AN EXPLORATION OF THE MISUSE OF OVER THE COUNTER AND PRESCRIPTION ONLY MEDICATION IN SUBSTANCE MISUSE TREATMENT SERVICES

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Thesis Summary

An Exploration of the Misuse of Over the Counter and Prescription Only Medication in Substance Misuse Treatment Services

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Background: There are growing concerns about the misuse of over the counter (OTC) and prescription only medication (POM), due to the associated negative socioeconomic and health implications. To improve care delivery, more needs to be known about how this affects people who are accessing specialist substance misuse services (SMS).

Aims and Objectives: The overall aim was to explore the misuse of OTC and POM by adults that were accessing community SMS. To achieve this, the objectives were to complete three linked phases:

1. Systematic review of the published literature *(PROSPERO: CRD42020135216)*;
2. Questionnaires completed by adults accessing English community SMS, to identify the OTC/POM types involved and associated characteristics;
3. Semi-structured interviews with adults accessing SMS, SMS staff and affected friends/family, to explore their associated experiences.

Methods and Key Findings: The systematic review identified thirteen relevant studies and highlighted the paucity of published literature. Oral sedating medication (especially opioids and benzodiazepines) predominated the findings from the fifty-six questionnaires, and demographic characteristics were typical of people who usually access English SMS (middle-aged White men). To enable a more in-depth understanding of the experiences of OTC/POM misuse in SMS, thematic analyses of 24 interviews with adults accessing SMS, 20 SMS staff and 8 affected friends/family were undertaken. This research was conducted during COVID-19, in community adult SMS, operated by a national treatment provider. OTC/POM misuse was associated with a wide range of adverse socioeconomic, physical, and psychological effects. Polypharmacy and concomitant use of other substances was commonplace. Unmanaged withdrawal symptoms caused concern and contributed to perpetuating misuse: sudden cessation in supplies created risks.

Conclusion: OTC/POM misuse should be routinely enquired about during healthcare reviews and tailored harm reduction, pharmacological and psychosocial interventions offered (including support for friends/family). Future research should investigate perceived barriers to SMS engagement and identify if demographic characteristics and treatment needs differ by OTC/POM type.

A variety of outputs from the work contained in this thesis, including publications in peer reviewed journals, oral and poster presentations at international conferences can be found in ***Appendix 1: Summary of Publications/Contributions*****.**

Dedication

This work is dedicated to my husband Andy and son Dan for their continued support during my studies. This research would not have been possible without the contributions of people who use substances, their family and friends, and the staff working in treatment provider services.

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Contents

Abbreviations

AA	Alcoholics Anonymous
ACMD	Advisory Council on the Misuse of Drugs
AMSTAR2	A Measurement Tool to Assess Systematic Reviews (version 2)
BRS	Barnsley Recovery Steps (Barnsley SMS operated by Humankind)
CERQual	Confidence in Evidence from Reviews of Qualitative research
CMHP	College of Mental Health Pharmacy
COVID-19	COronaVIrus Disease 2019 (contagious disease caused by severe acute respiratory syndrome coronavirus 2, a global pandemic which started in 2019)
CRS	Calderdale Recovery Steps (Calderdale SMS operated by Humankind)
EDP	Exeter Drugs Project (a subsidiary of Humankind, SMS provider for Devon and Dorset)
FL	Forward Leeds (Leeds SMS operated by Humankind)
GP	General Practitioner
GPhC	General Pharmaceutical Council
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HALO	Clinical records system used by SMS in Devon and Dorset
HIV	Human Immunodeficiency Virus, a blood born virus
IM	Ian Maidment (Research Supervisor)
IPED	Image and Performance Enhancing Drug
LM	Louise Missen, SMS pharmacist (reviewer involved with the systematic review)
LUCID-B	Living Under Coronavirus and Injecting Drugs in Bristol
MMAT	Mixed Methods Appraisal Tool
MS Excel®	Microsoft® Excel® (version 16), software used for creating spreadsheets
NA	Narcotics Anonymous

NDTMS	National Drug Treatment Monitoring System
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NSP	Needle Syringe Provision
NVivo®	Software (version 12) for analysing qualitative data
NYH	North Yorkshire Horizons (North Yorkshire SMS operated by Humankind)
OHID	Office for Health Improvement and Disparities: part of the UK Government Department of Health and Social Care, previously known as PHE
OST	Opioid Substitute Treatment (usually methadone or buprenorphine as a prescribed intervention for opioid dependence)
OTC	Over the Counter (medication which may be purchased from a pharmacy without a prescription)
PHE	Public Health England: now known as OHID
PIS	Participant Information Sheet
POM	Prescription Only Medication (medication which may only be legally obtained on a prescription)
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	Prospective Register of Systematic Reviews
PRUK	Pharmacy Research UK
PSI	Psychosocial Interventions
RCGP	Royal College of General Practitioners
REACH	Dorset SMS (operated by EDP)
RG	Rosalind Gittins (Researcher)
RV	Roya Vaziri, Humankind's Executive Medical Director (reviewer involved with the questionnaires/interviews)

SMS	Substance Misuse Service
SPSS®	Statistical Package for the Social Sciences (version 26), software for analysing quantitative data
STARS	Staffordshire Treatment and Recovery Service (Staffordshire SMS operated by Humankind)
SWiM	Synthesis Without Meta-analysis
Systm1	Clinical records system used by SMS in Barnsley, Calderdale, Leeds, North Yorkshire Horizons and Staffordshire
TOGETHER	Devon SMS (operated by EDP)
UK	United Kingdom

Tables and Figures

1. Introduction

The overall aim of this research was to explore the misuse of Over the Counter (OTC) and Prescription Only Medication (POM), by adults that were accessing specialist community substance misuse services (SMS). This introductory chapter provides an overview of the subject matter, including associated terminology, and the context in which this research was undertaken. This chapter concludes with a summary of how the overall aim and associated objectives were achieved through the structure of this thesis.

1.1. Background

1.1.1. Terminology

The published literature uses a variety of terms to describe when medicines are used in a way other than as the manufacturers intended, or as directed by a healthcare professional (Barrett, *et al.,* 2008; Smith *et al.,* 2013; UNODC, 2011). For this research, the specific term 'misuse' has been selected to describe the intentional, inappropriate use of medicinal products (where the administration route or dose may also be altered), for desired, non-medical purposes, on a single or repeated occasion (Smith *et al.,* 2013). This term was felt to be most appropriate because some people may not view their misuse as 'problematic' or 'non-medical', for example if they do not perceive that the medication is having a negative impact, or if they believe the medication is helping underlying health concerns.

Although the term 'misuse' is used widely, including to describe the use of illicit substances, it is important to note that this is contested by some who may view it as stigmatising and inaccurate; however, for medicines, it is considered that *"an exception may be claimed if people are using pharmaceuticals in ways that goes against advice from the supplier"* (SDF, 2020a). Dependence is defined as a mental health condition (NICE, 2010), and whilst misuse does not always result in dependency, (and the risk of this varies by the medication type and other risk factors that may be present), it is usually more likely to occur if the medication has a psychoactive effect, is taken regularly and/or in greater amounts.

For consistency, the term 'misuse' was also used in this research to describe specialist treatment services, since across the United Kingdom (UK), they continue to be commissioned as 'SMS' (PHE, 2020b). In England, community (primary care) SMS are commissioned by local authorities and are usually operated by National Health Service (NHS) or third sector (charity) providers. Although local commissioning arrangements vary, these SMS usually provide interventions for people regardless of which substances/medicines are problematic for them.

In the UK, the term OTC incorporates Pharmacy Only medicines which can only be sold from General Pharmaceutical Council (GPhC) registered pharmacies, either by or under the supervision of a pharmacist, or a General Sales List medication which can be purchased from additional retail outlets such as supermarkets (MHRA, 2024a). POM can only be supplied in accordance with the Human Medicines

Regulations 2012, which usually require a prescription to be written by an authorised healthcare professional, that is then used by a pharmacy to lawfully supply the medication (MHRA, 2024a; National Archives, 2024a). OTC and POM may therefore be legally sourced, though sometimes multiple outlets or healthcare professionals are used to obtain supplies; however, they may also be obtained illegally, for example via diverted supplies from friends or family, street dealers or unregulated internet purchases (Gossop and Moos, 2008; Fischer, *et al.,* 2006; Rosenblum, *et al.,* 2007).

1.1.2. Reasons for OTC and POM Misuse

For many years, the misuse of OTC and POM has been of growing international concern in both developed and developing countries (Klein, *et al.,* 2020; Nielsen, *et al.,* 2015b; Roberts and Skinner, 2014; Van Hout, *et al.,* 2017; Winstock and Strang, 1999). Some of these medicines, including antidepressants, stimulants, hypnotics, anxiolytics, and antipsychotics, are licenced for mental health conditions, such as attention deficit hyperactivity disorder, anxiety, depression, insomnia and schizophrenia. Others are licenced for physical health issues, such as opioid analgesics for pain management and antihistamines for allergies.

Medicines are most commonly misused when they are psychoactive, and especially when they are known to cause euphoric, stimulating, or hypnotic effects. Sometimes significantly high doses are required for these effects to become apparent, such as the antitussive dextromethorphan (Martinak, *et al.,* 2017) and the antidiarrheal loperamide (Akel and Bekheit, 2018; Antoniou and Juurlink, 2017; Eggleston, *et al.,* 2016).

When being misused, formulations may be manipulated, and/or the medication may be administered by other routes. For example, buprenorphine tablets may be crushed and administered by injection or snorted, and fentanyl may be extracted from transdermal patches and administered by a variety of other routes including by mouth, insertion into the rectum, nasal insufflation, inhalation, and injection (DrugWatch, 2017; Varescon, *et al.,* 2002). Sometimes the psychoactive effect of OTC/POM may only become apparent when taken via an alternative route, such as Buscopan® (hyoscine N-butyl bromide), which when smoked produces hallucinations (Jalali, *et al.,* 2014). Another example is codeine, which can be combined with other substances to create new concoctions such as ‘Lean’ (DrugWatch, 2018). The desired medication can also be separated from combination products using techniques such as ‘cold-water extraction’, where the medication is dissolved in warm water, then rapidly cooled and filtered in an attempt to separate out the different constituents (Harnett, *et al.,* 2020).

OTC/POM may be misused in isolation or in combination, including alongside alcohol, opioid substitute treatment (OST) and illicit substances (described as ‘on-top’ use) (Gossop and Moos, 2008). Typically, on-top use is driven by the desire to potentiate the effects, so that the person experiences a better ‘high’, such as when the antiemetic cyclizine is misused at the same time as methadone or heroin (Oyekan, *et al.,* 2021). On-top use also occurs for other reasons, for example benzodiazepines such as diazepam, used as an anxiolytic and for sedation to manage the ‘come down’ effects of stimulants like crack-cocaine (Motta-Ochoa, *et al.,* 2017). OTC/POM may also be taken to manage the physical side-effects of recreational drug use, such as erectile dysfunction due to methamphetamine use (Hosseinifard, *et al.,* 2014; Reeves and Ladner, 2014).

