcher:

Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath@wlv.ac.uk	Tel: 0190 232 2362
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details.

- Yours and your child's name
- A brief history of your child's medical condition
- Your contact details, such as an email address or telephone number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 0121 204 3000

Supporting young people to live well with Inflammatory Bowel Disease

Participant Information Sheet- Young person (aged 13-15)

We would like to ask for your help with our research project.

We would like to talk to you about what it is like to live with Inflammatory Bowel Disease (IBD), including Crohn's Disease and Ulcerative Colitis, and what makes it easy or difficult to manage your condition.

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information and discuss it with friends, family or us if you wish.

This research is being carried out by researchers from Aston University. If you would like more information please contact Cassie or Lou who are leading the project. Their emails and phone numbers can be found at the end of this information sheet.

What is this project about?

We would like to find out about what makes it easy or difficult to live with IBD. We would like to learn more about:

- How do you feel about having IBD?
- What challenges you might face, particularly with medication or lifestyle changes?
- How you think other young people can be supported to follow their treatment routine

Why have I been invited?

You have been invited to take part in this study because you contacted the research team, as you are a young person with IBD, who is interested in taking part in this study.

Do I have to take part?

No, it is your choice. If you decide to take part, you are free to change your mind without giving a reason and free to skip difficult questions. If you decide to stop taking part, just let the researchers know and they will stop the meeting. Nothing will happen to you if you decide not to participate.

What will happen to me if I take part?

A researcher will talk you through the study and answer your questions. If you are happy to join the study, the researcher will ask you to sign a form to say you are happy to take part. Then we will need to ask a parent or carer to give us permission to let you take part in the study by filling out a consent form.

You will then take part in an interview with Cassie. The interview will last around 60 minutes, depending on how much you have to say. Interviews will be conducted over the telephone or via video call (e.g. using Skype, Zoom, FaceTime) depending on your preference. During the interview, with your permission, Cassie will audio record your conversation. The conversation is recorded so that Cassie can listen back to everything you have said and type it up. Your name will be removed after the interview is typed so no one will know it was you.

Cassie will talk to you about your experiences of living with IBD and managing your condition. You will be asked how other young people could be supported to ensure they are managing their condition correctly.

Prior to their interview, you will be given the option to collect images representing barriers young people with IBD face to live well. These images can include photographs taken by yourself, or images found online. If you choose to do this, you will be asked to share these images with Cassie during your interview.

What are the possible risks or benefits of taking part?

If you decide to take part in this research, you may experience a small burden due to the time taken out of your day complete the interview. Efforts will be made to lessen this burden by arranging a convenient time for your interview to be held.

We do not expect there to be any risks to you in taking part in this study. In the unlikely event that you become upset during the interview, Cassie will stop the interview and audio recording and support you. A contact number for support will be offered. Some people like taking part as the findings could help other young people and families going through a similar experience.

Will other people know that I have taken part in the project?

No. Only the research team will know that you have taken part. Your name and other personal information will be removed from the typed-up interview so no one will know that it is you. The only time when we would need to tell someone else is if you tell us something that suggests a risk of harm to yourself or others. The research team will ensure that all information is kept securely and confidentially at Aston University. Only the research team will be able to access the interviews.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

We will send you a summary of the findings of the research in words you can understand.

The results of the study will also be used in Cassie's PhD Project.

Expenses and payments

A small token of thanks, in the form of a £10 shopping voucher, will be given to you if you if you take part.

Who has reviewed the study?

This study was has been reviewed and received a favourable ethical opinion from the School of Life and Health Sciences Ethics Committee at Aston University.

Who is organising the research?

The research is organised by Aston University in collaboration with Crohn's and Colitis UK.

Who can I contact if I have any questions or worries?

If you have any concerns about anything to do with this study, please speak to the research team and we will do our best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 4869.

Further information and Support

If you have any further questions about the study, please contact the research team whose contact details can be found at the end of this information sheet.

If you wish to access further support, you can contact: Crohn's and Colitis UK https://www.crohnsandcolitis.org.uk/ Tel: 0300 222 5700.

What do I do now?

If you would like to take part in the research, or would like further information, please contact Cassie, or you can ask your parent to contact Cassie, whose details can be found below.

Research Team

Researcher:

Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath@wlv.ac.uk	Tel: 0190 232 2362
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank You.
We look forward to hearing from you.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details.

- Your name, we will ensure the pseudonym given to you is different to that of your own.
- A brief history of your medical condition
- Your parents contact details, such as an email address or telephone number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 0121 204 3000

Appendix.8. Study information pack for young people aged 16-18 years recruited though IBD charities

Aston University CROHN'S & COLITIS UK cicra better lives for children with crohns and colitis

Supporting young people to live well with Inflammatory Bowel Disease

Dear ,

Researchers at Aston University are conducting research about what it is like for young people (aged 13-18) to live with Inflammatory Bowel Disease (IBD).

They would like to find out what makes it easy or difficult for young people to manage their IBD as well as ideas on how best to support young people to live well with IBD.

As a young person (aged 16-18) who has been diagnosed with IBD, I am writing to invite you to take part in this project.

I enclose an information sheet with more details. Please note that your participation in this study is voluntary.

If your child is interested in taking part, or would like more information about the study, please contact one of the research team directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,

Aston University CROHN'S & COLITIS UK cicra better lives for children with crohns and colitis

Supporting young people to live well with Inflammatory Bowel Disease

Participant Information Sheet- Young people (16-18 years)

Invitation

We would like to talk to you about what it is like to live with Inflammatory Bowel Disease (IBD) and what makes it easy or difficult to manage your condition.

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information and discuss it with friends, family or us if you wish.

This research is being carried out by researchers from Aston University, as part of Miss Cassie Screti's PhD thesis, and is part funded by Crohn's and Colitis UK. If you would like more information please contact Cassie or Lou who are leading the project. Their emails and phone numbers can be found at the end of this information sheet.

What is the purpose of the study?

We would like to understand what makes it easy or difficult to live with IBD. We would like to learn more about:

- How do you feel about having IBD?
- What challenges you might face, particularly with medication or lifestyle changes?
- How you think other young people can be supported to follow their treatment routine

This information will help to inform the development of a new intervention to improve treatment adherence in young people (aged 13-18) with IBD.

Why have I been invited?

You have been invited to take part in this study because you contacted the research team, as you are a young person with IBD, who is interested in taking part in this study.

What will happen to me if I take part?

A researcher will talk you through the study and answer your questions. If you are happy to join the study, the researcher will ask you to fill out a Consent form. The consent form will be sent to you via email, and will need to be completed and emailed to the researcher before your interview.

You will then take part in an interview with Cassie. The interview will last around 60 minutes, depending on how much you have to say. Interviews will be conducted over the telephone or via video call (e.g. using Skype, Zoom, FaceTime), depending on your preference. During the interview, with your permission, Cassie will audio record your conversation. The conversation is recorded so that the researcher can listen back to everything you have said and type it up. Your name will be removed after the interview is typed so no one will know it was you.

The researcher will talk to you about your experiences of living with IBD and managing your condition. You will be asked how other young people could be supported to ensure they are managing their condition correctly.

Prior to your interview, you will be given the option to collect images representing barriers young people with IBD face to live well. These images can include photographs taken by yourself, or images found online. If you choose to do this, you will be asked to share these images with the researcher during your interview.

How will the conversation during the interview be recorded and the information I provide managed?

With your permission we will audio record the interviews and take notes. The recording will be typed into a document (transcribed) by a transcriber approved by Aston University. This process will involve removing any information which could be used to identify individuals e.g. names, locations etc.

The audio recording from your interview will be transcribed within 24 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your data cannot be withdrawn.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything you have told us that is included in the reporting of the study will be anonymous.

You are free not to answer any questions that are asked, without giving a reason.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part. Nothing will happen to you if you decide not to participate.

If you do decide to participate, you will be asked to sign and date a consent form. You will still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform the design of a new behaviour change intervention, aiming to improve young people's treatment adherence.

What are the possible risks and burdens of taking part?

If you decide to take part in this research, you may experience a small burden due to the time taken out of your day complete the interview. Efforts will be made to lessen this burden by arranging a convenient time for your interview to be held.

We do not expect there to be any risks to you in taking part in this study. However, in the unlikely event that you become upset during the interview, Cassie will stop the interview and audio recording and support you. A contact number for support will be offered.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in Miss Cassie Screti's PhD Thesis.

Expenses and payments

A small token of thanks, in the form of a £10 shopping voucher, will be given to each participant who take part in this research.

Who is funding the research?

The study is being funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was has been reviewed and received a favourable ethical opinion from the School of Life and Health Sciences Ethics Committee at Aston University.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 4869.

Further information and Support

If you have any further questions about the study, please contact the research team whose contact details can be found at the end of this information sheet.

If you wish to access further support, you can contact: Crohn's and Colitis UK https://www.crohnsandcolitis.org.uk/ Tel: 0300 222 5700.

Research Team

Researcher:

Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath@wlv.ac.uk	Tel: 0190 232 2362
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details.

- Your name
- A brief history of your medical condition
- Your parents contact details, such as an email address or telephone number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 0121 204 3000

Appendix.9. Study information pack for parents recruited though IBD charities

Aston University CROHN'S & COLITIS UK cicra better lives for children with crohns and colitis

Supporting young people to live well with Inflammatory Bowel Disease

Dear ,
Researchers at Aston University are conducting research about how young people (aged 13-18) experience living with Intolerable Bowel Disease (IBD) and having to manage their condition.

They would like to find out about your experiences of parenting a young person with IBD, as well as your views on how young people with IBD can be supported to live well.

As the parent of a young person (aged 13-18) with IBD, I am writing to ask if you would be willing to take part in this study. Taking part would involve you talking to a researcher in an individual interview.

Interviews will be conducted using online methods such as Skype or over the phone. It is up to you how much you say, but interviews usually last for around one hour. You will receive a £10 voucher for taking part.

Findings will help us to improve the support offered for young people to help them to take their medications and to live well with IBD.

I enclose an information sheet with more details. Participation in this study is voluntary.

If you are interested in taking part or would like more information about the study, please contact the lead researcher directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,

Supporting young people to live well with Inflammatory Bowel Disease

Parent/or Guardian Participant Information Sheet

Invitation

Researchers at Aston University are conducting a study about how young people (aged 13-18) experience living with IBD and having to manage their condition. They would like to find out about your experiences of parenting a young person with IBD, as well as your beliefs about the most effective strategies to support treatment adherence.

Before you decide if you would like to participate, please take time to read the following information and, if you wish, discuss it with others such as your friends or family.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

What is the purpose of the study?

The purpose of this study is to understand the challenges of living with IBD for young people and families and what kinds of support would be useful to young people and families to help them live well with IBD. Through gathering detailed information from young people, parents/or guardians and health professionals, we will be able to identify the information and support needs of young people with IBD to help them adhere to their treatment regimes. This information will help to inform the development of a new programme of support to improve the health and well-being of young people with IBD.

Why have I been invited?

You have been invited to take part in this study because you contacted the research team, because you are a parent/or guardian of a young person (aged 13-18), who has been diagnosed with IBD.

What will happen to me if I take part?

A researcher will talk you through the study and answer your questions. If you are happy to join the study, the researcher will ask you to fill out a Consent form. The consent form will be sent to you via email, and will need to be completed and emailed to the researcher before your interview.
If you are happy to join the study, you will be invited to take part in an individual interview with a researcher. During the interview, the researcher will talk to you about your experiences of parenting a young person with IBD. The interview will last around 60 minutes, depending on how much you have to say. Interviews can be conducted over the telephone or via video call (e.g. using Skype, Zoom, FaceTime), depending on your preference. The researcher may use arts based research methods during your interview.