However, motivations for OTC/POM misuse may not always be for recreational or euphoric effect: some may self-medicate for alcohol or opioid withdrawal symptoms, underlying anxiety disorders or pain, for example with baclofen, loperamide, beta-blockers and opioids respectively (Akel and Bekheit, 2018; Carroll, *et al.,* 2018; Floyd, *et al.,* 2018; Fontanella, 2003; Garhy, *et al.,* 2019; Vorspan, *et al.,* 2015). As with the use of other substances, self-medicating for trauma, including adverse childhood experiences, (Dube, *et al.,* 2003; Johnsen and Blenkinsopp, 2024) is another important consideration. For example, in their student survey, Forster, *et al.,* (2017) identified that for every additional adverse childhood experience, the estimated rate of the number of POM used increased by 62%.

Additionally, iatrogenic dependence can occur, (where dependence occurs after the medication was initially commenced for a genuine clinical need), for example where opioids are misused following their initiation for an acute or chronic pain condition (Fischer, *et al.,* 2006; Gittins and Cole, 2021). Alternative reasons for OTC/POM misuse can include topical steroids to change skin pigmentation (Pal, *et al.,* 2018); diuretics, laxatives and stimulants for weight management (Austin, *et al.,* 2013); and cognitive enhancers to improve academic performance (McDermott, *et al.,* 2020).

1.1.3. Adverse Consequences

OTC/POM continue to feature in UK drug related deaths (ONS, 2023a), and in the United States, POM misuse is the leading cause of accidental death (Peteet, 2019). Therefore, the concomitant use of substances which have additive sedating and respiratory depressant effects are of particular concern, especially benzodiazepines, gabapentinoids and opioids, due to the risk of accidental overdose (Chan, *et al.,* 2006; Fiore, 2020; Jones, *et al.,* 2012; Lyndon, *et al.,* 2017; Macleod, *et al.,* 2019; Robinson, 2017).

OTC/POM misuse has been associated with notable drug interactions, physical and psychological effects (Schifano, *et al.,* 2021), such as delirium (Abeysundera, *et al.,* 2021), psychosis (Amaladoss and O'Brien, 2011), serotonin syndrome (Schwartz, *et al.,* 2008), and QT prolongation that can result in life threatening tachycardias such as torsades de pointes (Ali, *et al*, 2020; Katz, *et al.,* 2017; Parker, *et al.,* 2019). The risks of adverse effects are greater if an underlying health condition is sub-optimally managed or the medication is sourced illicitly, which then makes exposure to unregulated, contaminated, or counterfeit supplies, of unknown purity or strength more likely (ACMD, 2016).

Additionally, misuse can be associated with significant socio-economic effects on the person, their friends, family, and the wider community (UNODC, 2011). OTC/POM misuse can be associated with safeguarding concerns, especially in relation to risks to children and young people, and can create barriers to optimal care provision, for example by negatively impacting upon an individual's relationship with their healthcare provider, and the clinicians willingness to provide medication (ACMD, 2016; Hurwitz, 2005).

Problematic behaviour and accidents associated with OTC/POM misuse can be significant, such as falls, road traffic collisions and acts of violence against self or others (Ilgen and Kleinberg, 2011; Modi, *et al.,* 2013). The misuse of OTC/POM such as benzodiazepines has also been found to be associated with higher levels

of polysubstance use, injection-related health problems, blood borne virus transmission risk behaviours and criminal activity (Eiroa-Orosa, *et al.,* 2010; Ross, *et al.,* 1997).

Additionally, there are concerns that OTC/POM misuse may act as a 'gateway,' to the use of substances (Inciardi, *et al.,* 2009), or the misuse of other OTC/POM associated with greater risks of harm. For example, the UK governments' Advisory Council on the Misuse of Drugs (ACMD) have previously highlighted the need for increased vigilance surrounding OTC codeine as a potential *"precursor to the misuse of prescription opioids"* (ACMD, 2016).

1.2. Rationale, Context and Contribution

1.2.1. Prevalence

In the United States, POM misuse has been reported by one in five Americans (Peteet, 2019), and in 2013, government departments labelled it as a new epidemic (Gudin and Nalamachu, 2016; Harvin and Weber, 2015). The most recent national American survey indicated that in 2021, 5.1% (about 14.3 million) reported misusing prescription psychotherapeutic drugs in the preceding year (NIDA, 2021). Similar concerns have been raised in other countries, for example in Denmark, it has been estimated that approximately 2% of the general population are dependent on benzodiazepines (Jørgensen, 2007). There is no UK equivalent dataset to enable comparison, but in 2022, the YouGov Big Survey on Drugs results indicated that 9% of people know someone who has a serious problem with POM (YouGov, 2022).

Worldwide (and in the UK), prevalence data is particularly lacking with regards to estimates for OTC medication misuse. Whilst the misuse of OTC/POM is thought to be increasing, actual prevalence in the general population remains unknown due to a lack of appropriate monitoring systems (ACMD, 2016). For example, in 2016 the ACMD suggested that the diversion and illicit supply of POM painkillers, benzodiazepines, z-drugs, and increasingly gabapentinoids, is prevalent in the UK, but were unable to expand further on this because *"over half of the respondents perceived that the extent was unknown and over half of the impressions were anecdotal"* (ACMD, 2016).

In an attempt to quantify the size of the issue, Public Health England (PHE) (now known as the Office for Health Improvement and Disparities, OHID), published the results of their landmark review into dependency and withdrawal associated with a limited range of POM in 2019 (PHE, 2020b). Prescribing rates of antidepressants and gabapentinoids amongst the adult English population in primary care were found to have increased from 15.8% to 16.6% and from 2.9% to 3.3% respectively, between 2015/16 and 2017/18: conversely, opioid analgesics, benzodiazepines and z-drugs (such as zopiclone) slightly reduced, with 13%, 3% and 2% being prescribed these medicines respectively (PHE, 2020b). The review found that one in four English adults in primary care were dispensed medication which may be associated with dependence or withdrawal symptoms: prescribing was more prevalent amongst older adults, in areas of greater deprivation, and longer-term use was common (Marsden, *et al.,* 2019; PHE, 2020b).

More recently, in 2021 the national overprescribing review report from the Department of Health and Social Care, highlighted that the NHS Long Term Plan promoted medicines optimisation to reduce inappropriate prescribing of medicines associated with dependency (DHSC, 2021). The report states that *"almost two in three people who are taking eight or more medicines are on at least one drug that may cause dependency"* (DHSC, 2021). Furthermore, Davies, *et al.,* (2022) highlighted that unnecessary NHS England prescribing of medicines associated with dependency, annually costs £493,208,818 to £564,177,046.

A major limitation of these reviews is that they were selective in the type of OTC/POM and care settings that they included. Additionally, information from the suppliers of OTC/POM such as NHS prescribing systems and wholesalers cannot be used to determine prevalence of misuse, as it is not possible to identify if the medication that was supplied was consequently misused or not. Moreover, there is no such data available for private prescriptions, nationwide OTC sales from all retailers/pharmacies, and there is no way to account for supplies which are illicitly sourced or obtained from overseas.

The need for increased vigilance surrounding medicines such as quetiapine, baclofen, and stimulants, was also highlighted by the ACMD (2016). This may incorporate post-marketing surveillance for the prevalence of adverse effects, such as the use of Yellow Card reporting (MHRA, 2024b). However, this approach relies on spontaneous reports, does not assure that the adverse event is actually associated with that particular medication, and is further complicated by under reporting issues (ACMD, 2016).

Since drug-related deaths may be a consequence of OTC/POM misuse, reviewing drug-related deaths may be a useful indicator of changes in prevalence for some of the most high-risk medicines, as has been recently observed for pregabalin, where deaths in England and Wales have more than doubled between 2018 and 2022 (ONS, 2024). In the UK (and Europe), Scotland continues to have one of the highest levels of drug-related deaths, and in 2022, despite the reduction in prescribing rates, benzodiazepines accounted for 57% of recorded deaths, likely due to the misuse of illicit synthetic benzodiazepines (NRS, 2023). This was echoed by the analysis of data relating to Scottish needle syringe provision (NSP) services, which found that 52% had used non-prescribed benzodiazepines in the preceding six months (McAuley, *et al.,* 2023).

In America, POM overdose is the leading cause of death (Gudin and Nalamachu, 2016), and in England and Wales, opioids continue to account for the majority of drug related deaths; however, reports do not distinguish between illicit and legally obtained supplies, or in the case of opioids, the exact medication involved (for example differentiating between morphine or diamorphine, different formulations or brands) (NIDA, 2021; ONS, 2023a). Furthermore, information from Coroners and hospital toxicology results can be limited if the medication is not specifically tested for (Courts and Tribunals Judiciary, 2023; Oyekan, *et al.,* 2021), and determining the source of the medication supply, or if an overdose is intentional or not, can also be difficult.

Prevalence of OTC/POM misuse amongst people who use drugs has been estimated in other countries: for example, in 2019, 54.2% of Americans who use heroin, also misused POM analgesics in the preceding year (SAMHSA, 2020), and in Australia, a survey found that 35% of people who were injecting drugs had also

misused OTC codeine (Arora, *et al.*, 2013). However, these individuals were not necessarily in receipt of treatment, and data relating to the numbers requiring treatment from SMS is limited. This is especially difficult in the UK, where people may seek support via private services or their General Practitioner (GP) instead of SMS (RCGP, 2014a). Furthermore, details about the use of different referral routes for people who misuse OTC/POM into SMS is unknown, though in 2022-2023 for all substance types, self-referrals (which may be following advice from a GP) accounted for 59% and referral from health and social care made up 19% (OHID, 2023). As the misuse of OTC/POM is associated with increased contact with the criminal justice system and mandated SMS referrals, this has been explored by Lessenger and Feinberg (2008), who found that in Californian drug courts, 8.5% misused POM and nearly double (16.2%) misused OTC medicines.

When people access English SMS, the use of the National Drug Treatment Monitoring System (NDTMS) is mandated by the UK government to enable the centralised monitoring of people receiving treatment, and the comparing of different SMS. In 2022-2023, OTC/POM likely accounted for about 5% of the numbers in treatment, with benzodiazepines being the most significant (4.8%); however, of the 48% that were using opiates, it remains unclear how many of these include OTC/POM products (OHID, 2023). NDTMS data also does not capture details beyond the first three substances/medicines that an individual self-reports (PHE, 2020a); therefore, NDTMS data likely underestimates the true level of OTC/POM misuse by those accessing SMS.

Over the years, there have been attempts made to gain an improved understanding of the prevalence of OTC/POM misuse amongst those accessing SMS. For example, in Ireland the urinalysis of 440 individuals in receipt of OST provided an estimated pregabalin misuse prevalence rate of 7% (McNamara, *et al.*, 2015). At about the same time, a survey of individuals attending opioid treatment programmes in Germany and Italy identified that 36% misused POM opioids as their primary substance (Green, *et al.*, 2014). Furthermore, notably older UK research found that in a smaller English sample (n=53) of people who used drugs intravenously, 66% had misused OTC medication during their lifetime (Armstrong, 1992). Essentially, OTC/POM misuse by people who are accessing SMS is thought to be relatively common, poorly documented, and often underestimated (Laqueille, *et al.*, 2009).

1.2.2. Specialist Treatment Provision

Although OTC/POM misuse will not always require intervention, when it does become problematic (and especially in the case of dependence), SMS are ideally placed to assist. SMS may be provided in a variety of settings, such as specialist inpatient units, residential or prison environments, though community services predominate: in 2022-2023 98% of people who were in structured treatment received community-based interventions (OHID, 2023).

Historically, as well as alcohol, SMS have focused on the provision of care for people using crack-cocaine and opiates, because these substances have previously dominated the UK drug market (PHE, 2014). Therefore, individuals who only misuse OTC/POM may not wish to associate themselves with SMS which

they view as more appropriate for people who use less socially acceptable illicit substances, or the way in which SMS are delivered may not be in keeping with their needs (ACMD, 2016; Kmietowicz, 2016).

As previously outlined, OTC/POM misuse also occurs alongside the use of other substances; for example, of the 13,873 people who accessed English SMS for benzodiazepine misuse in 2022-2023, 10,871 also used opiates and 1,276 also used alcohol (OHID, 2023). SMS therefore need to accommodate the needs of those who misuse OTC/POM, whether or not they use other substances. They also need to adapt and change to meet the needs of these individuals, as once engaged, people who misuse OTC/POM often respond well to therapeutic interventions, and have high rates of successful treatment retention, completion and abstinence rates, even when compared to other substances (McCabe, *et al.,* 2013; PHE, 2014; Rigg and Monnat, 2015).

Unfortunately, fear of stigmatisation, shame and embarrassment can affect individuals seeking help, especially if they have experienced care refusal, or a lack of privacy or dignity from healthcare professionals (Harris, *et al.,* 2022), which may be compounded if they are an ethnic minority (Claffey, *et al.,* 2017). This may explain the low rates of treatment-seeking, (including when compared to the rates for other substances) identified by Blanco, *et al.,* (2013), where the cumulative lifetime probability of treatment seeking rate of 42%, and a median delay in receiving POM misuse treatment of 3.83 years was found. People who misuse OTC/POM that present with high-risk behaviours, are more likely to be experiencing polysubstance use (Morley, *et al.,* 2015), which should increase the likelihood of them having contact with SMS. However, Lee and Cooper (2019), suggest that those affected may be a *"hard-to-reach group who do not engage with formal treatment services"*.

High quality treatment interventions are especially important where illicit substances are used alongside OTC/POM, because this may be associated with a lower quality of life and greater mental health issues (Pv, *et al.,* 2018). OST used in SMS (such as buprenorphine and methadone) may also be used inappropriately, and people who access SMS are more likely to experience comorbid mental health conditions and be prescribed psychotropic medication, including for unlicensed indications (Fountain, *et al.,* 2000; Gale-Grant, *et al.,* 2019; Reimer, *et al.,* 2016). Additionally, individuals who access SMS and disclose misusing OTC/POM, exhibit greater severity of substance use and poorer mental health (Bohnert, 2013). It is therefore essential to be able to offer timely and effective interventions to reduce the risk of using other substances, severity of functional problems and riskier drug related behaviours, as these have been found to escalate the longer that misuse continues (Butler, *et al.,* 2010).

In line with national guidance (DHSC, 2017), SMS predominantly focus on providing psychosocial interventions (PSI). These can be wide ranging, and may incorporate talking therapies such as motivational interviewing, counselling, cognitive behavioural therapy, and family therapy, which may be delivered on a one-to-one or group basis, and either face-to-face or online. Exercise and other activity groups (such as photography, cooking, dance, music, and art), as well as alternative therapies such as acupuncture are sometimes offered. Harm reduction interventions such as take-home naloxone (short-acting medication administered in an emergency to reverse opioid overdoses) (DHSC, 2019) and NSP are essential. Physical

health interventions, for example vaccinations, electrocardiograms and blood pressure checks are also provided where they are clinically indicated. Pharmacological interventions, including prescribing for stabilisation, maintenance, detoxification, and relapse prevention, and providing safe storage boxes to store this medication in, are generally limited to people who are dependent on alcohol or opioids. Signposting to other services is also provided if the support cannot be provided internally, such as sexual health, wound care, psychiatry, housing, employment, and financial support.

Guidance is important, to enable safe, high quality, cost-effective care to be provided in a consistent way by SMS staff, regardless of geographical location. The UK's Clinical Guidelines on Drug Misuse and Dependence (DHSC, 2017) is perhaps the most seminal for those working in SMS, though the content that is specific to OTC/POM misuse is minimal and somewhat limited to the mention of just benzodiazepines, gabapentinoids and opioids. There are some additional supportive resources and guidelines specific to these three medicine types, such as the Ashton Manual (2013) and the Public Health Scotland medication assisted treatment standards (2023) for the management of benzodiazepines, and the 2014 guidance relating to the gabapentinoids produced by PHE and NHS England (PHE & NHSE, 2014). Also in 2014, the Royal College of General Practitioners (RCGP) produced four factsheets relating to OTC/POM misuse, which incorporate a summation of the steps that can be taken to prevent, identify and treat occurrence (RCGP, 2014a). However, by its nature, this guidance is centred around the primary care setting and is focused on the prescribing relating to opioids, hypnotics/anxiolytics, stimulants and gabapentinoids (RCGP, 2014a).

Following the 2019 PHE review (PHE, 2020b), the National Institute for Health and Care Excellence (NICE), developed guidelines for the management of medicines associated with dependence or withdrawal symptoms (NICE, 2022). However, not all medicines that are misused are necessarily associated with addiction, dependency or withdrawal symptoms, and the SMS setting and all types of OTC/POM which are known to be misused were not specifically covered by these documents either. Therefore, because of the limited evidence base and the consequent gaps in national guidance, there remains a lack of clarity about what OTC/POM misuse-specific interventions can be provided, how and by who (DHSC, 2017; NICE, 2022).

1.2.3. Characteristics of Individuals

Identifying the demographic characteristics of people who misuse OTC/POM is important, to enable the tailoring of interventions to any specific needs that people may have, and consequent improvement in SMS treatment outcomes (McCabe, *et al.,* 2013; Rigg and Monnat, 2015). The characteristics associated with OTC/POM misuse may be different to those who choose to primarily use street drugs; however, people who use street drugs or who may be in receipt of OST, are also known to misuse OTC/POM (Rosenblum, *et al.,* 2007; Shapiro, *et al.,* 2013; Tkacz, *et al.,* 2012).

In the UK, although White middle-aged men typically predominate SMS (OHID, 2023), 7.5% of Black people have reported drug dependency in the past year, compared with 3% of White British people (NHS Digital, 2024). The proportions of different ethnicities and ages who access SMS for the misuse of OTC/POM in the UK remains unclear, but is important to establish, because there may be unique racial/ethnic profiles

associated with different types of OTC/POM misuse (Harrell and Broman, 2009). Furthermore, the United Nations Office on Drugs and Crime (2011), and researchers such as Feingold and Lev-Ran (2017) and Nielsen, *et al.,* (2011), have identified that young people and older adults may be more at risk of OTC/POM misuse (ACMD, 2016). The latter is of particular concern because of the higher risks of adverse effects that older people may consequently experience (Chhatre, *et al.,* 2017; Gossop and Moos, 2008; Kalapatapu and Sullivan, 2010). Additionally, there is limited evidence to suggest that OTC/POM misuse may be moderately heritable (Gillespie, *et al.,* 2019), which in part may explain why familial histories relating to OTC/POM misuse (and other substances) are reported (Nielsen, *et al.,* 2011). This may add another dimension to SMS provision and highlights the importance of interventions such as family therapy (DHSC, 2017).

Worldwide trends indicate that although drug related deaths relating to OTC/POM misuse are greatest amongst men, the rate amongst women has risen more steeply, and there is a gender difference in the medicines involved (Lynn, *et al.,* 2021; Nielsen, *et al.,* 2015a). Additionally, the 2019 PHE review and the related publication by Marsden, *et al.,* (2019), identified higher rates of UK prescribing amongst women for medication associated with dependency and withdrawal (PHE, 2020b). Similar prescribing patterns have been identified in the United States and elsewhere in Europe (Goetz, *et al.,* 2021; Henricson, *et al.,* 1999), and Simoni-Wastila (2000) identified that women may be 48% more likely to misuse POM than men. Concerningly, Lund, *et al.,* (2013), also found that amongst Norwegian pregnant women on OST, a notable number were co-prescribed benzodiazepines, opioids or z-drugs, which are known to be liable to misuse, and may increase the risk of adverse effects, such as negative pregnancy outcomes.

Overall, women are thought to be more likely to misuse OTC/POM, whereas men are more likely to use other substances (ACMD, 2016; Feingold and Lev-Ran, 2017; Seaman, *et al.,* 2014; UNODC, 2011). However, in 2022-2023, 67.9% of people who accessed SMS were male (OHID, 2023), highlighting how women remain 'hidden', and under-represented in both research and SMS (Ramlagan, *et al.,* 2010). This has important consequences, because women experience more severe outcomes, and subsequently account for an increasing proportion of associated emergency department admissions (Carey, *et al.,* 2014; Ford, *et al.,* 2014; Scholz, *et al.,* 2019; Simoni-Wastila, 2000). Their needs are also often different to that of men: for example, OTC/POM may be associated with more deliberate self-harm amongst women, whereas interventions for men are more likely to need to target concomitant alcohol use (Gittins, *et al.,* 2022c; Hulse, *et al.,* 2001; Matsumoto, *et al.,* 2011).

Lower levels of education, employment and subsequent income have been associated with greater levels of misuse of medicines, such as benzodiazepines (Iqbal, *et al.,* 2011), codeine (Gisev, *et al.,* 2016; Nielsen, *et al.,* 2011), and more potent opioid POM (Nielsen, *et al.,* 2015a), with consequent unfavourable socioeconomic outcomes (Henricson, *et al.,* 1999; Ramlagan, *et al.,* 2010; Simoni-Wastila, 2000). Furthermore, in the UK, areas known to be associated with greater rates of deprivation such as the North East of England, are associated with the highest rates of prescribing POM which are known to be liable to misuse (ACMD, 2016). In America, Rigg and Monnat (2015), compared the differences in characteristics of adults who used heroin only, those who misused POM opioids only, and a combination of both. They found

that individuals who misused POM only were *"the most economically stable, most connected to social institutions"* (Rigg and Monnat, 2015).