The researcher will audio record your conversation so that she can listen back to everything you have said and type it up. Your name will be removed after the interview is typed so no one will know it was you.
During the interview you can choose to skip any questions that you find difficult. At any point during the interview you can choose to stop and withdraw from the study. After the interview, demographic information will be collected; this information will be used to explore the range of participants that have taken part.

How will the conversation during the interview be recorded and the information I provide managed?

With your permission we will audio record the interview and take notes. The recording will be typed into a document (transcribed), by the student researcher. This process will involve removing any information which could be used to identify you e.g. names, locations etc.

The audio recording from your interview will be transcribed within 24 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your data cannot be withdrawn.
Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything you have told us that is included in the reporting of the study will be anonymous.

You are free not to answer any questions that are asked, without giving a reason.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You will still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.
Confidentiality may need to be broken in cases where sensitive information is disclosed that could reveal potential harm to yourself or another person, which will be discussed with the research participants and escalated to the researcher's supervisor. Should there be any concerns over the welfare of any child, the interview will be stopped and Birmingham Children and Women's hospital's protocol for information sharing will be implemented.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform the design of a new behaviour change intervention, aiming to improve young people's treatment adherence.

What are the possible risks and burdens of taking part?
If you decide to take part in this research, you may experience a small burden due to the time taken out of your day complete the interview. Efforts will be made to lessen this burden by arranging a convenient time for your interview to be held.

We do not expect there to be any risks to you in taking part in this study. However, in the unlikely event that you become upset during the research, you will have the option to stop the interview and the research team will support you.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

A summary of the study results will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in Ms Cassie Screti's PhD Thesis.

Expenses and payments

As a thank you for their time, a £10 shopping voucher will be given to each person who takes part in the research.

Who is funding the research?

The study is funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.
Who has reviewed the study?

This study was has been reviewed and received a favourable ethical opinion from the University Research Ethics Committee at Aston University.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 4869.

Further information and Support

If you have any further questions about the study, please contact the research team whose contact details can be found at the end of this information sheet.
If you wish to access further support, you can contact: Crohn’s and Colitis UK https://www.crohnsandcolitis.org.uk/ Tel: 0300 222 5700.

Research Team
Researcher:
Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath@wlv.ac.uk	Tel: 0190 232 2362
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Appendix.10. Relevant Consent/Assent and Demographic form for young people aged 13-15 years

Supporting young people to live well with Inflammatory Bowel Disease

Parental Consent Form

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please initial boxes

1.	I confirm that I have read and understand the Participant Information Sheet (X) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my child's participation is voluntary and that they are free to withdraw at any time, without giving a reason.	
3.	I agree to my child's personal data and data relating to my child collected during the study being processed as described in the Participant Information Sheet.	
4.	I understand that if during the study, my child tells the research team something that causes them to have concerns in relation to my child's health and/or welfare, or that of another child, they may need to breach my child's confidentiality.	
5.	I agree to my child's interview being audio recorded and to anonymised direct quotes from my child being used in publications resulting from the study.	
6.	I agree for my child to take part in this study.	

Tick box

I would like to be sent a copy of the study results	
Please email a copy of the study results to:	

Name of participant Date Signature

Name of Person receiving consent. Date Signature

Supporting young people to live well with Inflammatory Bowel Disease

Assent Form

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

		Tick if you agree
1.	I confirm that I have read or had explained to me the information sheet (X) for the above study.	
2.	I understand the information sheet and what this study is about.	
3.	I have had the chance to ask questions and have had all my questions answered	
4.	I understand that I can change my mind, stop and not take part at any time without having to explain why	
5.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare, or that of another child, they may need to breach my confidentiality.	
6.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.	
7.	I agree to my interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.	
8.	I agree to take part in this study.	

✓

Please CIRCLE one option below

I want to take part in this study

✗

I do not want to take part in this study

Name of participant __________ Date __________ Signature __________

Name of Parent/Guardian __________ Date __________ Signature __________

Name of Person receiving consent. __________ Date __________ Signature __________

Young person demographic questionnaire

Title: **Supporting young people to live well with Inflammatory Bowel Disease**

Researcher: Miss Cassie Screti

Contact details: School of Life & Health Sciences
Aston University
Aston Triangle
Birmingham
B4 7ET

Email: scretic@aston.ac.uk

Telephone: 0121 204 4541

Research Supervisors:
Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw
This information will help us to see if we have spoken to a range of people with different experiences and will help us to analyse the data. All details will be kept strictly confidential to the research team.

Section 1: About You	
Age: ____________ years	**Gender:** MALE FEMALE
How would you describe your ethnicity?	
White ○ White British ○ White Irish ○ Other White Background Asian ○ Indian ○ Pakistani ○ Bangladeshi ○ Other Asian ethnic background Black ○ Caribbean ○ African ○ Other Black ethnic background	*Mixed* ☐ White and Black Caribbean ☐ White and Black African ☐ White and Asian ☐ Other mixed ethnic background Chinese or other ethnic group ☐ Chinese ☐ Any other ethnic group ☐ *Prefer not to say*

Section 3: Your condition	
At what age were you diagnosed with IBD:	What medications do you take? How often do you need to take these?
How well controlled is your IBD:	

Thank you

Appendix.11. Relevant Consent and Demographic form for young people aged 16-18 years

Supporting young people to live well with Inflammatory Bowel Disease

Consent Form

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please initial boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version X, Date) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time.	
3.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.	
4.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare, or that of another child they may need to breach my confidentiality.	
5.	I agree to my interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.	
6.	I agree to take part in this study.	

	Tick box
I would like to be sent a copy of the study results	
Please email a copy of the study results to:	

Name of participant ______________ Date ______________ Signature ______________

Name of Person receiving consent. ______________ Date ______________ Signature ______________

Young person demographic questionnaire

Title: Supporting young people to live well with Inflammatory Bowel Disease

Researcher: Miss Cassie Screti

Contact details:
School of Life & Health Sciences
Aston University
Aston Triangle
Birmingham
B4 7ET

Email: scretic@aston.ac.uk

Telephone: 0121 204 4541

Research Supervisors:
Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

This information will help us to see if we have spoken to a range of people with different experiences and will help us to analyse the data. All details will be kept strictly confidential to the research team.

Section 1: About You

Age:
____________ years

Gender:
MALE FEMALE

How would you describe your ethnicity?

White
○ White British
○ White Irish
○ Other White Background

Asian
○ Indian
○ Pakistani
○ Bangladeshi
○ Other Asian ethnic background

Black
○ Caribbean
○ African
○ Other Black ethnic background

Mixed
☐ White and Black Caribbean
☐ White and Black African
☐ White and Asian
☐ Other mixed ethnic background

Chinese or other ethnic group
☐ Chinese

☐ Any other ethnic group

☐ *Prefer not to say*

Section 3: Your condition

At what age were you diagnosed with IBD:	**What medications do you take? How often do you need to take these?**
How well controlled is your IBD:	

Thank you

Appendix.12. Relevant Consent and Demographic form for parents

Supporting young people to live well with Inflammatory Bowel Disease

Consent Form

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please initial boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 1, 03/04/2020) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.	
3.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.	
4.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare (or that of a child I care for) they may need to breach my confidentiality.	
5.	I agree to my interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.	
6.	I agree to take part in this study.	

Tick box

I would like to be sent a copy of the study results	
Please email a copy of the study results to:	

_______________ _______________ _______________

Name of participant Date Signature

_______________ _______________ _______________

Name of Person receiving consent. Date Signature

Parent participant demographic questionnaire

Title: Supporting young people to live well with Inflammatory Bowel Disease

Researcher: Miss Cassie Screti
Contact details: School of Life & Health Sciences
Aston University
Aston Triangle
Birmingham
B4 7ET

Email: scretic@aston.ac.uk

Telephone: 0121 204 4541

Research Supervisors:
Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

This information will help us to see if we have spoken to a range of people with different experiences and will help us to analyse the data. All details will be kept strictly confidential to the research team.

Section 1: About You	
Age: ____________ years	**Gender:** MALE FEMALE
How would you describe your ethnicity?	
White o White British o White Irish o Other White Background Asian o Indian o Pakistani o Bangladeshi o Other Asian ethnic background Black o Caribbean o African o Other Black ethnic background	*Mixed* ☐ White and Black Caribbean ☐ White and Black African ☐ White and Asian ☐ Other mixed ethnic background Chinese or other ethnic group ☐ Chinese ☐ Any other ethnic group ☐ *Prefer not to say*
Section 2: About your child	
Age: ____________ years	**Gender:** MALE FEMALE

How would you describe your child's ethnicity?

White
○ White British
○ White Irish
○ Other White Background

Asian
○ Indian
○ Pakistani
○ Bangladeshi
○ Other Asian ethnic background

Black
○ Caribbean
○ African
○ Other Black ethnic background

Mixed
☐ White and Black Caribbean
☐ White and Black African
☐ White and Asian
☐ Other mixed ethnic background

Chinese or other ethnic group
☐ Chinese

☐ Any other ethnic group

☐ *Prefer not to say*

Section 3: Your child's condition

At what age was your child diagnosed with IBD:	**Does your child take medication? YES / NO** **If yes, how often does your child take medication?**
How well controlled is your child's IBD:	

Thank you

Appendix.13. Relevant Consent and Demographic form for healthcare professionals

Supporting young people to live well with Inflammatory Bowel Disease

Consent Form: Professionals

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please initial boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 2, 05/02/2020) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.	
3.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.	
4.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare (or that of a child I care for) they may need to breach my confidentiality.	
5.	I agree to my interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study.	
6.	I agree to take part in this study.	

Tick box

I would like to be sent a copy of the study results	
Please email a copy of the study results to:	

_______________________ _______________ _________________

Name of participant Date Signature

_______________________ _______________ _________________

Name of Person receiving consent. Date Signature

Health Professional participant demographic questionnaire

Title: **Supporting young people to live well with Inflammatory Bowel Disease**

Researcher: Miss Cassie Screti
Contact details: School of Life & Health Sciences
Aston University
Aston Triangle
Birmingham
B4 7ET

Email: scretic@aston.ac.uk

Telephone: 0121 204 4541

Research Supervisors:
Dr Lou Atkinson, Dr Gemma Health, Dr Rachel Shaw

This information will help us to see if we have spoken to a range of people with different experiences and will help us to analyse the data. All details will be kept strictly confidential to the research team.

1. Job title ……………………………………………………………………………………………………

2. Number of years (qualified) in role………………………………………………………………

Thank you

Appendix.14. Young person (aged 13-18) interview schedule

Interview guide –young people

- Tell me a bit about yourselves?
    - What do you like to do in your spare time?
    -

- Tell me about your health condition?
    - What is it like to have Inflammatory Bowel Disease?
    - What symptoms does your condition cause?
    - How old were you when you were diagnosed?

What does having Inflammatory Bowel Disease mean to you?

- How does it impact your life?
- Does it limit you from doing things you want to do?

- Tell me about how you manage your Inflammatory Bowel Disease?
    - What medication do you take?
    - How often do you have to take their medication?
    - What impact does your Inflammatory Bowel Disease have on the food you eat?
    - Do you feel you are doing a good job at managing your Inflammatory Bowel Disease?

- Tell me about how your family or friends help you to manage your condition?
    - How do your parents help you?
    - How do you feel about your parents helping you?

- What challenges or difficulties do you think other young people face in sticking to their treatment routine?
    - Are there challenges/difficulties in sticking to a treatment routine?
    - Are there any social challenges/difficulties in sticking to a treatment routine?
    - Are there any emotional challenges/difficulties in sticking to a treatment routine?