In the UK, education and employment rates amongst people accessing SMS are generally low: whilst it is unclear how this varies between people misusing different OTC/POM types or when compared to other substances, employment support that is integrated into SMS is thought to have a 97% probability of cost-effectiveness for people who use 'other drugs' (non-alcohol/non-opioids) (OHID, 2024). When in employment, there are some occupations which are thought to carry a higher risk of OTC/POM misuse, such as military service (ACMD, 2016), financiers (Abelson and Smialek, 2017) and doctors (especially anaesthetists) (Akvardar*, et al.,* 2002; Al-Maaz, *et al.,* 2019). However, with greater levels of affluence, or depending upon job role, individuals may be more likely to access private or specialist healthcare services (Combat Stress, 2024; NHS Practitioner Health, 2024), rather than local authority funded community SMS.

OTC/POM misuse is also of notable concern amongst people who are incarcerated (Tamburello, *et al.,* 2017; UNODC, 2011), which has an impact on community SMS following prison release. These individuals can present with greater levels of complexity, for example due to co-existing mental health conditions such as attention deficit hyperactivity disorder, depression, and dependent substance use, and they may be in receipt of increased amounts of prescribed medicines, including for chronic pain conditions and OST (Silbernagl, *et al.,* 2019; Tamburello, *et al.,* 2017).

Chronic pain also has a notable association with OTC/POM misuse in the community setting, and particularly when symptoms are poorly managed (Dhokia, *et al.,* 2020). In these circumstances, the use of other substances (including illicit opioids) and depression are also more likely (Becker, *et al.,* 2009; Fong, *et al.,* 2015; Gittins, *et al.,* 2018b). Indeed, there are well established associations between OTC/POM misuse, chronic pain, the use of other substances and mental health conditions (ACMD, 2016; Novak, *et al.,* 2016).

A historic UK inquiry into the dependence on POM (Reay, 2009), identified that co-existing mental health conditions such as depression were commonplace. Similar has been found by subsequent and more recent research; for example, Chen, *et al.,* (2011), found that people who misuse benzodiazepines were more likely to be in receipt of prescribed interventions for co-existing mental health problems, and especially for anxiety. The latest data from OHID (2023) indicates that over two-thirds of people starting treatment via SMS in 2022-2023 declared having a mental health need, and this was similar regardless of their primary substance or medication being misused.

Furthermore, Salom, *et al.,* (2017) identified that individuals misusing OTC/POM alongside psychostimulants were more likely to exhibit co-existing mental health issues and higher levels of psychological distress, but were less likely to receive prescribed interventions for them. Concerningly, people with co-existing mental health and known substance use histories may also be more likely to be prescribed medication which is known to be liable to misuse, at higher doses and more so amongst people who have experienced difficult life events, such as divorce or bereavement (ACMD, 2016; Weisberg, *et al.,* 2014).

The concomitant use of substances and the pattern and type of medication being misused may vary by the type of mental health condition; for example, in eating disorders a variety of OTC/POM (including stimulants, insulin, laxatives and diuretics) are known to be misused alongside the use of other substances (Gregorowski, *et al.,* 2013; Marsh, *et al.,* 1997; Wiss and Waterhous, 2014). How this impacts upon people accessing SMS remains unknown, and this may be because conditions such as eating disorders are under-recognised by SMS (Gittins, *et al.,* 2018a).

Individuals with human immunodeficiency virus (HIV) are thought to commonly misuse OTC/POM and substances like alcohol to self-manage associated symptoms such as pain and depression (Newville, *et al.,* 2015). Individuals who use drugs are also at greater risk of being exposed to HIV (especially those who inject, are involved in transactional sex working and men who have sex with men), and the side-effects of antiretroviral therapy may further increase the risk of OTC/POM misuse (Newville, *et al.,* 2015). SMS play a key role in the testing, vaccination and supporting access to treatment for blood borne viruses such as HIV, so need to be especially vigilant for OTC/POM misuse amongst affected individuals.

Laqueille*, et al.,* (2009), found that individuals in receipt of OST who misused benzodiazepines were more likely to commence the use of opioids in adolescence, and present with more significant psychological vulnerability (perhaps as a result of experiencing a greater number of adverse childhood experiences, contact with the criminal justice system, medicolegal, social and mental health problems). Although it does not necessarily confer misuse, Tachi, *et al.,* (2018) and Serdarevic, *et al.,* (2019), found that people who use alcohol also consume significantly more OTC and POM respectively, which is an important consideration for SMS when individuals present with alcohol as their primary substance. Since people who misuse OTC/POM opioids are less likely to inject than those who use illicit opioid substances like heroin (Nielsen, *et al.,* 2015b), their consequent need for interventions such as NSP may also be different and likely reduced.

Since the characteristics of individuals who misuse OTC/POM vary, then they may also have differing risks of experiencing adverse events (Green, *et al.,* 2011), and SMS need to take this into account when providing interventions (Fong, *et al.,* 2015). More research is also required to improve the understanding of the interplay between different characteristics and their impact upon OTC/POM misuse, which may also enable the development of more targeted prevention strategies (Carey, *et al.,* 2014).

1.2.4. Impact Upon Others

The effects of problematic OTC/POM misuse upon local communities, carers, family and friends (and especially children) are not to be underestimated (Manthorpe, *et al.,* 2015; OHID, 2022). The impact may be deep and long-lasting, and previous work (Gittins, *et al.,* 2018a), has highlighted a gap in knowledge regarding any changes in needs depending on what the person is taking. As outlined by Adfam (2024), the impact of substance use on an individual's friends and family are variable, and can include stigma; isolation; stress and anxiety; mental and physical health; trauma; strain upon relationships and finances: it is unclear if this is the same for OTC/POM misuse. Although Wolf (2021) suggested that OTC/POM misuse in isolation is not associated with child maltreatment, it is thought to have negative consequences on relationships

(Kirschbaum, *et al.,* 2020).

Friends and family have been identified as having a significant role in facilitating (often free) access to OTC/POM (AOG, 2012; Pancari and Baird, 2014). Where individuals are able to speak to their loved ones about their misuse, this has been found to positively impact upon the persons' recovery, for example by providing support and prompting change, managing access to supplies and monitoring for indicators of relapse (Cooper, 2011; Cooper, 2013a; Kirschbaum, *et al.,* 2020; Nielsen, *et al.,* 2010). Support from significant others has also been found to positively enable individuals on their OTC/POM misuse recovery journey, for example by supporting reductions in the use of substances and underlying wellbeing issues, motivating and sustaining change and associated improvements in outcomes where pharmacological interventions are utilised, and even when there is no SMS involvement (Carballo, *et al.,* 2007; Cooper and Nielsen, 2017).

Friends and family often absorb the role of being the person's carer in the case of problematic and dependent use, and the need to involve carers in treatment system approaches has been previously highlighted by Gittins, *et al.,* (2018a). Services must support the adequate assessment of carer needs in accordance with the Care Act 2014 (Manthorpe, *et al.,* 2015) and signpost effectively to supportive resources. Furthermore the UK Government's new drug strategy 'From Harm to Hope' highlights the need to prioritise the needs of families (DHSC, 2022a), outlining the need for "family hubs" which join up families, professionals and treatment providers, and supports the investment of £200 million in the 'Supporting Families Programme'. However, it is not known if the need of the carer varies depending on the type of drug, such alcohol, or illicit substances that their loved one is using, or the OTC/POM being misused, either in isolation or in combination.

There is a particular lack of published research relating to the experiences of friends and family from their own perspectives. Improving an understanding of this should enable identification of developments required (such as SMS quality improvement approaches), which could engage more people with SMS, and further optimise the provision of care delivery for individuals and concomitant support for their significant others. Whilst the numbers seeking support from SMS is likely lower than those in broader primary care, this is of particular importance since those accessing specialist SMS can be more vulnerable and experience more harms due to comorbidities and situational factors such as other substance use issues and homelessness.

1.2.5. Impact of the Pandemic

In 2020, the COVID-19 pandemic reached the UK, which coincided with when this research commenced. As COVID-19 is transmitted via aerosols and droplets, including on contaminated surfaces, it poses additional risks to people who share paraphernalia when using substances, have problems accessing handwashing facilities, and have comparatively high rates of comorbidity (Crew, 2021; Dunlop, *et al.,* 2020; EMCDDA, 2020b; Mallet, *et al.,* 2021; RCPsych, 2021). As previously outlined, this can be assumed to therefore have a degree of impact upon people who misuse OTC/POM (including those accessing SMS), because substance use can be co-occurring.

The published evidence base is still emerging; however, community pharmacy and SMS provision, and the consequent care individuals received as a result of COVID-19 was severely affected, particularly during the early stages of the pandemic. This was for a variety of reasons, including reduced staff availability and ability to drug test, individuals self-isolating or shielding, and liberalisation of dispensing arrangements, leading to individuals having notably greater access to medicines which can be misused, with reduced supervised consumption and monitoring arrangements (Dunlop, *et al.,* 2020; EMCDDA, 2020a).

COVID-19 impacted upon the ability to obtain OTC/POM, which may have resulted in individuals misusing legally procured supplies: it had variable impact upon the illicit drug market, with reported changes relating to product availability, price and quality (Aldridge, *et al.,* 2021; Crew, 2021; EMCDDA, 2020c). In a report from Crew (2021), 65% reported changes to drug supplies, with 77% outlining that the *"face to face market has been impacted the most"* in Europe. Increasing addictive behaviours during COVID-19 has been reported internationally (Sun, *et al*, 2020), and interim findings from Release's Coronavirus Drug Purchases Impact Survey found that there was greater occurrence of withdrawal symptoms, non-fatal overdoses and sharing of paraphernalia (Aldridge, *et al.,* 2021). This advocacy organisation also identified anecdotal reports of more people trying to access POM (especially benzodiazepines) on the darknet (Aldridge, *et al.,* 2021). Individuals who use substances (and are also likely to misuse OTC/POM), were also thought to be at greater risk of relapse or withdrawal during the pandemic (Mallet, *et al.,* 2021), for example because of isolation, boredom, increased anxiety, domestic violence, job loss or the inability to finance drug use through begging or sex working (Alcohol Change UK, 2020; Kesten, *et al.,* 2021).

It is also important to consider the impact that changes in access to OST during COVID-19 may have had upon OTC/POM misuse, for example if people tried to source alternatives when OST supplies become more restricted, or if increases in supplies resulted in more overdoses. Brothers, *et al.,* (2021) found that relaxed prescribing arrangements for OST did not result in increased fatal overdoses and highlighted the need for continuation of the changes in the longer term. European recommendations equally supported the priority need for SMS to adapt (EMCDDA, 2020b); and in the UK, during the midst of the pandemic, national guidance and professional leadership bodies supported liberalisation of dispensing arrangements and changes to SMS delivery (NHSE & I, 2020; PHE, 2021a; RCPsych, 2021; SDF, 2020b; Welsh Government, 2020).