What help or support do you think young people need to help them to stick to their treatment routine?

- Why would this be helpful?
- Can you think of any help or support you have received in the past that has been helpful?
- Do you need more support from other people (e.g. parents/health care professionals/peers)?
- What support would not be useful??

- Is there anything you would like to add?

Appendix.15. Parent interview schedule

Interview guide –parents

- Tell me a bit about your child
    - What do they like to do in your spare time?

Tell me about your child's health condition?
    - What is it like to parent a child with Inflammatory Bowel Disease?
    - How do the symptoms of your child's condition impact your child?
    - How old was your child when they were diagnosed

What does your child having Inflammatory Bowel Disease mean to you?
    - How does it affect your child's life?
    - How does it affect family life?
    - What do you think caused your child's IBD?
    - How long do you think it will last?
    - How well controlled do you feel your child's IBD is?

- Tell me about how your child manages their Inflammatory Bowel Disease?
    - What medication does your child take?
    - How do you feel about your child's medication?
    - How often does your child have to take their medication?
    - How has your child's lifestyle changed, (e.g their diet or exercise)?
    - How well do you feel your child is managing their condition?

- As a parent, tell me about the role you play in the management of your child's Inflammatory Bowel Disease?
    - What kind of help or support do you give your child?
    - What are the challenges in supporting your child to manage their condition?

- What barriers do you think young people face in adhering to their treatment routine?
    - What are the physical demands on young people to stick to their treatment routine?
    - What are the barriers friends or social groups place on young people to stick to their treatment routine?
    - What are the emotional demands on young people to stick to their treatment routine?

- In your experience, what help or support do young people need to improve their treatment adherence?
    - Can you think of any help or support your child has received in the past that has been helpful?
    - Do young people need more support from other people (e.g. parents/health care professionals/peers)?
    - How would this support best be delivered?

- Is there anything you would like to add?

Appendix.16. Healthcare professionals interview schedule

Interview guide – Professionals

- Tell me a bit about your professional role
    - How does your role relate to young people with IBD?

- Tell me about your experiences of working with young people with IBD?
    - How often do you see young people with IBD

- Tell me about how young people need to manage their IBD?
    - What medication to they have to take, how often do they have to take their medication?

- Tell me about your experience of the role parents play in the management of their child's health condition?
    - How beneficial is this for the young person?

- In your experience how well do young people adhere to their treatment?
    - How do you define adherence?

- What barriers do you people face in adhering to their treatment?
    - What are the physical demands of young people adhering to their treatment?
    - What are the social demands of young people adhering to their treatment
    - What are the emotional demands of young people

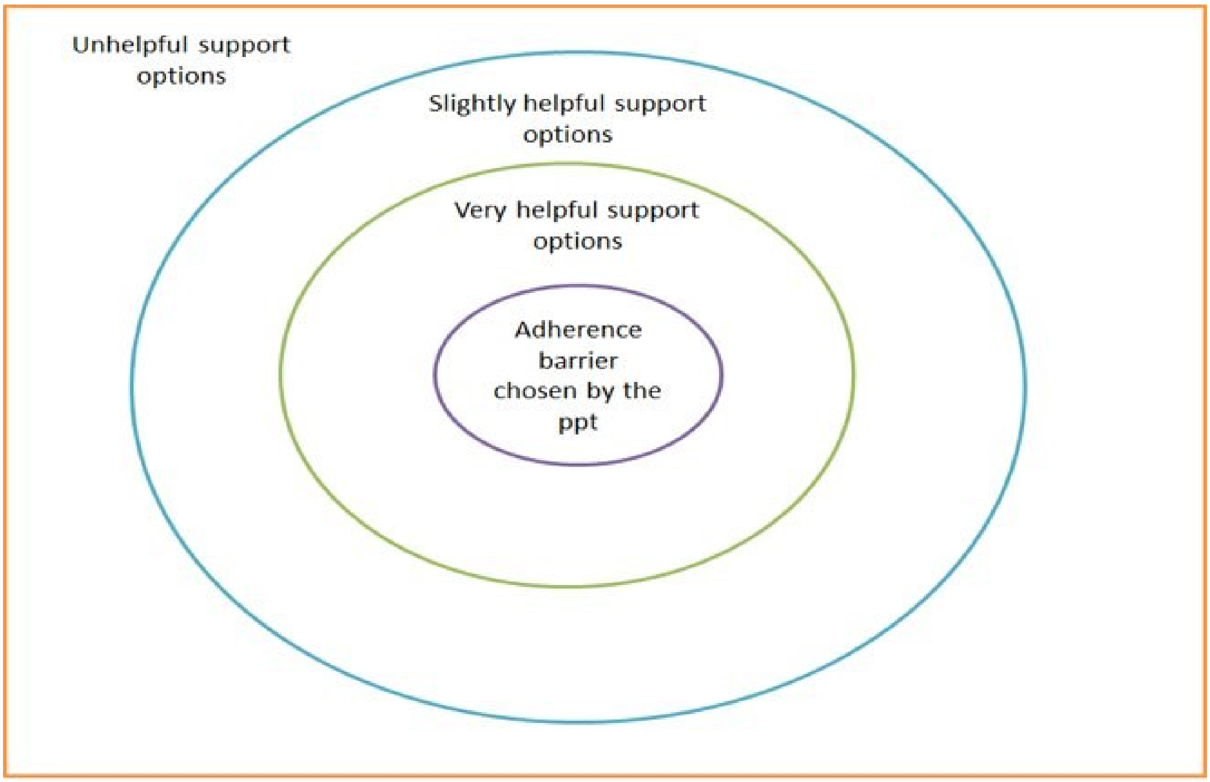
- In your experience, what help or support do young people need to improve their adherence?
    - What things have you tried? What worked well?
    - What further information do you think young people need?
    - What further emotional support do young people need?
    - What further practical support do young people need?

- Do you know of any past intervention or methods that have been beneficial in improving young people's adherent behaviour?
    - How was this beneficial?

- In your experience, what help or support do health care professionals need to assist young people in their adherence behaviour?
    - What barriers do health care professionals face when trying to help young people ?

- Is there anything you would like to add?

Appendix.17. Creative task outline



Appendix.18. Example of framework analysis matrix

Quote	Code	Code explanation
"I guess some other people would feel a bit, not not self-conscious, but it's a feeling of being different isn't it? That's not, that's not the best because obviously not everyone our age has to take this stuff just to make sure you're somewhat ok so there's that, but thankfully my friends are all really understanding so I never really had that umm but I recon it would be a problem for some people" *(Laura, young person)*	Embarrassment taking treatment in front of others	Young people feeling embarrassed to take treatment in front of friends (e.g., tablets, injections, liquid diet)
"the azathioprine definitely, I one hundred percent missed missed a day or two, but I was on that for about a year or so. And it is just sometimes like you're busy at night and you just forget, and then your just tired and fall asleep, but it's not like if I had in the morning to make sure that I wouldn't have not had it for the day or whatever, I've never, never missed a, a humira but that's because that's once every two weeks, it's not like it's it's just that one day so I do remember it" *(Jordan, young person)*	Remembering to take medication	Experiences of remembering and/or forgetting to take medications, including the outcomes
maybe because they feel like umm maybe they think ah why do I have to take this? Why am I like this? Like almost they're questioning like why me. Like thinking I haven't done anything, why do I have to take this umm. I don't know, maybe they just think but why do I have to take it? What what have I done, to make me take this every morning, or have this injection every so often. Because honestly, it's not it's not fair for people because I have done nothing wrong to have it and it's not their fault but they they have to take it anyway. They can't feel sorry for themselves sometimes. (Erika, young person)	Questioning why medication is needed	Young people question why they medication is needed and their rationale for feeling it is not necessary (e.g., feeling well)

Appendix.19. PPIE study information pack for young people aged 13-15 years

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Supporting young people to live well with Inflammatory Bowel Disease – A Patient and Public Involvement and Engagement (PPIE) Group

Dear Parent/Caregiver,

Researchers at [redacted] and Aston University are creating an online Patient and Public Involvement and Engagement (PPIE) group to help with the development of a new intervention to improve treatment adherence in young people (aged 13-18) with Inflammatory Bowel Disease (IBD).

They would like a group of young people (aged 13-18) who have been diagnosed with IBD, to assist in the design of the proposed intervention to ensure it is both appropriate and engaging to other young people.

As a parent of a young person (aged 13-15) who has been diagnosed with IBD, I am writing to yourself to invite your child to take part in this PPIE group.

To access an information sheet with more details about this project please use the following link or scan the QR code at the bottom on this letter.
https://astonpsychology.eu.qualtrics.com/jfe/form/SV_doLbXKRz0upxA9g
If you would prefer this information to be sent you through the post, please contact a member of the research team (listed below) who can arrange this.

If your child is interested in joining the PPIE group, or would like more information about the study, please contact one of the research team directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,
Ms Cassie Screti, Dr Lou Atkinson, Dr Gemma Heath, and Dr Rachel Shaw

Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease
A Patient and Public Involvement and Engagement (PPIE) Group

Participant Information Sheet- Parents of young people (13-15 years)

Invitation

We would like to invite your child to take part in a Patient and Public Involvement and Engagement (PPIE) Group to assist in the development of a new intervention to help young people to live well with their Inflammatory Bowel Disease (IBD). This study is being carried out by researchers from Aston University and the Gastroenterology department at [redacted] as part of the researcher's PhD thesis, and is part funded by Crohn's and Colitis UK.

Before you decide if you are happy for your child to take part in the PPIE group, take time to read the following information carefully and, if you wish, discuss it with others such as your family and friends.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

What is the purpose of the PPIE Group?

PPIE groups allow patients and members of the public to have a say in the care they receive as well as to have a direct influence in the development of new services.

The research team are developing a new intervention to improve treatment adherence in young people (aged 13-18) with IBD.

To ensure that the intervention is both appropriate and engaging, the research team are creating a virtual PPIE group of young people who have been diagnosed with IBD. The PPIE group sessions will explore young people's views on how to ensure the proposed intervention's content and mode of delivery is engaging for young people, and the outcomes of the PPIE sessions will directly influence the intervention's development.

Why has my child been invited?

Your child has been invited to take part in this study because you are a young person who has been diagnosed with IBD and under the care of the Gastroenterology clinic at [redacted] or because your child contacted the research team as they are a young person with IBD, who is interested in taking part in this study.

What will happen to my child if they take part?

A researcher will talk to your child about the PPIE group and answer their questions. If you and your child are happy for your child to join the PPIE group, the researcher will ask you to fill out an online consent form and demographic form and your child to complete an assent form.

Your child will then be invited to join an online introductory PPIE group session where your child, along with other children interested in joining the group, will learn more about the proposed intervention and how the PPIE group's views will assist in the development of the intervention. To join the introductory session and to join the PPIE group session your child will need a laptop or device with internet access. This group session will take place outside of school time.

At the end of the session, your child will be asked if you would be happy to partake in the PPIE group; those who do not want to join the PPIE group, will be asked to leave the online session, while those who do wish to join the group will have the chance to give the PPIE group a name, as well to decide on the dates and starting times of the future PPIEs sessions. As to not impact your child's education, the session will only be conducted outside of school hours. In addition to this, those who wish to join the group will also decide on which digital platform they would like the PPIE groups to be hosted on.

Those who wish to join the PPIE group will be invited to participate in a further four by-weekly virtual sessions. To attend these sessions your child will need access to a laptop or device with internet access. The PPIE group will include around 8 young people. The group sessions will be conducted by a PhD researcher, and a Health Psychology MSc student from Aston University. During the PPIE group sessions a variety of creative methods (e.g. Drawing; Collage; playdough modelling; Lego modelling) will be used to allow young people to express their thoughts and opinions. In order for these creative methods to take place, your child will be sent an activity pack in the post prior to the first session. We ask that your child brings these to each group session. Each PPIE group session will contain a mixture of discussions, creative tasks and a comfort break; with each session estimated to last around 90 minutes. During the introductory session, the PPIE group will be asked to choose how long of a comfort break they would like within the following sessions; this may alter the duration of each session.
Your child can choose if they would like to have their camera turned on during the introductory session and following group sessions. If your child does wish to have their camera turned on, they will be asked to ensure that the camera cannot see anyone who is not involved in the group sessions.

How will the conversation during the PPIE group be recorded and the information I provide managed?

With yours and your child's permission we will audio record the PPIE group sessions and take notes. The researcher will listen to the audio files of each PPIE group session to make sufficient notes on the discussions within PPIE session. Once the researcher has achieved this, the digital audio files (stored on the University server) will be destroyed.
With yours and your child's permission photographs may also be taken of the outcomes of creative tasks conducted within the PPIE group sessions. Your child will not be expected to take photographs that include people's faces. These images will be stored on the University server.

We will ensure that anything your child may tell us that is included in the reporting of the PPIE group will be anonymous.

If you agree for your child to take part in the PPIE group full confidentiality cannot be guaranteed on behalf of the other group members, although all group members will be asked to maintain confidentiality at the start of each group session.

Does my child have to take part in the PPIE group?

No. It is up to you and your child to decide whether or not your child wishes to take part. Nothing will happen to your child if your child decides not to participate. The care your child receives from [redacted] will not be affected if your child decides not to take part.

If your child does decide to join the PPIE group, your child will be asked to sign and date a consent form. Your child will still be free to withdraw from the study at any time without giving a reason.

Will my Child's taking part in this PPIE group be kept confidential?

Yes. Only the research team and the other members of the group will know you child will have taken part.
A code will be attached to all the data your child provides to maintain confidentiality.

Your child's personal data (name and contact details) will only be used if the researchers need to contact your child. Confidentiality will only be broken if information regarding risk of harm to a child is disclosed.

This study's assent form, consent form and demographic form will be placed on the secure online platform, Qualtrics. For you and your child to access these documents, the lead researcher will email you a dedicated link. Qualtrics is a secure online survey platform and is GDPR (General Data Protection Regulation) compliant. This third party organisation will temporarily store a copy of yours and your child's data until it is deleted by the lead researcher at Aston University. All information stored by Qualtrics will be deleted prior to the start of the first PPIE group session.

The data we collect will be stored by Aston University, in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

What are the possible benefits of taking part?

While there are no direct benefits to your child taking part in this PPIE group, the input from the PPIE group will inform the design of a new behaviour change intervention, aiming to improve young people's treatment adherence.

What are the possible risks and burdens of taking part?

If your child decides to take part in this PPIE group, your child may experience a small burden due to the time taken out of your day to attend the PPIE group sessions. Efforts will be made to lessen this burden by allowing the group to choose a convent time for the PPIE group sessions to be held. The group session will take place outside of school hours.

We do not expect there to be any risks to you in taking part in this PPIE group. However, in the unlikely event that your child does become upset during the PPIE group session, the researcher will stop the audio recording and support your child. A contact number for support will be offered.

What will happen to the results of the PPIE group?

The outcome of the PPIE group sessions will actively influence the development of a new intervention to improve young people's treatment adherence. The outcomes of the PPIE group may be published in scientific journals and/or presented at conferences. If the results of the study are published, your identity will remain confidential.

A lay summary of the outcomes of the PPIE groups will be available for the group members when the PPIE group sessions has been completed and the researchers will ask if you and your child would like to receive a copy.

The outcomes of the PPIE group sessions will also be used in the researcher's PhD Thesis.

Expenses and payments

As small token of thanks for their time, a £15 Amazon shopping voucher, will be emailed to your child at the end of each PPIE group session they attend.

Who is funding the research?

The study is being funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

What if I have a concern about my child joining the PPIE group?

If you or your child have any concerns about your child joining the PPIE group, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research

Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 5069.

Further information

To speak to an independent advisor, you can contact: [redacted]

Research Team

Researcher:
Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath1@aston.ac.uk	Tel: 0121 204 4284
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

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Supporting young people to live well with Inflammatory Bowel Disease

A Patient and Public Involvement and Engagement (PPIE) Group

Participant Information Participant Information Sheet- Young People (aged 13-15)

Invitation

We would like to ask for your help with our research project.

We would like to invite you to take part in a Patient and Public Involvement and Engagement (PPIE) Group to help with the development of a new programme to support young people to live well with their Inflammatory Bowel Disease (IBD), including Crohn's Disease and Ulcerative Colitis.

Before you decide whether to take part, it is important for you to understand why the PPIE group is being created and what it will involve. Please take your time to read this information and discuss it with friends, family or us if you wish.
This research is being carried out by researchers from Aston University with the Doctor from the Gastroenterology clinic at [redacted] If you would like more information please contact Cassie or Lou who are leading the project. Their emails and phone numbers can be found at the end of this information sheet.

What is the purpose of the PPIE Group?

A PPIE group, is where patients and members of the public work with researchers to produce better quality research. Members of PPIE groups have the opportunity to be involved in research projects, and their opinions can actively shape all or parts of the research.

The research team at Aston University are developing a new programme to help young people (aged 13-18) with IBD to live well. The programme will look to overcome challenges young people may experience to follow their treatment plan.

We are creating an online PPIE group of young people who have been diagnosed with IBD, to help us design the new programme.

The PPIE group will be asked to tell researchers what they think about the proposed programme, and the outcomes of the PPIE sessions will directly influence the programme's development.

Why have I been invited?

You have been invited to take part in this group because you are a young person who has been diagnosed with IBD and under the care of the Gastroenterology clinic at [redacted] or because you contacted the research team as you are a young person with IBD, who is interested in taking part in this study.

Do I have to take part in the PPIE group?

No, it is your choice. If you decide to take part, you are free to change your mind without giving a reason. If you decide to stop taking part in the PPIE group, just let the researchers know and they will not ask you to attend any more PPIE group meetings. Nothing will happen to you if you decide not to join the group. The care you receive from [redacted] will not be affected if you decide not to take part.

What will happen to me if I take part in the PPIE group?

A researcher will talk to you about the PPIE group and answer your questions. If you are happy to join the PPIE group, the researcher will ask you to sign an online form to say you are happy to take part. Then we will need to ask a parent or carer to give us permission to let you take part in the group by filling out a consent form. You will also be asked to complete a short demographic form.

To begin with, you will be asked to join an online introductory PPIE group session, with around 8 other young people interested in joining the group, where you will learn more about the new programme and how your views will help in the development of the programme. To join the introductory session you will need a laptop or device with internet access. This group session will take place outside of school time.

At the end of the session, you will be asked if you would like to join the PPIE group; if you choose not to join the group, you will be asked to leave the introductory PPIE group session. However, if you choose to join the group, you and the others who want to join the group, will be asked to decide on the dates and starting times of the future PPIE group sessions, as well as the digital platform the group will meet on. The group sessions will take place outside of school time.

The PPIE group will meet for a further four online group sessions, which will take place fortnightly. To attend these sessions you will need access to a laptop or device with internet access. The PPIE group will include around 8 young people. The group sessions will be conducted by a PhD researcher, and a Health Psychology MSc student from Aston University.

During the PPIE sessions, you will have the chance to use a range of creative materials (e.g. Drawing; Collage; playdough modelling; Lego modelling) to help you express your thoughts and opinions. The research team will send you an activity pack in the post containing all the creative materials you will need before the first session. Each PPIE group session will contain a mixture of conversation, creative tasks and a comfort break; with each session estimated to last around 90 minutes. During the introductory session, the group will be asked to choose how long of a comfort break they would like within the following sessions; this may change the duration of each session.
It is your choice if you would like to have your camera turned on during the introductory session and the following group sessions. If you do want to have your camera turned on, you will need to make sure that the camera cannot see people who are not involved in the group sessions.

How will the conversation during the PPIE group be recorded and the information I provide managed?

With yours and your parents/caregiver's permission we will audio record the PPIE group sessions and take notes. The researcher will listen to the audio files of each group session to make notes on the conversations within the session. Once the researcher has achieved this, the digital audio files (stored on the University server) will be destroyed.
With yours and your parent's permission photographs may also be taken of the outcomes of creative tasks conducted within the PPIE group sessions. We will not need to see people's faces in these photographs.
We will ensure that anything you tell us that is included in the reporting of the PPIE group will be anonymous.

If you agree to take part in the PPIE group full confidentiality cannot be guaranteed, due to the other PPIE group members, although all group members will be asked to maintain confidentiality at the start of all group sessions.

Will other people know that I have taken part in the project?

No. Only the research team and the other members of the group will know that you have taken part. Your name and other personal information will be removed from any information published about the PPIE group. The only time when we would need to tell someone else is if you tell us something that suggests a risk of harm to yourself or others.

This study's assent form and demographic form will be placed on the secure online platform, Qualtrics. The lead researcher will email you a specific link to allow you to access these documents. Qualtrics is a secure online platform and is GDPR (General Data Protection Regulation) compliant. Qualtrics will temporarily store a copy of your information until it is removed by the lead researcher at Aston University. Your information will be removed from Qualtrics prior to the start of the first PPIE group session.

The research team will ensure that all information is kept securely and confidentially at Aston University. Only the research team will be able to access your information.

What are the possible risks or benefits of taking part?

If you decide to take part in this PPIE group, you may experience a small burden due to the time taken out of your day to attend the PPIE group sessions. We will try to reduce this burden by allowing the group to choose the date and time of the group sessions. The group session will take place outside of school time.

We do not expect there to be any risks to you in taking part in this PPIE group. In the unlikely event that you become upset during a group session, the researcher will stop the session and support you. A contact number for support will be offered. Some people like taking part as the outcomes of the group will help create a new programme, aiming to help young people follow their treatment plan.

What will happen to the results of the PPIE group?

The outcome of the PPIE group sessions will actively influence the development of a new programme to help young people follow their treatment routine. The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes or photographs may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

We will send you a summary of the findings of the research in words you can understand.

The results of the study will also be used in the researcher's PhD Project.

Expenses and payments

As a small token of thanks for your time, a £15 Amazon shopping voucher will be emailed to you at the end of each PPIE group session you attend.

Who is funding the research?

The study is being funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

Who can I contact if I have any questions or worries?

If you have any concerns about anything to do with this study, please speak to the research team and we will do our best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 5069.

Further information

To speak to an independent advisor, you can contact: [redacted]

Research Team

Researcher:
Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath1@aston.ac.uk	Tel: 0121 204 4284
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team

Appendix.20. PPIE study information pack for young people aged 16-18 years

Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease- A Patient and Public Involvement and Engagement (PPIE) Group

Dear

Researchers at [redacted] and Aston University are creating an online Patient and Public Involvement and Engagement (PPIE) group to help with the development of a new intervention to improve treatment adherence in young people (aged 13-18) with Inflammatory Bowel Disease (IBD).

They would like a group of young people (aged 13-18) who have been diagnosed with IBD, to assist in the design of the proposed intervention to ensure it is both appropriate and engaging to other young people.