Research commissioned by Alcohol Change UK (2020), found that more people drank alcohol during COVID-19, and that they planned to continue drinking at increased levels, which may have created greater risk where there was co-existing OTC/POM misuse. Concerningly, preliminary data from PHE's Drug Harms Assessment and Response Team suggests that deaths in SMS for primary opiate use increased, though not as a direct result of contracting COVID-19 (PHE, 2021b). Therefore, the impact upon people who misuse OTC/POM remains unclear.

1.2.6. SMS Development Requirements

Following the PHE review, Marsden, *et al.,* (2019) highlighted the need for enhanced OTC/POM misuse monitoring, improved guidance, and shared decision-making. With growing media attention, SMS commissioners and the public have demonstrated an active and increased interest in the misuse of OTC/POM, which will likely put SMS under ongoing increased pressure. SMS providers have a significant role in managing POM and OTC misuse, especially when there are concurrent other substance use issues. This can become particularly difficult when considering the associated SMS costs, and where the prescribing may otherwise sit with GPs in primary care. Consequently, SMS need to adapt to meet the growing demand and any associated long-term impact of COVID-19. There is also a need to review service configuration and treatment pathways, so that SMS do not become overwhelmed, and to enable primary care to respond more appropriately to initial concerns about OTC/POM misuse.

It also remains unclear if SMS or primary care (or an alternative setting) is preferred by individuals requiring support, or how they generally view SMS. Qualitative interviews and questionnaires have been used to explore experiences amongst people who use SMS (service users) and the clinicians that work in them (Matheson, 1998; McKeown, *et al.,* 2003; Radcliffe and Stevens, 2008; Roberts, *et al.,* 2007; Sheridan and Barber, 1997). The experiences and views of service-user facing ('front-line') staff may benefit from further exploration due to limited published data. For example, to understand what barriers to treatment may exist from their perspectives: Butler and Sheridan (2010) and Buttram, *et al.,* (2019) have outlined a particular need for more research into the views expressed by SMS staff in relation to OTC/POM misuse too.

SMS staff may offer a unique insight because they are embedded within the treatment system, so may be able to readily identify opportunities for optimising the provision of care delivery. Additionally, exploring staff experiences may offer the opportunity to identify their own development needs, and an improved understanding may enable SMS managers to consider changes to how their staff teams can be best supported and consequently upskilled and retained in their current employment. This is especially important when considering wide-spread issues with staff recruitment and retention across the sector (DHSC, 2022a; Murphy, 2022; RCPsych, 2020), and the negative impact that vicarious trauma (trauma experienced as a result of providing care) has on SMS staff (Johnsen and Blenkinsopp, 2024; O'Callaghan and Lambert, 2022).

As previously outlined, there are no comprehensive international or national OTC/POM misuse treatment guidelines to which SMS staff can currently refer. It is therefore difficult to improve services because of the limited literature on which to base any recommendations. Further research is also required to improve prevention strategies, early identification of potential problematic use, and enable more people to seek the prompt and appropriate help and support that they require (Fischer, *et al.,* 2006).

More UK research is also required because SMS, legislation and illicit drug markets can be very different to other countries. As different healthcare systems, medicines supply routes and drivers for misuse also vary, different policy responses and approaches to SMS provision may be necessary. For example, in Africa, people may be more likely to misuse opioids due to poor access to healthcare resulting in unmanaged pain

conditions, whereas in North America this may be due to over-prescribing (Klein, *et al.*, 2020). SMS developments need to utilise an informed, evidence-based approach. This requires an improved understanding about the extent of the problem, including which OTC and POM are commonly misused, and any bespoke treatment needs. Such an approach is especially important for those who access SMS, since they are more likely to present with more complex psychosocial issues or have additional health needs. Associated research should therefore positively contribute to the existing evidence base.

1.2.7. Research Funding

This research is funded by the 2019 Research Award from Pharmacy Research UK (PRUK) and the College of Mental Health Pharmacy (CMHP) (CMHP, 2021; PRUK, 2021): [*PRUK_CMHP-2019-2-RG*].

1.3. Aim and Objectives

The overall aim of this research was to explore the misuse of OTC and POM by adults that are accessing community SMS, and the associated experiences of their friends/family and SMS staff. To achieve this, the objectives are to undertake:

- A systematic review to examine the existing published literature on OTC/POM misuse among adults who are accessing SMS, including the identification of the types of medication involved, the pattern of misuse and associated demographic characteristics ***(see Chapter 2 – Systematic Review)***. This will inform the approach taken for selected methodologies ***(see Chapter 3 - Research Strategy and Design)*** used for the four subsequent studies.
- An anonymous questionnaire completed by people who are currently accessing SMS to identify their misuse of different types of OTC/POM, as well as their use of other substances and associated demographic characteristics ***(see Chapter 4 – Study 1 Questionnaires)***
- Confidential semi-structured interviews with people who are currently using SMS, specialist SMS staff and affected friend/family members ***(see Chapter 5 - Study 2: Service User Interviews, Chapter 6 - Study 3: Staff Interviews and Chapter 7 - Study 4: Friend/Family Interviews respectively)*** to further explore the experiences of OTC/POM misuse amongst these different groups.

A summary of the key findings, associated strengths, limitations, and implications for clinicians, policymakers and researchers, with reference to existing research and suggestions for future research, can be found in the penultimate chapter ***(see Chapter 8 – Programme of Research Discussion)***, with associated conclusions in the final chapter ***(see Chapter 9 – Programme of Research Conclusion)***. Where this work has been published, this is highlighted in individual chapters. These publications have been collated, alongside additional details of where else the findings have been shared (including oral and poster presentations at international conferences), and can be found in ***Appendix 1: Summary of Publications/Contributions***.

2. Systematic Review

The purpose of this chapter is to present the findings from a systematic review of the literature. Conducting a systematic review was imperative to gain a robust understanding of what was already known about the misuse of OTC/POM by adults that are accessing community SMS in the UK. This was important to undertake because there are currently no other known systematic reviews which have focused on the misuse of OTC/POM by people accessing SMS. The findings from this systematic review consequently informed the approach taken for selected methodologies ***(see Chapter 3 - Research Strategy and Design)*** for the four subsequent studies.

2.1. Protocol Development and Publication of Findings

A protocol for this systematic review was required to clearly outline the steps that needed to be taken, and to enable replication of a similar approach by other researchers. The protocol for this systematic review included the review question, search strategy, inclusion criteria, approach to quality assessment, method for data extraction and synthesis (NIHR, 2022). To avoid other researchers duplicating this exact same systematic review and to alert them that it was being undertaken, the protocol was registered on the Prospective Register of Systematic Reviews (PROSPERO) *[CRD42020135216]* in 2020 (NIHR, 2022).

To provide further evidence of quality of the protocol as a consequence of critique via peer review, the protocol for this systematic review has been published:
Gittins R, Missen L, Maidment I. 2021. Misuse of medication in adult substance misuse services: a systematic review protocol. BMJ Open. 11(6): e047283. doi: 10.1136/bmjopen-2020-047283.

The findings from this systematic review were used to inform subsequent study design. They have also been shared at international conferences ***(see Appendix 1: Summary of Publications/Contributions)*** and an abstract from a poster presentation of the initial findings was published in an international peer reviewed journal:
Gittins R, Missen L, Maidment I. 2022b. Misuse of over the counter and prescription only medication by people accessing specialist treatment services: a systematic review. Int J Pharm Pract. 30(s1): i45–6. doi: 10.1093/ijpp/riac019.063.

Although a systematic review methodology was used to identify potential studies for inclusion, the complete findings were published as a narrative synthesis due to the final methodology which was applied:
Gittins R, Missen L, Maidment I. 2022a. Misuse of Over the Counter and Prescription Only Medication by Adults Accessing Specialist Treatment Services in the UK: A Narrative Synthesis. Subst Abuse. 16: 11782218221111833. doi: 10.1177/11782218221111833.

To add robustness, this systematic review was undertaken in line with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher, *et al.,* 2009), and the PRISMA 2020 checklist (Page, *et al.,* 2021).

2.2. Aim and Objectives

This systematic review aimed to examine the literature on OTC and POM misuse among adults who are accessing SMS in the UK. The objectives were to identify the types of medication involved, the pattern of misuse and associated demographic characteristics.

2.3. Methods

2.3.1. Eligibility Criteria

This review consisted of published studies which met all of the following criteria:

- Adult participants (18 years or over)
- People who are misusing OTC/POM for non-medical purposes
- Participants in receipt of psychological and/or pharmacological interventions in the UK for their substance use (in any setting, such as prison, community, or hospital).

The definition of 'prescription medication' did not include those that are being prescribed for the management of substance use disorder. Letters and comments outlining the views, experiences and opinions of individual professionals, researchers, commentators, or people receiving interventions were excluded; however, reports that summarise and/or collate individual experiences were considered. There were no other restrictions on the type of study population or publication time frame. For practical reasons, results from all countries and in all languages were noted; however only English language results were considered.

2.3.2. Search Strategy

A comprehensive search of the published literature was undertaken by the Researcher, Rosalind Gittins (RG) using the Cochrane (Wiley, 2021), OVID Medline (Wolters Kluwer, 2021), Pubmed (NLM, 2021), Scopus (Elsevier, 2021) and Web of Science (Clarivate Analytics, 2020) databases. Grey literature was also checked for relevant information. Truncation and a combination of keywords, medical subject heading and Boolean operator terms (Booth, *et al.,* 2016) related to POM and OTC misuse in SMS such as (Over-the-Counter Drug Misuse) OR (Prescription Drug Misuse) AND (Substance Abuse Treatment Centres) were used ***(see Appendix 2 - Systematic Review Search Strategy)***. To ensure a comprehensive search, the reference lists of eligible studies were manually searched by RG and another member of the systematic review team, Louise Missen (LM) a SMS pharmacist, to identify any additional relevant references. Andrew Doyle from the Library staff team at Aston University also verified the suitability of this search strategy.

2.3.3. Study Selection and Data Extraction

RG conducted preliminary screening of titles to exclude all publications that were clearly irrelevant. The Researcher (RG) and the reviewer (LM) then worked independently to conduct the initial title and abstract screenings, followed by full text reviews, using the predetermined criteria for inclusion and exclusion. Another reviewer, Research Supervisor Ian Maidment (IM), was available to resolve disagreements if a consensus could not be reached.

If selected for inclusion, full-text data extraction was conducted independently by RG and LM, using a pilot-tested data extraction form. An iterative approach was taken to improve the usability and to assure the functionality of the forms during the piloting process. Completed pilot forms were assessed to ensure that they were fit for purpose, and that a consistent approach was taken by RG and LM. Where required, the authors of the papers would have been contacted to provide any missing information.

The extracted data was simultaneously captured by RG and LM using Google forms, which they were both familiar with. The form prompts for retrieval of data including primary author surname, year of publication, title of the publication and journal name, details of medication and other substances, sample size and characteristics, study design, setting, methodology, statistical methods and results, summary of findings and limitations.