As a young person (aged 16-18) with IBD, I am writing to ask if you would be willing to take part in this PPIE group.
To access an information sheet with more details about this project please use the following link or scan the QR code at the bottom on this letter.
https://astonpsychology.eu.qualtrics.com/jfe/form/SV_bgBxgRMJTMZydoi
If you would prefer this information to be sent to you through the post, please contact a member of the research team (listed below) who can arrange this.
If you are interested in taking part or would like more information about the study, please contact the lead researcher directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,
Ms Cassie Screti, Dr Lou Atkinson, Dr Gemma Heath, and Dr Rachel Shaw

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Supporting young people to live well with Inflammatory Bowel Disease
A Patient and Public Involvement and Engagement (PPIE) Group

Participant Information Sheet- Young people (16-18 years)

Invitation

We would like to invite you to take part in a Patient and Public Involvement and Engagement (PPIE) group to assist in the development of a new intervention to help young people to live well with their Inflammatory Bowel Disease (IBD). This study is being carried out by researchers from Aston University and the Gastroenterology department at [redacted] as part of the researcher's PHD and is part funded by Crohn's and Colitis UK.

Before you decide if you would like to take part in the PPIE group, take the time to read the following information carefully and, if you wish, discuss it with others such as your family, and friends.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

What is the purpose of the PPIE Group?

PPIE groups allow patients and members of the public to have a direct influence on the development of new services. Members of PPIE groups have the opportunity to be involved in research projects, and their opinions can actively shape all or parts of the research.

The research team are developing a new intervention to improve treatment adherence in young people (aged 13-18) with IBD. The intervention will aim to assist young people overcome challenges they face to follow their treatment plan.

To ensure that the intervention is both appropriate and engaging, the research team are creating an online PPIE group of around eight young people who have been diagnosed with IBD. The PPIE group sessions will explore young people's views on how to ensure the proposed intervention's content and mode of delivery is engaging for young people, and the outcomes of the PPIE group sessions will directly influence the intervention's development.

Why have I been chosen?

You have been invited to take part in this study because you are a young person who has been diagnosed with IBD and under the care of the Gastroenterology clinic at [redacted] [redacted] or because you contacted the research team as you are a young person with IBD, who is interested in taking part in this study.

What will happen to me if I take part?

A researcher will talk to you about the PPIE group and answer your questions. If you are happy to join the PPIE group, the researcher will ask you to fill out an online consent form and demographic form. To begin with, you will asked to join an online introductory PPIE group session where you and around 8 other young people interested in joining the group, will learn more about the proposed intervention and how the PPIE group's views will assist in the development of the intervention. To join the introductory session and to join the PPIE group session you will need a laptop or device with internet access. This group session will take place outside of school time.

At the end of the session, you will be asked if you would be happy to partake in the PPIE group. If you do not want to join the PPIE group, you will be asked to leave the online session, while those who do wish to join the group will have the chance to give the PPIE group a name as well to decide on the dates and starting times of the future PPIEs sessions. The group will only be conducted outside of school time as to not impact your education. In addition to this, those who wish to join the group will also decide on which digital platform they would like the PPIE groups to be hosted on.
If you do wish to join the PPIE group, you will be invited to participate in a further four group online sessions, which will take place fortnightly. To attend these sessions you will need access to a laptop or device with internet access. The PPIE group will include around 8 young people and will be conducted by a PhD researcher, and a Health Psychology MSc student from Aston University. During the PPIE sessions a variety of creative methods (e.g. Drawing; Collage; playdough modelling; Lego modelling) will be used to allow you to express their thoughts and opinions. In order for these creative methods to take place, you will be sent an activity pack in the post, containing all the materials you will need, prior to the first session. We ask that you bring these to each group session. Each PPIE group session will contain a mixture of discussions, creative tasks and a comfort break; with each session estimated to last around 90 minutes. During the introductory session, the PPIE group will be asked to choose how long of a comfort break they would like within the following sessions; this may alter the duration of each session.
It is your choice whether you would like to have your camera turned on during the introductory session and the following group sessions. If you do wish to have your camera turned on, you will need to make sure that the camera cannot see anyone who is not involved in the group sessions.

How will the conversation during the PPIE group sessions be recorded and the information I provide managed?

With your permission we will audio record the group sessions and take notes. The researcher will listen to the audio files of each group session to make sufficient notes on the discussions within PPIE session. Once the researcher has achieved this, the digital audio files (stored on the University server) will be destroyed.

During the group sessions, with your permission, photographs of the outcomes of creative tasks may be taken. You will not be expected to take photographs that include people's faces. These images will be stored on the University server.

We will ensure that anything you have told us that is included in the reporting of the group sessions will be anonymous.

If you agree to take part in the PPIE group full confidentiality cannot be guaranteed on behalf of the other group members, although all group members will be asked to maintain confidentiality at the start of each group session.

Do I have to take part?

It is up to you to decide whether or not you wish to take part. Nothing will happen to you if you decide not to participate. The care you receive from [redacted] will not be affected if you decide not to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You will still be free to withdraw from the PPIE group at any time without giving a reason.

Will my taking part in this PPIE group be kept confidential?

Yes. Only the research team and the other members of the group will know you have taken part.
A code will be attached to all the data you provide to maintain confidentiality.

Your personal data (name and contact details) will only be used if the researchers need to contact you about this research project. Confidentiality will only be broken if information regarding risk of harm to a child is disclosed.

This study's consent form and demographic form will be placed on the secure online platform, Qualtrics. The lead researcher will email you a link to allow you to access these documents. Qualtrics is a secure online survey platform and is GDPR (General Data Protection Regulation) compliant. Qualtrics will temporarily store a copy of your data until it is deleted by the lead researcher at Aston University. All information stored by Qualtrics will be deleted prior to the start of the first PPIE group session.

The data we collect will be stored by Aston University in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the input from the PPIE group will inform the design of a new behaviour change intervention, aiming to improve young people's treatment adherence.

What are the possible risks and burdens of taking part?

If you decide to take part in this PPIE group, you may experience a small burden due to the time taken out of your day to attend the sessions. We will try to reduce this burden by allowing the group to choose a convent time for the group sessions to be held. The group session will take place outside of school hours.

We do not expect there to be any risks to you in taking part in this PPIE group. However, in the unlikely event that you become upset during the PPIE group, Cassie will stop the session and support you. A contact number for support will be offered.

What will happen to the results of the PPIE group?

The outcome of the PPIE group sessions will actively influence the development of a new intervention to improve young people's treatment adherence. The outcomes of the PPIE group may be published in scientific journals and/or presented at conferences. If the results of the study are published, your identity will remain confidential.

A lay summary of the outcomes of the PPIE groups will be available for the group members when the PPIE group sessions has been completed and the researchers will ask if you would like to receive a copy.

The outcomes of the PPIE group sessions will also be used in the researcher's PhD Thesis.

Expenses and payments

As a small token of thanks for your time, a £15 Amazon shopping voucher, will be emailed to you at the end of each PPIE group session you attend.

Who is funding the research?

The study is being funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 5069.

Further information

To speak to an independent advisor, you can contact: [redacted]

Research Team

Researcher:
Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath1@aston.ac.uk	Tel: 0121 204 4284
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Appendix.21. PPIE parental consent and young person (aged 13-15) assent form

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Supporting young people to live well with Inflammatory Bowel Disease
A Patient and Public Involvement and Engagement (PPIE) Group

Parental Consent Form

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please tick the boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 4, 28/10/2021) for the above Patient and Public Involvement and Engagement (PPIE) group. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my child's participation is voluntary and that they are free to leave the PPIE group at any time, without giving a reason and that withdrawal will not affect the care that my child receives from [redacted].	
3.	I agree to my child's personal data and data relating to my child collected during the study being processed as described in the Participant Information Sheet.	
4.	I understand that if during the PPIE group sessions, my child tells the research team something that causes them to have concerns in relation to my child's health and/or welfare, or that of another child, they may need to breach my child's confidentiality.	
5.	I agree to my child's PPIE group session's being audio recorded and to anonymised direct quotes from my child being used in publications resulting from the study.	
6.	I agree to photographs being taken of the outcome of my child's creative tasks produced within the PPIE group and for these anonymised photographs to be used in publications resulting from the PPIE group.	
7.	I understand that the online survey platform Qualtrics will temporarily store a copy of the information my child provides when completing this study's assent form (Version 4, 28/10/2021) and demographic form (Version 2, 03/08/2021), which will be deleted by the lead researcher at Aston University before the first PPIE group meeting.	
8.	I understand that the online survey platform Qualtrics will temporarily store a copy of the information I have provided when completing this study's parental consent form (Version 4, 28/10/2021), which will be deleted by the lead researcher at Aston University before the first PPIE group meeting.	
9.	I agree for my child to take part in this PPIE group.	

We will be sending your child an activity pack, as part of this research. Please provide us with a postal address to send this activity pack to.	

	Tick box
I would like to be sent a copy of the PPIE group results	
Please email a copy of the PPIE group results to:	
I am happy to be contacted by the research team about future research projects	
Please email information about future research projects to:	

Name of participant	Date	Signature
Name of Person receiving consent.	Date	Signature

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CROHN'S & COLITIS UK

Supporting young people to live well with Inflammatory Bowel Disease

A Patient and Public Involvement and Engagement (PPIE) Group

Assent Form, Young Person (13-15 years old)

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please tick the answers you agree with

1. Have you read and understood the information sheet (Version 4, 28/10/2021) for this project? Yes/No

2. Have you had a chance to ask questions about the research and do you understand the answers given? Yes/No

3. Do you understand that it is up to you if you want to take part in the research? Yes/No

4. Do you understand that you can change your mind, stop and not take part at any time without having to explain why and that you will still receive your usual care at [redacted] Yes/No

5. Do you understand that what you say in the PPIE group sessions will be tape recorded to allow the researcher to make detailed notes after the sessions? Yes/No

6. Do you understand that photographs may be taken of the outcome of creative tasks produced by yourself within the PPIE group sessions? Yes/No

7. I understand that Qualtrics will temporarily keep a copy of the information I provide when completing this study's consent form (Version Number 4, 28/10/2021) and demographic form (Version Number 2, 03/08/2021). Yes/No

8. Are you happy to begin the study? Yes/No

________________ ____________ ______________
Your Name Date Signature

________________ ____________ ______________

Appendix.22. PPIE Consent form for young people aged 16-18 years

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Supporting young people to live well with Inflammatory Bowel Disease
A Patient and Public Involvement and Engagement (PPIE) Group

Consent Form- Young People (16-18 years)

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please tick the boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version Number 4, 28.10.2021) for the above Patient and Public Involvement and Engagement (PPIE) group. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to leave the PPIE group at any time, without giving any reason and without affecting the usual care I receive at [redacted]	
3.	I agree to my personal data and data relating to me collected during the PPIE group being processed as described in the Participant Information Sheet.	
4.	I understand that if during the PPIE group I tell the research team something that causes them to have concerns in relation to my health and/or welfare they may need to breach my confidentiality.	
5.	I agree to the PPIE group sessions being audio recorded and to anonymised direct quotes from me being used in publications resulting from the PPIE group.	
6.	I agree to photographs being taken of the outcome of creative tasks produced by myself within the PPIE group sessions and for these anonymised photographs to be used in publications resulting from the PPIE group.	
7.	I understand that the online survey platform Qualtrics will temporarily store a copy of the information I provide when completing this study's consent form (Version Number 4, 28/10/2021) and demographic form (Version Number 2, 03/08/2021), which will be deleted by the lead researcher at Aston University before the first PPIE group meeting.	
8.	I agree to take part in this PPIE group.	