The final data extraction form is available from:
https://forms.office.com/Pages/ResponsePage.aspx?id=QcO8NJelvkGbFh8f5c750aYIOkR_0sBEosdK0UfjRnpUNEhYRTBYRlRCSkQ5MDcyMzVMN0lSUlVaOS4u

2.3.4. Ethical Approval

Service users were not directly involved in the protocol study design, and participant recruitment was not required for a systematic review involving secondary data analysis, so ethical approval was not applicable.

2.3.5. Risk of Bias

The quality assessment from the Mixed Methods Appraisal Tool (MMAT) (Hong, *et al.,* 2018) was used to consider the risk of bias as it accommodates quantitative, qualitative, and mixed methods, so the same tool could be used for all studies. It was completed by RG and LM for each study using the same Google form that was used for data extraction. If systematic reviews had been identified, the MMAT would have been supplemented by A Measurement Tool to Assess Systematic Reviews version 2 (AMSTAR2) (Shea, *et al.,* 2017). The MMAT tool was applied by RG and LM independently, and the results were tabulated to enable easy comparison. Similarly, as with data extraction methodology, to further minimise bias, discrepancies would have been discussed and IM would have been consulted to resolve any disagreements.

2.3.6. Synthesis of Results

All included studies were appraised with a qualitative summary and the main review findings were summarised in table format using Microsoft® Excel® version 16 (MS Excel®). The synthesis of qualitative data

aimed to follow a thematic analysis approach, or otherwise a narrative synthesis if there was insufficient data. If the quantitative data had allowed, a meta-analysis would have been undertaken and the outcomes captured in a forest plot, or otherwise the numerical descriptors would have been captured as a narrative. Quantitative data synthesis methodology and potential for meta-analysis was dependent upon the number and quality of studies identified. Had there been a sufficient number of studies, heterogeneity would have been assessed using the I^2 test, and as outlined by Higgins, *et al.,* (2021), heterogeneity is impacted by a variety of factors so cut-off values would not have been enforced; however, heterogeneity would have been considered likely if I^2 was greater than 40%. If this had occurred, subgroup analyses would have been undertaken, and this may have been more likely to occur for example for age, gender, and type of medication.

If a meta-analysis was not possible, then Synthesis Without Meta-analysis (SWiM) would have been utilised (Campbell, *et al.,* 2020). As with the data extraction process, an independent reviewer would have quality assured the analysis and any discrepancies would have been resolved through discussion with IM. The resulting cumulative strength of the quality of evidence was assessed using Grading of Recommendations, Assessment, Development and Evaluation (GRADE) (Balshem, *et al.,* 2011).

2.4. Results

2.4.1. Search Strategy Findings

The search was undertaken on 10th May 2021 which provided a total of 3684 results from all databases included ***(see Appendix 2 - Systematic Review Search Strategy)***. This was reduced to 1989 after duplicates were removed. The grey literature was searched, and all publications (total 2047) were checked by hand for potentially relevant references. Following this, publications were screened at title and abstract level, and ineligible publications excluded. This resulted in 143 potentially relevant papers being identified, and this was further restricted by including only UK-based publications, reducing the number to thirteen. The predominant reasons for exclusions were non-SMS, under 18 years of age or where the relevant data could not be extracted, such as mixed age ranges, in the case of Sakol, *et al.,* (1989). The Researcher and the independent reviewer agreed in all instances: however, the Research Supervisor was consulted on one occasion, when determining the suitability to include Cooper (2013a), since the online 'treatment' setting with peer support provision was notably different.

The selection process is summarised in ***Figure 1*** and the final papers selected for inclusion alongside a qualitative summary of their findings are stated in ***Table 1***.

Table 1: *Summary of publications including key findings*

Study ID	Author(s)	Year	Title of publication	Journal name	Summary of findings
1	Armstrong, *et al.*	1992	The use of over-the-counter preparations by drug users attending an addiction treatment unit	Br J Addict	OTC misuse common. Easy to obtain in large amounts but not primary substance and only disclosed when asked. Duration of use and amount consumed varied greatly. Stimulants often used intermittently and regardless of street drug availability. Opioids often used for several days, for self-detoxification, if street drugs unavailable, to supplement use, for its own effect, to avoid withdrawal symptoms and experimentation.
2	Baird, *et al.*	2014	Gabapentinoid Abuse in Order to Potentiate the Effect of Methadone: A Survey among Substance Misusers	Eur Addict Res	Gabapentinoids used to potentiate methadone/to become intoxicated
3	Coombes, *et al.*	2019	Staff perceptions of prescription and over-the-counter drug dependence services in England: a qualitative study	Addict Sci Clin Pract	Staff concerns about stigma and lack of support, awareness, guidelines, pathways, funding, and resources affecting treatment (especially for opioids). Current services perceived as inappropriate, variable, and more suited for people who use illicit substances. Suggested service improvements include commissioning new services, developing national guidelines/pathways and increasing awareness.
4	Cooper	2013	'I can't be an addict. I am.' Over-the-counter medicine abuse: a qualitative study	BMJ Open	Mainly codeine combination products, but also decongestant and sedative antihistamines, usually started for genuine medical reasons. Considered themselves different from people who use illicit substances, self-blamed for losing control following cessation of prescribing. Subsequent use was for the 'buzz', obtained unproblematically via pharmacies/online. Withdrawal symptoms described, with employment and health problems at higher doses. Mixed views about treatment options. Standard drug treatment services considered inappropriate. Concerns of 'hidden addiction' recorded in medical notes. Most supported continued OTC availability with addiction warnings and pharmacy training.
5	Fleming, *et al.*	1986	Dependence on dextromethorphan hydrobromide	Br Med J	Analysis of a sample of white powder believed to be an amphetamine of high purity detected dextromethorphan hydrobromide. Highlights need for continued vigilance as potential for abuse of any psychoactive drug and supports routine testing of substances (including drug checking).
6	Jaffe, *et al.*	2004	A postmarketing study of relative abuse liability of hypnotic sedative drugs	Addiction	Benzodiazepines have high abuse potential, commonly used, more than antidepressants and non-benzodiazepine hypnotics. More likely to be purchased to get high and on the street than via GP. Converse for antihistamines and other medicines used to aid sleep. Recommend benzodiazepines should not be prescribed with history of substance use: sedating antidepressants or non-benzo hypnotics could be alternatives.
7	McBride, *et al.*	1996	Three cases of nalbuphine hydrochloride dependence associated with anabolic steroid use	Br J Sports Med	Three case reports of nalbuphine hydrochloride dependence, obtained from illicit sources and alongside performance enhancing drugs. Supports further research into dependence potential of nalbuphine and relationship between anabolic steroid, other drug use and high-risk behaviours.
8	Oyefeso, *et al.*	1996	Prevalence and pattern of benzodiazepine abuse and dependence among patients in a methadone detoxification programme: a repeated cross-sectional analysis (benzodiazepine abuse among opiate addicts)	Addiction Res	Prevalence of benzodiazepine dependency, obtained from GPs, combined use of multiple benzodiazepines, cannabis, amphetamines, and cocaine. Rates of injecting increased and age of first benzodiazepine use and prevalence of barbiturates decreased. On admission, for methadone detoxification need to routinely assess for use of benzodiazepines, barbiturates, cannabis and severity of dependence, and monitor treatment completion rates.
9	Perera, *et al.*	1987	The Use of Benzodiazepines Among Drug Addicts	Br J Addict	High prevalence of benzodiazepines (especially diazepam). No difference in average age and sex ratios from people who do not use. Continued use for sleep, anxiety, and withdrawal reactions. Minority stated using to intensify the 'high', to reduce or limit the quantity of their primary substance. Mostly oral, some injecting. Males more likely to use alcohol/greater polypharmacy. Majority cited easy (and initial) availability from GP/others with a prescription (parents/elderly relatives) as a reason for using.
10	Ruben, *et al.*	1992	Temazepam misuse in a group of injecting drug users	Br J Addict	Gel-filled temazepam capsules readily injected, causing medical complications. Obtained via GP, friends/relatives, street dealers, elderly people selling excess supplies, doctor shopping under false names/registering as a temporary resident, some attempted burglary. Used for desired drug effects, also sedating/relaxing effect to alleviate anxiety/depression. Some used as more available than heroin, to help sleep, commit crime, or suppress opiate withdrawals. Some mixed with illicit heroin to provide a better "hit". Temazepam tablets reported to be easier to inject than gel formulation.
11	Seivewright, *et al.*	1993	Withdrawal symptoms from high dose benzodiazepines in poly drug users	Drug Alcohol Depend	Withdrawal symptoms from high dose benzodiazepines prevalent amongst people who use substances, uncomplicated by simultaneous cessation of other drugs. Range of withdrawal symptoms similar but greater severity with higher doses, multiple benzodiazepines, and oral use.
12	Strang, *et al.*	1994	Survey of use of injected benzodiazepines among drug users in Britain	Br Med J	Prevalence of benzodiazepine use, especially diazepam and temazepam. Notable levels of injecting, especially for temazepam capsules.
13	Thomas, *et al.*	2009	Diphenhydramine abuse and detoxification: a brief review and case report	J Psychopharmacol	Addiction to diphenhydramine significantly impacted on finances and travel to different community pharmacies. Withdrawal symptoms experienced within hours of missed doses. Experienced insomnia and memory impairment leading to accidents including fires, overdoses, blackouts, and seizures. Highlighted need to ask about OTC/POM use and caution repeat requests.

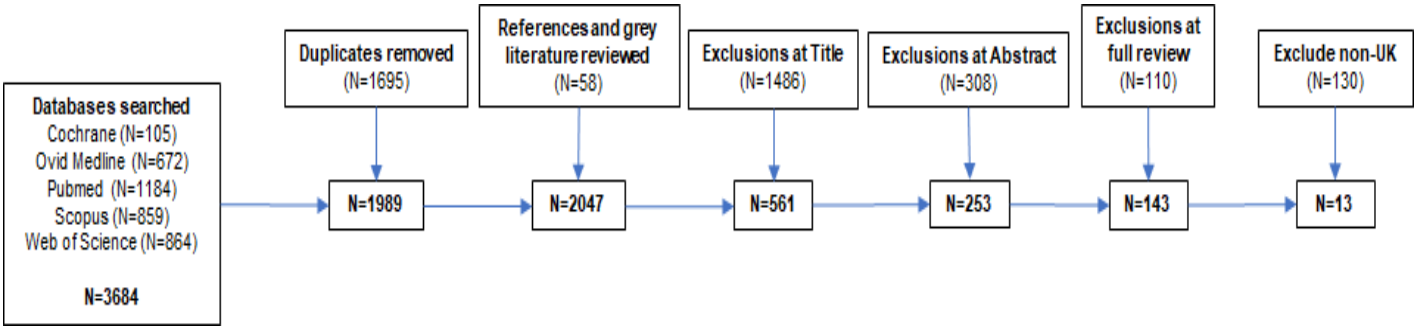

Figure 1: *Summary of the publication selection process*

2.4.2. Sample Size and Study Setting

Figure 2 demonstrates that community and inpatient SMS settings were most prevalent. Studies using interviews and surveys/questionnaires yielded the greatest sample sizes as outlined in ***Table 2***. Where gender and age was stated, the majority were males, generally in their mid to late twenties.