We will be sending you an activity pack, as part of this research. Please provide us with a postal address to send this activity pack to.	

please tick

I would like to be sent a copy of the PPIE group results	
Please email a copy of the PPIE group results to:	
I am happy to be contacted by the research team about future research projects	
Please email information about future research projects to:	

Name of participant Date Signature

Name of Person receiving consent Date Signature

Appendix.23. PPIE group demographic form

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Supporting young people to live well with Inflammatory Bowel Disease -

A Patient and Public Involvement and Engagement (PPIE) Group

Young person demographic questionnaire

This information will help us to see if we have spoken to a range of people with different experiences and will help us to analyse the data. All details will be kept strictly confidential to the research team.

Section 1: About You	
Age: ____________ years	**Gender:** MALE FEMALE
How would you describe your ethnicity?	
White ○ White British ○ White Irish ○ Other White Background Asian ○ Indian ○ Pakistani ○ Bangladeshi ○ Other Asian ethnic background Black ○ Caribbean ○ African ○ Other Black ethnic background	*Mixed* ☐ White and Black Caribbean ☐ White and Black African ☐ White and Asian ☐ Other mixed ethnic background Chinese or other ethnic group ☐ Chinese ☐ Any other ethnic group ☐ *Prefer not to say*
Section 3: Your condition	
At what age were you diagnosed with IBD:	**What medications do you take? How often do you need to take these?**

Appendix.24. CCTV group evaluation information pack for young people aged 13-15 years

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CROHN'S & COLITIS UK

Supporting young people to live well with Inflammatory Bowel Disease- An evaluation of the CCTV group

Dear Parent/Caregiver,

We are writing to you as your child previously took part in the CCTV and you indicated you were happy to be contacted about future research.

We are conducting research into young people's (aged 13-18) experiences of joining a Public Involvement and Engagement (PPIE) group to inform the development on a new programme aimed at improving treatment adherence in young people with Inflammatory Bowel Disease (IBD).

As the parent of a young person (aged 13-18) who has recently taken part in a PPIE group, I am writing to ask if you would be willing for your child to take part in a focus group with other young people who took part in the CCTV Group, to discuss your experiences of taking part in the CCTV group.
To access an information sheet with more details about this project please use the following link https://astonpsychology.eu.qualtrics.com/jfe/form/SV_d73Rvhh2Xamn6Zw or scan the QR code at the bottom on this letter. If you would prefer this information to be sent to you through the post, please contact a member of the research team (listed below) who can arrange this.
If you are interested in taking part or would like more information about the study, please contact the lead researcher directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,
Ms Cassie Screti, Dr Lou Atkinson, Dr Gemma Heath, and Dr Rachel Shaw

Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease

An evaluation of the CCTV group

Participant Information Sheet- Parent of a Young Person (13-15 years)

Invitation

We would like to invite your child to take part in a research study, exploring how young people experienced taking part in CCTV group. This study is being carried out by researchers from Aston University and the Gastroenterology department at [redacted] as part of the researcher's PhD thesis, and is part funded by Crohn's and Colitis UK.

Before you decide if you are happy for your child to participate in this study, please take time to read the following information and, if you wish, discuss it with others such as your family or friends.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

What is the purpose of the study?

We would like to understand young people's experiences of taking part in [insert PPIE group name], a virtual Patient and Public Involvement and Engagement (PPIE) group to help develop a new intervention to improve treatment adherence in young people with Inflammatory Bowel Disease (IBD).
This information will help to inform the development of future PPIE groups with young people.

Why has my child been invited?

Your child has been invited to take part in this study because they have taken part in an online PPIE group to help develop a new intervention to improve treatment adherence in young people with IBD, and you have previously consented for the research team to contact you about future research projects.

What will happen to my child if they take part?

A researcher will talk your child through the study and answer their questions. If you and your child are happy for your child to join the study, the researcher will ask you to fill out an online consent form and demographic form, and your child will be asked to complete an online assent form.

Your child will then take part in a focus group with other young people who took part in the same PPIE group. To be able to take part in this research, your child must follow the focus group's ground rules, which are:

- All group members will respect everybody's opinions
- All group members will ensure what is discussed in this focus group remains' within this focus group. All group members will not discuss other group member's confidential information with people outside of the group.
- When one person is speaking, group members will listen to what they have to say.
- When one person is speaking, group members will wait for them to finish speaking before they speak

The researcher will talk to your child about their experiences of taking part in the PPIE group. The focus group will last around 90 minutes, depending on how much the group has to say. The focus group will be held virtually on an online platform such as Zoom, MS Teams or Google Meet. To join the focus group your child will need a laptop or device with internet access. The focus group will take place outside of school time.

During the focus group, with your permission, a researcher will audio record the focus group's conversation. The conversation is recorded so that the researcher can listen back to everything your child has said and type it up. Your child's name will be removed after the focus group is typed so no one will know it was your child.

It is your child's choice whether they would like to have their camera turned on during the focus group. If your child does wish to have their camera turned on, they will need to ensure that the camera cannot see anyone who is not involved in the focus group.

How will the conversation during the interview be recorded and the information my child provides be managed?

With your permission we will audio record the focus group/interview and take notes. The recording will be typed into a document (transcribed) by a transcriber approved by Aston University. This process will involve removing any information which could be used to identify individuals e.g. names, locations etc.

The audio recording from your child's focus group will be transcribed within 24 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your child's data cannot be withdrawn.
Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything your child has told us that is included in the reporting of the study will be anonymous.

Your child is free not to answer any questions that are asked, without giving a reason.

If you child agrees to take part in a focus group full confidentiality cannot be guaranteed on behalf of the other focus group participants, although all participants will be asked to maintain confidentiality at the start of the focus group

Does my child have to take part?

No. It is up to you and your child to decide whether or not your child wishes to take part.

If your child does decide to participate, your child will be asked to sign and date a consent form. Your child will still be free to withdraw from the study at any time without giving a reason.

Will my child's taking part in this study be kept confidential?

Yes. Only the research team and the other focus group members will know you have taken part. A code will be attached to all the data your child provides to maintain confidentiality. Confidentiality will only be broken if information regarding risk of harm to a child is disclosed.

Your child's personal data (name and contact details) will only be used if the researchers need to contact your child to arrange study visits or collect data by phone. Analysis of your data will be undertaken using coded data.

This study's assent form, consent form and demographic form will be placed on the secure online platform, Qualtrics. For you and your child to access these documents, the lead researcher will email you a dedicated link. Qualtrics is a secure online survey platform and is GDPR (General Data Protection Regulation) compliant. This third party organisation will temporarily store a copy of yours and your child's data until it is deleted by the lead researcher at Aston University. All information stored by Qualtrics will be deleted prior to the start of the focus group.

The data we collect will be stored by Aston University, in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

What are the possible benefits of taking part?

While there are no direct benefits to your child of taking part in this study, the data gained will inform the development of future PPIE groups.

What are the possible risks and burdens of taking part?

If you and your child decide for your child to take part in this research, you may experience a small burden due to the time taken out of your child's day to attend the focus group. We will try to reduce this burden by arranging a convenient time for the focus group to be held. The group session will take place outside of school hours.
We do not expect there to be any risks to your child in taking part in this study. However, in the unlikely event that your child becomes upset during the research, the focus group will be terminated and the research team will be able to guide your child towards sources of support.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your child's identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in the researcher's PhD Thesis.

Expenses and payments

As a small token of thanks for their time, a £15 Amazon shopping voucher, will be emailed to each participant who takes part in this research

Who is funding the research?

The study is being funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

What if I have a concern about my child's participation in the study?

If you have any concerns about your child's participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 5069.

Further information

To speak to an independent advisor, you can contact: [redacted]

Research Team

Researcher:
Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath1@aston.ac.uk	Tel: 0121 204 4284
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

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CROHN'S & COLITIS UK

Supporting young people to live well with Inflammatory Bowel Disease

An evaluation of the CCTV group

Participant Information Sheet- Young person (aged 13-15)

Invitation

We would like to ask for your help with our research project.

We would like to talk to you about your experiences of taking part in the CCTV group. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take the time to read this information and discuss it with friends, family or us if you wish.
This research is being carried out by researchers from Aston University with the Doctor from the Gastroenterology clinic at [redacted] If you would like more information please contact Cassie or Lou who are leading the project. Their emails and phone numbers can be found at the end of this information sheet.

What is this project about?

We would like to understand your experiences of taking part in [insert PPIE group name], a virtual Patient and Public Involvement and Engagement (PPIE) group to help develop a new programme to help young people with Inflammatory Bowel Disease (IBD) follow their treatment plan.
This information will help to inform the development of future PPIE groups with young people.

Why have I been invited?

You have been invited to take part in this study because you are a young person who has taken part in an online PPIE group, to help develop a new programme to help young people with IBD follow their treatment plan, and your parents/caregiver has consented for us to contact you about future research projects.

Do I have to take part?

No, it is your choice. If you decide to take part, you are free to change your mind without giving a reason and free to skip difficult questions. If you decide to stop taking part, just let the researchers know and they will stop the meeting. Nothing will happen to you if you decide not to participate. The care you receive from [redacted] [redacted] will not be affected if you decide not to take part.

What will happen to me if I take part?

A researcher will talk you through the study and answer your questions. If you are happy to join the study, the researcher will ask you to sign an online form to say you are happy to take part. Then we will need to ask a parent or carer to give us permission to let you take part in the study by filling out an online consent form and a demographic form.

You will then take part in a focus group with other young people who took part in the [insert PPIE group name]. The conversation is recorded so that the researcher can listen back to everything you have said and type it up. Your name will be removed after the interview is typed so no one will know it was you.
To be able to take part in this research, you must follow the focus group's ground rules which are:

- All group members will respect everybody's opinions.
- All group members will ensure what is discussed in this focus group remains' within this focus group. All group members will not discuss other group member's confidential information with people outside of the group.
- When one person is speaking, group members will listen to what they have to say.
- When one person is speaking, group members will wait for them to finish speaking before they speak.

The researcher will talk to you about your experiences of taking part in the PPIE group. The focus group last around 90 minutes, depending on how much the group has to say. The focus group will be held virtually on an online platform such as Zoom, MS Teams or Google Meet. To join the focus group you will need a laptop or device with internet access. The focus group will take place outside of school time.

You can choose if you would like to have your camera turned on during the focus group. If you do wish to have your camera turned on, you will need to make sure that the camera cannot see anyone who is not involved in the focus group.

What are the possible risks or benefits of taking part?

If you decide to take part in this research, you may experience a small burden due to the time taken out of your day to attend the focus group location. We will try to reduce this burden by arranging a convenient time for the focus group to be held. The focus group will take place outside of school time.

We do not expect there to be any risks to you in taking part in this study. In the unlikely event that you become upset during the focus group, the researcher will stop the interview and audio recording and support you. A contact number for support will be offered. Some people like taking part as the findings could help with the development of future PPIE groups.

Will other people know that I have taken part in the project?

No. Only the research team, your parents and the other focus group members will know that you have taken part. Your name and other personal information will be removed from the typed-up interview so no one will know that it is you. The only time when we would need to tell someone else is if you tell us something that suggests a risk of harm to yourself or others. The research team will ensure that all information is kept securely and confidentially at Aston University. Only the research team will be able to access the interviews.

This study's assent form and demographic form will be placed on the secure online platform, Qualtrics. The lead researcher will email you a specific link to allow you to access these documents. Qualtrics is a secure online platform and is GDPR (General Data Protection Regulation) compliant. Qualtrics will temporarily store a copy of your information until it is removed by the lead researcher at Aston University. Your information will be removed from Qualtrics prior to the start of the focus group.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

We will send you a summary of the findings of the research in words you can understand.

The results of the study will also be used in the researcher's PhD Project.

Expenses and payments

As a small token of thanks for your time, a £15 Amazon shopping voucher, will be emailed to you if you take part.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

Who is organising the research?