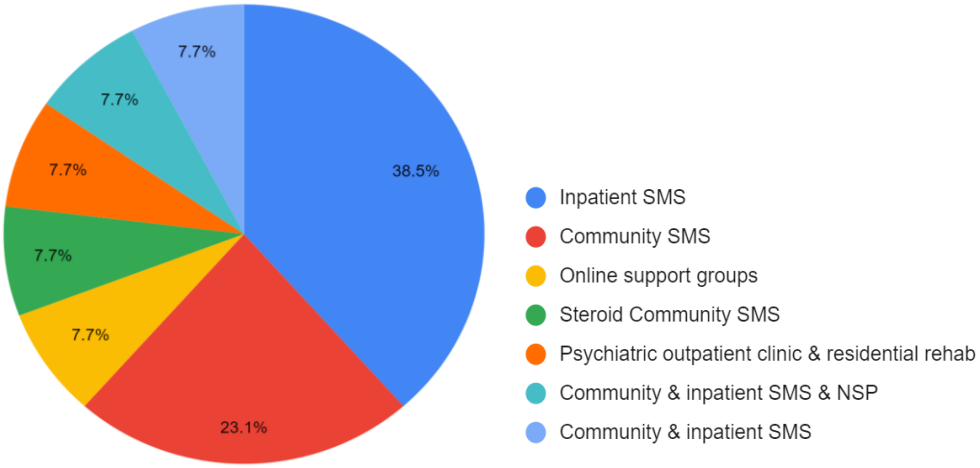

Figure 2: *Settings in which the published research were based*

Table 2: *Summary of publication characteristics*

Study ID	Demographic characteristics of people misusing OTC/POM (e.g. age, gender)	Sample size	Methodology
1	Range 20-49 years (mean 26.8 years)	53	Interviews
2	Not stated	129	Survey/Questionnaire
3	*"different genders, socioeconomic groups and ages…majority… middle-aged"*	15	Interviews
4	20-60 years, 48% male	25	Interviews
5	30 years, 100% male	1	Case report
6	78% male	297	Interviews
7	22-27 years, 100% male, 66.6% single and unemployed	3	Case report
8	Cohort 1: mean 28.7 years, 55% male, 55% single, 95% unemployed; Cohort 2: mean 27.7 years, 58.8% male, 43.1% single, 96.1% unemployed	71	Patient records
9	Mean 24.4 years, 64.6% male	79	Survey/Questionnaire
10	19-26 years (mean 24.5 years), 74% male	23	Interviews
11	21-48 years (median 28 years), 54.5% male	33	Interviews & patient records
12	Mean 31 years, 67.8% male	208	Survey/Questionnaire
13	56 years, 100% female	1	Case report

2.4.3. Analyses of Study Findings

Meta-analyses and subgroup analyses were not feasible due to an absence of randomised controlled trials and systematic reviews. Due to the limited number of studies, a more structured analysis of heterogeneity using the I^2 test was not possible, though the Researcher observed a degree of heterogeneity between publications (for example differing medication types). When considering the limited number of studies identified, their methodologies and (lack of) statistical findings, they were too dissimilar to be able to pool statistically or to undertake a thematic analysis, so a narrative synthesis was conducted instead (Higgins, *et al.,* 2021; Ryan, 2016). This 'narrative' uses the words from the studies to *"tell the story"* of the study findings using a textual approach (Popay, *et al.,* 2006).

Due to the limited consistent information and insufficient detail across all publications, it proved difficult to implement the SWiM checklist (Campbell, *et al.,* 2020) or GRADE (Balshem, *et al.,* 2011), and AMSTAR2 (Shea, *et al.,* 2017) was not indicated. Consequently, GRADE-Confidence in Evidence from Reviews of Qualitative research (CERQual) (Lewin, *et al.,* 2018a; Lewin, *et al.,* 2018b) was applied.

CERQual was utilised to add robustness to the qualitative narrative synthesis of the extracted data, which is summarised in ***Table 3***. This approach considered the MMAT (Hong, *et al.,* 2018) assessment that was undertaken by RG and LM, and determined the degree of confidence placed in the findings in relation to methodological limitations, coherence, data adequacy and relevance (Lewin, *et al.,* 2018a; Lewin, *et al.,* 2018b). Despite the methodological limitations being assessed as 'moderate' when the studies were considered as a whole, the CERQual assessment indicated overall 'high confidence' for each of the review findings, which has been similarly found by Lewin, *et al.* (2018b). Methodological limitations included lack of details provided in some studies, such as no mention of accounting for non-responder rates, confounding factors, or statistical/analysis methods that were only partially reported or not disclosed at all.

To further reduce the risk of bias, every publication was included in the analyses, as they all met the inclusion criteria. Statistical methods were not routinely stated in all publications (such as case reports); therefore, no standardisation metrics or transformation methodologies were utilised (Campbell, *et al.,* 2020).

2.4.4. Summary of Findings

The following are the key findings from the narrative synthesis:

- Benzodiazepines, opioids and antihistamines were cited as the most misused OTC/POM by people accessing SMS, as outlined in ***Table 3*** (Row 1), with further detail summarised in ***Figure 3***. These medicines were mentioned in twelve of the thirteen publications: in nine, six and five for benzodiazepines, opioids, and antihistamines respectively. Three older studies mentioned products such as temazepam capsules which are no longer available in the UK.

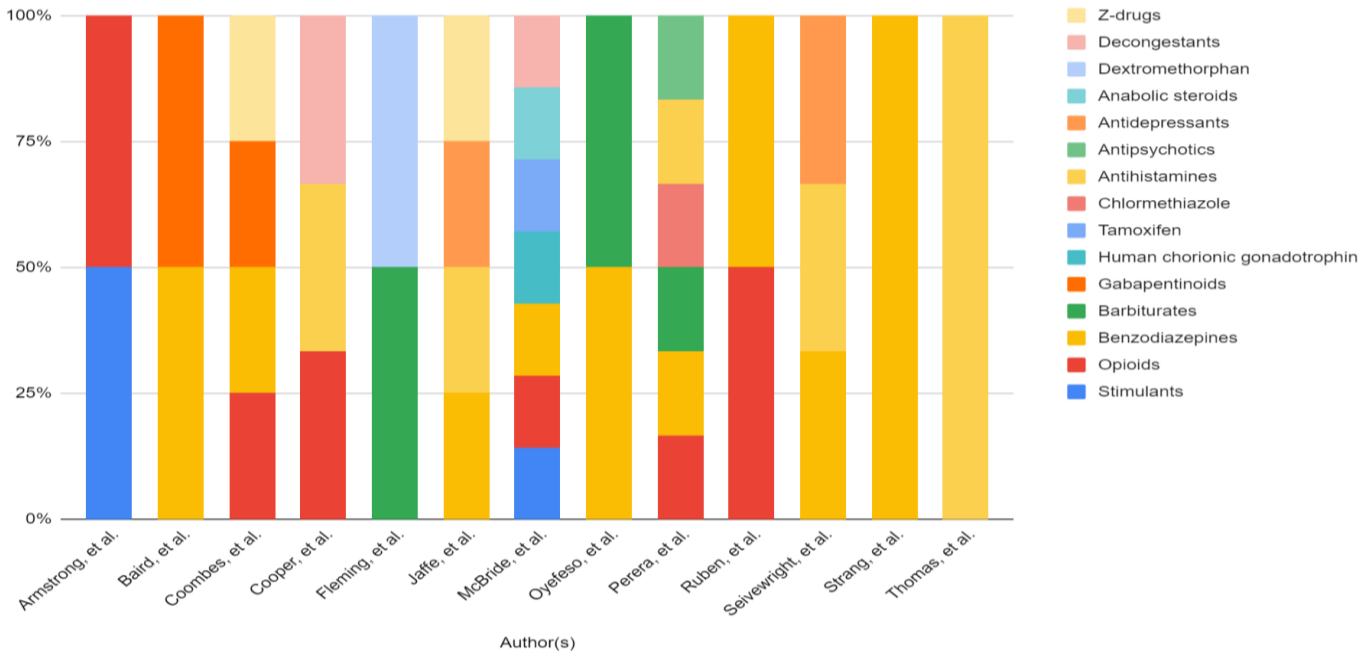

Figure 3: *OTC/POM type noted in the included publications (where medication name/type was stated)*

- When misused, OTC/POM were usually administered orally or injected. As outlined in ***Table 3*** (Row 2), seven studies described oral consumption (though not all stated this explicitly), and six described injecting (a mixture of intravenous, intramuscular, and subcutaneous routes). One publication additionally mentioned snorting, and four studies did not clearly state the route of administration.

- OTC/POM misuse often occurred alongside illicit substance use, especially amphetamine, cannabis, and opioids. As summarised in ***Table 3*** (Row 3) and ***Figure 4***, eleven of the thirteen studies specified the use of other substances, and at least one of amphetamine, cannabis and opioids was explicitly mentioned in nine of them (seven, six and six for cannabis, amphetamines and opioids respectively). All stated substances were illicit, apart from alcohol, which was specified in only four publications.

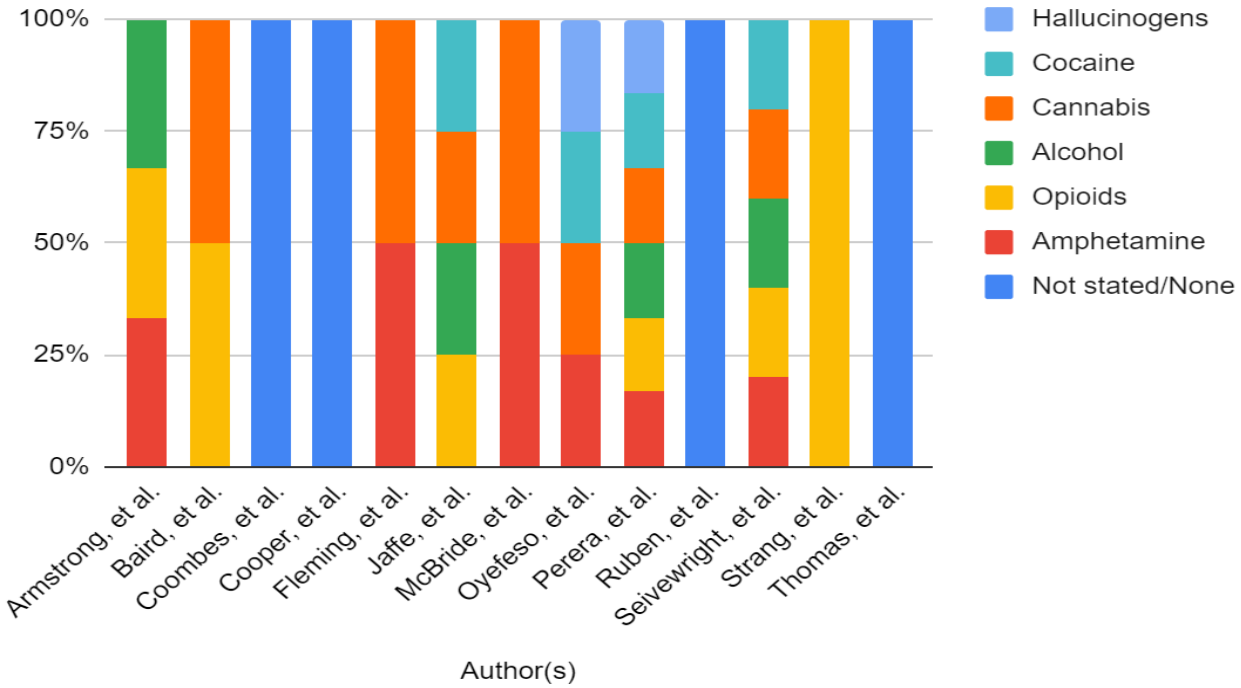

Figure 4: *Other substances noted in the included publications*

- The OTC/POM being misused were sourced from a variety of places, including online, from (various) pharmacies/GPs, street dealers and friends/family. As described in ***Table 3*** (Row 4), where the source was stated, information about at least one source was provided, though sometimes the details were limited. Three studies did not provide any explicit details about how the medication was obtained.