The research is organised by Aston University in collaboration with Crohn's and Colitis UK.

Who can I contact if I have any questions or worries?

If you have any concerns about anything to do with this study, please speak to the research team and we will do our best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 5069.

Further information

To speak to an independent advisor, you can contact: [redacted]

What do I do now?

If you would like to take part in the research, or would like further information, please contact Cassie, or you can ask your parent to contact Cassie, whose details can be found below.

Research Team

Researcher:
Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath1@aston.ac.uk	Tel: 0121 204 4284
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

Appendix.25. CCTV group evaluation information pack for young people aged 16-18 years

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CROHN'S & COLITIS UK

Supporting young people to live well with Inflammatory Bowel Disease- An evaluation of the CCTV group

Dear ,

We are writing to you as you previously took part in the CCTV group and you indicated you were happy to be contacted about future research.

We are conducting research into young people's (aged 13-18) experiences of joining a Public Involvement and Engagement (PPIE) group to inform the development on a new programme aimed helping young people live well with Inflammatory Bowel Disease (IBD).

As a young person (aged 13-18) who has recently taken part in a PPIE group, I am writing to ask if you would be willing to take part in a focus group with other young people who took part in the CCTV group, to discuss your experiences of taking part in the CCTV group.
To access an information sheet with more details about this project please use the following link https://astonpsychology.eu.qualtrics.com/jfe/form/SV_djrUfVxc56M4dr8 or scan the QR code at the bottom on this letter. If you would prefer this information to be sent to you through the post, please contact a member of the research team (listed below) who can arrange this.
If you are interested in taking part or would like more information about the study, please contact the lead researcher directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,
Ms Cassie Screti, Dr Lou Atkinson, Dr Gemma Heath, and Dr Rachel Shaw

Supporting young people to live well with Inflammatory Bowel Disease

An evaluation of the CCTV group

Participant Information Sheet- Young people (16-18 years)

Invitation

We would like to talk to you about what it was like to participate in the CCTV group. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information sheet and discuss it with friends, family or us if you wish.
This research is being carried out by researchers from Aston University with the Doctors from the Gastroenterology clinic at [redacted] as part of the researcher's PhD thesis, and is part funded by Crohn's and Colitis UK. If you would like more information please contact Cassie or Lou who are leading the project. Their emails and phone numbers can be found at the end of this information sheet.

What is the purpose of the study?

We would like to understand your experiences of taking part in the [insert PPIE group name] group, a virtual Patient and Public Involvement and Engagement (PPIE) group to assist in the development of a new intervention to improve treatment adherence in young people with Inflammatory Bowel Disease (IBD).
This information will help to inform the development of future PPIE groups with young people.

Why have I been invited?

You have been invited to take part in this study because you have taken part in an online PPIE group to help develop a new intervention to improve treatment adherence in young people with IBD, and you consented for us to contact you about future research projects.

What will happen to me if I take part?

A researcher will talk you through the study and answer your questions. If you are happy to join the study, the researcher will ask you to fill out a Consent form and demographic form online.

You will then take part in a focus group with other young people who took part in the same PPIE group as yourself. To be able to take part in this research, you must follow the focus group's ground rules which are:

- All group members will respect everybody's opinions
- All group members will ensure what is discussed in this focus group remains' within this focus group. All group members will not discuss other group member's confidential information with people outside of the group.
- When one person is speaking, group members will listen to what they have to say.
- When one person is speaking, group members will wait for them to finish speaking before they speak

The researcher will talk to you about your experiences of taking part in the PPIE group. The focus group will last around 90 minutes, depending on how much the group has to say. The focus group will be held virtually on an online platform such as Zoom, MS Teams or Google Meet. To join the focus group you will need a laptop or device with internet access. The focus group will take place outside of school time.

During the focus group, with your permission, the researcher will audio record your conversation. The conversation is recorded so that the researcher can listen back to everything you have said and type it up. Your name will be removed after the focus group is typed so no one will know it was you.

It is your choice whether you would like to have your camera turned on during the focus group. If you do wish to have your camera turned on, you will need to make sure that the camera cannot see anyone who is not involved in the focus group.

How will the conversation during the focus group be recorded and the information I provide managed?

With your permission we will audio record the focus groups and take notes. The recording will be typed into a document (transcribed) by a transcriber approved by Aston University. This process will involve removing any information which could be used to identify individuals e.g. names, locations etc.

The audio recording from the focus group will be transcribed within 24 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your data cannot be withdrawn.
Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything you have told us that is included in the reporting of the study will be anonymous.

You are free not to answer any questions that are asked, without giving a reason.

If you agree to take part in a focus group full confidentiality cannot be guaranteed on behalf of the other focus group participants, although all participants will be asked to maintain confidentiality at the start of the focus group

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part. Nothing will happen to you if you decide not to participate. The care you receive from [redacted] will not be affected if you decide not to take part.

If you do decide to participate, you will be asked to sign and date a consent form. You will still be free to withdraw from the study at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. Only the research team and the other focus group members will know you have taken part. A code will be attached to all the data you provide to maintain confidentiality. Confidentiality will only be broken if information regarding risk of harm to a child is disclosed.

Your personal data (name and contact details) will only be used if the researchers need to contact you about this research project.

This study's consent form and demographic form will be placed on the secure online platform, Qualtrics. The lead researcher will email you a link to allow you to access these documents. Qualtrics is a secure online survey platform and is GDPR (General Data Protection Regulation) compliant. Qualtrics will temporarily store a copy of your data until it is deleted by the lead researcher at Aston University. All information stored by Qualtrics will be deleted prior to the start of the focus group.

The data we collect will be stored by Aston University, in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform the design of future PPIE groups with young people.

What are the possible risks and burdens of taking part?

If you decide to take part in this research, you may experience a small burden due to the time taken out of your day to participate in the focus group. We will try to reduce this burden by arranging a convenient time for the focus group to be held. The focus group will take place outside of school time.

We do not expect there to be any risks to you in taking part in this study. However, in the unlikely event that you become upset during the focus group, the researcher will stop the interview and audio recording and support you. A contact number for support will be offered.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in the researcher's PhD Thesis.

Expenses and payments

As a small token of thanks for your time, a £15 Amazon shopping voucher, will be given to each participant who takes part in this research.

Who is funding the research?

The study is being funded by Crohn's and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 5069.

Further information
To speak to an independent advisor, you can contact: [redacted]

Research Team

Researcher:
Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath1@aston.ac.uk	Tel: 0121 204 4284
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Appendix.26. CCTV group evaluation parental consent and young person (aged 13-15) assent form

Aston University
Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease

An evaluation of the CCTV group

Parental Consent Form

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please tick the boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 4, 28/10/2021) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my child's participation is voluntary and that they are free to withdraw at any time during the focus group, without giving a reason and that withdrawal will not affect the care that my child receives from [redacted]	
3.	I agree to my child's personal data and data relating to my child collected during the study being processed as described in the Participant Information Sheet.	
4.	I understand that if during the study, my child tells the research team something that causes them to have concerns in relation to my child's health and/or welfare, or that of another child, they may need to breach my child's confidentiality.	
5.	I agree to my child's focus group being audio recorded and to anonymised direct quotes from my child being used in publications resulting from the study.	
6.	I understand that the online survey platform Qualtrics will temporarily store a copy of the information my child provides when completing this study's assent form (Version 4, 28/10/2021) and demographic form (Version 2, 03/08/2021), which will be deleted by the lead researcher at Aston University before the start of the focus group.	
7.	I understand that the online survey platform Qualtrics will temporarily store a copy of the information I have provided when completing this study's parental consent form (Version 4, 28/10/2021), which will be deleted by the lead researcher at Aston University before the start of the focus group.	
8.	I agree for my child to take part in this study.	

	Tick box
I would like to be sent a copy of the study results	
Please email a copy of the study results to:	

Name of participant Date Signature

Name of Person receiving consent Date Signature

Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease

An evaluation of the [insert PPIE group name]

Assent Form

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please tick the answers you agree with

1. Have you read and understood the information sheet (Version 4, 28.10.2021) for this project? Yes/No

2. Have you had a chance to ask questions about the research and do you understand the answers given? Yes/No

3. Do you understand that it is up to you if you want to take part in the research? Yes/No

4. Do you understand that you can change your mind, stop and not take part at any time without having to explain why and that you will still receive the same care from [redacted] Yes/No

5. Do you understand that what you say in the focus group will be tape recorded and typed out after the focus group by a different group of people? Yes/No

6. I understand that Qualtrics will temporarily keep a copy of the information I provide when completing this study's consent form (Version Number 4, 28/10/2021) and demographic form (Version Number 2, 03/08/2021). Yes/No

7. Are you happy to begin the study? Yes/No

____________________ ________________ ____________________

Your Name Date Signature

____________________ ________________ ____________________

Researchers Name Date Signature

Appendix.27. CCTV group evaluation young person (aged 16-18) consent form

Supporting young people to live well with Inflammatory Bowel Disease

An evaluation of the CCTV group

Consent Form- Young Person (aged 16-18 years)

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please tick the boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 4, 28/10/2021) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time during the focus group, without giving any reason and without affecting the usual care I receive at [redacted]	
3.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.	
4.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare, or that of another child they may need to breach my confidentiality.	
5.	I agree to the focus group being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study Sign if you wish to participate in focus group.	
6.	I understand that the online survey platform Qualtrics will temporarily store a copy of the information I provide when completing this study's consent form (Version Number 4, 28/10/2021) and demographic form (Version Number 2, 03/08/2021), which will be deleted by the lead researcher at Aston University before the start of the focus group.	
7.	I agree to take part in this study.	

	Tick box
I would like to be sent a copy of the study results	
Please email a copy of the study results to:	

Name of participant   Date   Signature

Name of Person receiving consent.   Date   Signature

Appendix.28. CCTV group evaluation interview schedule

Illustration removed for copyright restrictions

PPIE Focus Group Interview guide

Before we begin, I would like to remind you of the rules we will be following during this focus group.

- All group members will respect everybody's opinions
- All group members will ensure what is discussed in this focus group remains' within this focus group. All group members will not discuss other group member's confidential information with people outside of the group.
- When one person is speaking, group members will listen to what they have to say.
- When one person is speaking, group members will wait for them to finish speaking before they speak

- How did you first hear about the PPIE group?
    - What made you get involved?
- Can you tell me about your experiences of attending the introductory session to join PPIE group?
    - What did you like about it?
    - What did you not like about it?
- Can you tell me about your experiences of taking part in the PPIE group sessions?
    - What did you like about it?
    - What could have been improved?
    - What was it like meeting online rather than face to face?
- What do you think about the use of creative methods within the PPIE group session?
    - What did you like about it?
    - What did you not like about it?
- What did you learn during your time with the PPIE group?
    - How did the PPIE group allow you to learn this?
    - Is there any other skills you would have liked to have learnt?
- What was the most important part of the PPIE group for you?
    - What did you like the best?
    - What was the least important part of the programme?

- How could the PPIE group be improved?
    - Did the PPIE group meet your expectations?
    - Did you receive all the help you needed whilst part of the PPIE group?

- Would you be interested in joining another PPIE group in the future?
    - Why would you be interested I joining another group
    - What would make you want to join another group

- Is there anything else we haven’t discussed that you think is important?
    - Why do you feel this is important?

Appendix.29. CCTV group evaluation participant demographic form

Supporting young people to live well with Inflammatory Bowel Disease - An evaluation of the CCTV group

Young person demographic questionnaire

This information will help us to see if we have spoken to a range of people with different experiences and will help us to analyse the data. All details will be kept strictly confidential to the research team.

Section 1: About You	
Age: ____________ years	**Gender:** MALE FEMALE
How would you describe your ethnicity?	
White o White British o White Irish o Other White Background Asian o Indian o Pakistani o Bangladeshi o Other Asian ethnic background Black o Caribbean o African o Other Black ethnic background	*Mixed* ☐ White and Black Caribbean ☐ White and Black African ☐ White and Asian ☐ Other mixed ethnic background Chinese or other ethnic group ☐ Chinese ☐ Any other ethnic group ☐ *Prefer not to say*
Section 3: Your condition	
At what age were you diagnosed with IBD:	**What medications do you take? How often do you need to take these?**

Appendix.30. Podcast audio

See Supplementary File.1 on Box.

Appendix.31. Intervention assessment study information pack for parents

Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease

Dear Parent/Caregiver,

Researchers at [redacted] and Aston University are conducting an online focus group of parents of young people (aged 13-18) with IBD, to help with the development of a new intervention to improve treatment adherence in young people (aged 13-18) with Inflammatory Bowel Disease (IBD).

As the parent of a young person (aged 13-18) with IBD, I am writing to ask if you would be willing to take part in a focus group with other parents of young people with IBD. During the focus group, the researchers will demonstrate the new intervention to you, and then ask you to share your thoughts on the feasibility of the new intervention.
To access an information sheet with more details about this project please use the following link https://astonpsychology.eu.qualtrics.com/jfe/form/SV_5h9dhgHA6cuCsRM or scan the QR code at the bottom on this letter. If you would prefer this information to be sent to you through the post, please contact a member of the research team (listed below) who can arrange this.
If you are interested in taking part or would like more information about the study, please contact the lead researcher directly:

Researcher: Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541
Research Supervisors: Dr Lou Atkinson, Dr Gemma Heath, Dr Rachel Shaw

Yours sincerely,

Ms Cassie Screti, Dr Lou Atkinson, Dr Gemma Heath, and Dr Rachel Shaw

Illustration removed for copyright restrictions

Supporting young people to live well with Inflammatory Bowel Disease

A parental evaluation of a new intervention for young people with IBD

Participant Information Sheet

Invitation

We would like to learn more about parent's views on a new intervention to improve treatment adherence in young people (aged 13-18) with Inflammatory Bowel Disease (IBD).

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information sheet and discuss it with friends, family or us if you wish.

This research is being carried out by researchers from Aston University with the Doctors from the Gastroenterology clinic at [redacted] as part of the researcher's PhD thesis, and is part funded by Crohn's and Colitis UK. If you would like more information please contact Cassie or Lou who are leading the project. Their emails and phone numbers can be found at the end of this information sheet.

What is the purpose of the study?

We would like to understand your views on a newly developed intervention, aiming to improve young people (ages 13-18 years) treatment adherence. The design and content of this intervention has been informed by the views of young people with IBD. We are now interested to hear parent's thoughts of this intervention, including the feasibility of this intervention.

This information will help to inform the further development of the intervention.

Why have I been invited?

You have been invited to take part in this study because you are the parent of a young person (ages 13-18 years) with IBD.

What will happen to me if I take part?

A researcher will talk you through the study and answer your questions. If you are happy to join the study, the researcher will ask you to fill out a consent form and demographic form online.

You will then take part in a focus group with other parents of young people with IBD. To be able to take part in this research, you must follow the focus group's ground rules which are:

- All group members will respect everybody's opinions.
- All group members will ensure what is discussed in this focus group remains' within this focus group. All group members will not discuss other group member's confidential information with people outside of the group.
- When one person is speaking, group members will listen to what they have to say.
- When one person is speaking, group members will wait for them to finish speaking before they speak.

The researcher will start the focus group by sharing the content of the intervention with the group members, and will parents will be able to share their views on the intervention. The focus group will last around 90 minutes, depending on how much the group has to say. The focus group will be held virtually on an online platform such as Zoom, MS Teams or Google Meet. To join the focus group you will need a laptop or device with internet access.

During the focus group, with your permission, the researcher will audio record your conversation. The conversation is recorded so that the researcher can listen back to everything you have said and for the conversation to be typed up. Your name will be removed after the focus group is typed so no one will know it was you.

It is your choice whether you would like to have your camera turned on during the focus group. If you do wish to have your camera turned on, you will need to make sure that the camera cannot see anyone who is not involved in the focus group.

How will the conversation during the focus group be recorded and the information I provide managed?

With your permission we will audio record the focus groups and take notes. The recording will be typed into a document (transcribed) by a transcriber approved by Aston University. This process will involve removing any information which could be used to identify individuals e.g. names, locations etc.

The audio recording from the focus group will be transcribed within 24 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your data cannot be withdrawn.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything you have told us that is included in the reporting of the study will be anonymous.

You are free not to answer any questions that are asked, without giving a reason.

If you agree to take part in a focus group full confidentiality cannot be guaranteed on behalf of the other focus group participants, although all participants will be asked to maintain confidentiality at the start of the focus group

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part. Nothing will happen to you if you decide not to participate.

If you do decide to participate, you will be asked to sign and date an online consent form. You will still be free to withdraw from the focus group at any time without giving a reason.

Will my taking part in this study be kept confidential?

Yes. Only the research team and the other focus group members will know you have taken part. A code will be attached to all the data you provide to maintain confidentiality. Confidentiality will only be broken if information regarding risk of harm to yourself or a child is disclosed.

Your personal data (name and contact details) will only be used if the researchers need to contact you about this research project.

This study's consent form and demographic form will be placed on the secure online platform, Qualtrics. The lead researcher will email you a link to allow you to access these documents. Qualtrics is a secure online survey platform and is GDPR (General Data Protection Regulation) compliant. Qualtrics will temporarily store a copy of your data until it is deleted by the lead researcher at Aston University. All information stored by Qualtrics will be deleted prior to the start of the focus group.

The data we collect will be stored by Aston University in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will inform the design of future PPIE groups with young people.

What are the possible risks and burdens of taking part?

If you decide to take part in this research, you may experience a small burden due to the time taken out of your day to participate in the focus group. We will try to reduce this burden by arranging a convenient time for the focus group to be held.

We do not expect there to be any risks to you in taking part in this study. However, in the unlikely event that you become upset during the focus group, the researcher will stop the interview and audio recording and support you. A contact number for support will be offered.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

A lay summary of the results of the study will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

The results of the study will also be used in the researcher’s PhD Thesis.

Expenses and payments

As a small token of thanks for your time, a £15 Amazon shopping voucher, will be emailed to each participant who takes part in this research.

Who is funding the research?

The study is being funded by Crohn’s and Colitis UK and Aston University.

Who is organising this study and acting as data controller for the study?

Aston University is organising this study and acting as data controller for the study. You can find out more about how we use your information in Appendix.A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the London Bloomsbury Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or telephone 0121 204 5069.

Further information

To speak to an independent advisor, you can contact: [redacted]

Research Team

Researcher:

Ms Cassie Screti Email: scretic@aston.ac.uk Tel: 0121 204 4541

Research Supervisors:

Dr Lou Atkinson	Email: l.akinson1@aston.ac.uk	Tel: 0121 204 4541
Dr Gemma Heath	Email: g.heath1@aston.ac.uk	Tel: 0121 204 4284
Dr Rachel Shaw	Email: r.l.shaw@aston.ac.uk	Tel: 0121 204 5040

Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details.

- Your name
- Your contact details, such as an email address or telephone number.
- Information about your employment

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 0121 204 3000

Appendix.32. Intervention assessment parental focus group consent form

Aston University
BIRMINGHAM UK

Aston University
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CROHN'S & COLITIS UK

Supporting young people to live well with Inflammatory Bowel Disease

An evaluation of a new intervention for young people with IBD

Consent Form

Researchers: Ms Cassie Screti; Dr Lou Atkinson; Dr Rachel Shaw; Dr Gemma Heath

Please tick the boxes

1.	I confirm that I have read and understand the Participant Information Sheet (Version 3, 28/10/2021) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time during the focus group.	
3.	I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet.	
4.	I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare, or that of another child they may need to breach my confidentiality.	
5.	I agree to the focus group being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study	
6.	I understand that the online survey platform Qualtrics will temporarily store a copy of the information I provide when completing this study's consent form (Version Number 3, 28/10/2021) and demographic form (Version Number 1, 03/08/2021), which will be deleted by the lead researcher at Aston University before the start of the focus group.	
7.	I agree to take part in this study.	

	Tick box
I would like to be sent a copy of the study results	
Please email a copy of the study results to:	

Name of participant Date Signature

Name of Person receiving consent. Date Signature

Appendix.33. Intervention assessment parental focus group consent form

Aston University
BIRMINGHAM UK

Aston University
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CROHN'S & COLITIS UK

Supporting young people to live well with Inflammatory Bowel Disease

An evaluation of a new intervention for young people with IBD

Parent participant demographic questionnaire

This information will help us to see if we have spoken to a range of people with different experiences and will help us to analyse the data. All details will be kept strictly confidential to the research team.

Section 1: About You

Age: ____________ years

Gender: MALE FEMALE

How would you describe your ethnicity?

White
☐ White British
☐ White Irish
☐ Other White Background

Asian
☐ Indian
☐ Pakistani
☐ Bangladeshi
☐ Other Asian ethnic background

Black
☐ Caribbean
☐ African
☐ Other Black ethnic background

Mixed
☐ White and Black Caribbean
☐ White and Black African
☐ White and Asian
☐ Other mixed ethnic background

Chinese or other ethnic group
☐ Chinese

☐ Any other ethnic group

☐ *Prefer not to say*

Section 2: About your child

Age: ____________ years

Gender: MALE FEMALE

How would you describe your child's ethnicity?

White
☐ White British
☐ White Irish
☐ Other White Background

Asian

Mixed
☐ White and Black Caribbean
☐ White and Black African
☐ White and Asian
☐ Other mixed ethnic background

☐ Indian
☐ Pakistani
☐ Bangladeshi
☐ Other Asian ethnic background

Black
☐ Caribbean
☐ African
☐ Other Black ethnic background

Chinese or other ethnic group
☐ Chinese

☐ Any other ethnic group

☐ *Prefer not to say*

Section 3: Your child's condition

At what age was your child diagnosed with IBD:	**Does your child take medication? YES / NO** **If yes, how often does your child take medication?**
How well controlled is your child's IBD:	

Thank you

Appendix.34 Intervention assessment parental focus group interview schedule

Parental Focus Group Interview guide

Before we begin, I would like to remind you of the rules we will be following during this focus group.

- All group members will respect everybody's opinions
- All group members will ensure what is discussed in this focus group remains' within this focus group. All group members will not discuss other group member's confidential information with people outside of the group.
- When one person is speaking, group members will listen to what they have to say.
- When one person is speaking, group members will wait for them to finish speaking before they speak

- Tell me your first impressions of the proposed interventions?
    - Why do you think this?

- What do you like about the intervention?
    - Why do you like this?
    - What don't you like about the intervention?

- How practical do you think the intervention will be for young people?
    - How practical is the intervention?
    - What do you think about the time commitments needed to engage with the intervention?

- How suitable do you think the intervention will be for young people?
    - In your experience, how appropriate is the interventions content?
    - In your experience, how suitable are the materials used within the intervention?

- What challenges or difficulties do you think young people might face during this intervention?
    - Are there any social challenges/difficulties to taking part in this intervention?
    - Are there any emotional challenges/difficulties to taking part in this intervention?

- What changes could be made to this intervention to further improve young people's treatment adherence?
    - Why would this be helpful?
    - How would you make these changes?
- Is there anything you would like to add?