- Adverse consequences were commonly reported, and included complications from injecting, impact on personal finances, pharmacy bans, overdoses, accidents, criminal activity, and physical health issues, including problems with withdrawal and harmful excessive paracetamol/ibuprofen intake from codeine combination products. ***Table 3*** (Row 5), outlined that four studies did not provide any details about adverse effects and some provided limited information. Withdrawal symptoms, for example from opioids were a notable issue, and perpetuated misuse, as people continued to take them to alleviate withdrawal.

- OTC/POM were misused for a variety of reasons, including to self-detoxify, for desired psychoactive effect, to experiment, to manage street drug shortages, psychiatric conditions, pain disorders, withdrawal symptoms, and to potentiate the effects of other substances. ***Table 3*** (Row 6), described that rationale for use was mentioned in ten studies, though some provided only limited details. Similar to adverse consequences, withdrawal symptom management was frequently cited.

- There was likely significant variance in the pattern of OTC/POM misuse by people accessing SMS. ***Table 3*** (Row 7), summarised that variation was observed both within and between publications, including in relation to duration, amount, and frequency, ranging from single one-off or minimal use, to routine, daily, heavy use. Where details were provided, the levels of use were sometimes significant, and gave notable cause for concern. Six studies did not provide any tangible information about patterns of use.

Additionally, it was observed that the need for improvements to healthcare provision were frequently commented upon, and ten studies highlighted the need for increased awareness of OTC/POM misuse. None of the studies were found to have used a validated questionnaire.

Table 3: *Summary of CERQual assessment and review findings*

Row	Summary of review finding	Study ID contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence	Explanation of CERQual assessment
1	Benzodiazepines, opioids, and antihistamines were cited as the most misused OTC/POM by people accessing SMS	1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 13	Moderate methodological limitations (some studies did not provide full details e.g., non-responder rates unclear, statistical methods not stated, and confounders not accounted for)	No or very minor concerns about coherence	Minor concerns about adequacy (some had limited sample sizes e.g. case reports)	No or very minor concerns about relevance (3 studies mentioned products no longer used in the UK)	High confidence	12 of the 13 studies specified at least one of these medicines (9 publications mentioned benzodiazepines, 6 mentioned opioids, and 5 mentioned antihistamines)
2	When misused, OTC/POM were usually taken orally or injected	4, 5, 7, 8, 9, 10, 11, 12, 13	Moderate methodological limitations (some studies did not provide full details e.g. non-responder rates unclear, statistical methods not stated and confounders not accounted for)	Very minor concerns about coherence (not all were explicit)	Minor concerns about adequacy (some had limited sample sizes e.g. case reports)	No concerns about relevance	High confidence	7 described oral, 6 described injecting (various) and 1 reported snorting, No other routes were reported/explicitly stated
3	OTC/POM misuse often occurred alongside illicit substance use, especially amphetamine, cannabis, and opioids	1, 2, 3, 5, 6, 7, 8, 9, 10, 11, 12	Moderate methodological limitations (some studies did not provide full details e.g. non-responder rates unclear, statistical methods not stated and confounders not accounted for)	No concerns about coherence	No or very minor concerns about adequacy (2 did not specify which illicit substance)	No concerns about relevance	High confidence	11 of the 13 studies specified illicit use (7 mentioned cannabis, 6 mentioned amphetamines and 6 mentioned opioids). The remaining studies did not provide any details (but an absence of details does not equate to no use)
4	The OTC/POM being misused were sourced from a variety of places, including online, from (various) pharmacies/GPs, street dealers and friends/family	2, 3, 4, 5, 6, 7, 8, 9, 10, 11	Moderate methodological limitations (some studies did not provide full details e.g. non-responder rates unclear, statistical methods not stated and confounders not accounted for)	Minor concerns about coherence (some provided limited details)	Minor concerns about adequacy (some provided limited details)	No concerns about relevance	High confidence	Where provided, at least one source was stated. The remaining 3 studies did not provide any explicit details
5	Adverse consequences were common and included complications from injecting, impact on finances, pharmacy bans, overdoses, accidents, criminal activity, and physical health issues including withdrawal symptoms and harm from excessive paracetamol/ibuprofen codeine combination products	1, 2, 4, 5, 7, 8, 10, 11, 13	Moderate methodological limitations (some studies did not provide full details e.g. non-responder rates unclear, statistical methods not stated and confounders not accounted for)	Minor concerns about coherence (some provided limited details)	Minor concerns about adequacy (some provided limited details)	No concerns about relevance	High confidence	The remaining 4 studies did not provide any details about adverse effects (but an absence of details does not equate to none being experienced). Withdrawal symptoms were a notable issue and perpetuated misuse
6	OTC/POM were misused for a variety of reasons, including to self-detoxification, for desired psychoactive effect, to experiment, to manage street drug shortages, psychiatric conditions, pain disorders, withdrawal symptoms, and to potentiate other substances	1, 2, 3, 4, 5, 6, 7, 9, 10, 11	Moderate methodological limitations (some studies did not provide full details e.g. non-responder rates unclear, statistical methods not stated and confounders not accounted for)	Minor concerns about coherence (some provided limited details)	Minor concerns about adequacy (some provided limited details)	No or very minor concerns about relevance	High confidence	The remaining 3 studies did not provide any details about reasons for use. Withdrawal symptoms were a notable issue
7	There was significant variance in the pattern of OTC/POM misuse by people accessing SMS	1, 4, 7, 8, 9, 10, 11	Moderate methodological limitations (some studies did not provide full details e.g. non-responder rates unclear, statistical methods not stated and confounders not accounted for)	Minor concerns about coherence (some provided limited details)	Minor concerns about adequacy (some provided limited details)	No concerns about relevance	High confidence	Significant variation in use reported within and between publications, including duration, amount, and frequency, ranging from single one-off/minimal use to routine daily heavy use. The remaining 6 studies did not provide any notable details about patterns of use

2.5. Discussion

2.5.1. Key Findings

The prevalence of oral and injecting over any other routes of administration were notable. The latter was to be expected in the context of people who are actively injecting other substances, since latest OHID data indicates that 17% of all people who started treatment in 2022-23 had experience of injecting, and this increased to about 52% for problematic opiate use (OHID, 2023). Predominant oral administration is also in keeping with the findings of other researchers such as Cassidy, *et al.,* (2015).

The variety of sources that OTC/POM were obtained from have been identified by others (Gossop and Moos, 2008; Rosenblum, *et al.,* 2007). The endemic use of more than one source has been similarly reported by Bouland, *et al.,* (2015), who found that individuals accessed an average of at least two different healthcare providers, with 78% using more than one pharmacy. When considering adverse consequences and reasons for use, the need to manage withdrawal symptoms was stated in most of the studies, and the importance of withdrawal symptom management, as well as other contributory factors such as mental health and pain management, have been emphasised in national guidance (DHSC, 2017). Adverse consequences, such as the impact on health and occurrence of accidents has similarly been reported by others (Abeysundera, *et al.,* 2021; Amaladoss and O'Brien, 2011; Modi, *et al.,* 2013; Schifano, *et al.,* 2021).

The relatively limited mention of OTC/POM stimulants has also been found in early findings from an American surveillance system (Cassidy, *et al.,* 2015), and the frequent citing of benzodiazepines and opioids is in keeping with current UK national data trends. For example, in 2022-2023, 4.8% of people accessing SMS who used illicit substances/misused OTC/POM reported misuse of benzodiazepines, and 48% reported using opiates (although the latter included traditional street drugs such as heroin, and those available OTC and on prescription) (OHID, 2023). The prevalence of benzodiazepines and opioids was also found in the meta-analysis by Wang, *et al.,* (2018), who included 80 eligible studies from English and Chinese databases, and found that amongst people who use opioids, they had a pooled prevalence of 40.6% and 23.2% for benzodiazepines and POM opioids respectively, (though individuals were not necessarily accessing SMS).

Prevalent use of other substances, particularly illicit opioids and cannabis, were to be expected given that individuals were accessing specialist SMS, where about half of people seeking support are known to have issues with opiates, and about 20% use cannabis (OHID, 2023). It was unexpected that alcohol or cocaine did not feature as frequently, since about half of individuals presenting to SMS report problems with the former and 13% with the latter (OHID, 2023). Amphetamine was cited more commonly than would perhaps be expected as the latest data suggests that just over 2% of people accessing SMS currently report this substance as an issue (OHID, 2023). These differences may have been observed because older publications are unlikely to be reflective of current drug trends or OTC/POM availability (such as temazepam capsules), or because the information wasn't stated or could not be captured through the study design. It should be noted that some studies did not comment on concomitant use, though an absence of this information being provided does not equate to a lack of use.

The variance in the pattern of misuse (for example from occasional to several times a day, every day), was reflective of what is seen in SMS with other substances and in national trends. For example, in 2022-23 about 2.3% of people were using frequently (defined as having used more than once a month in the last year) (ONS, 2023b). Although some studies provided limited details, significant levels of use and exceptionally high doses were reported. This is of concern because of the associated risk of harms, especially when considering the degree of polypharmacy evidenced in ***Figure 3*** and ***Figure 4.*** Concomitant illicit drug use and the mention of substances/medicines which have additive sedating and respiratory depressant effects such as benzodiazepines and opioids, is concerning because of their increased association with adverse consequences such as drug related death due to accidental overdose (Chan, *et al.,* 2006; Jones, *et al.,* 2012; Macleod, *et al.,* 2019; NRS, 2023; Robinson, 2017).

2.5.2. Strengths and Weaknesses

This was thought to be the first systematic review of the published literature pertaining to OTC/POM misuse in adult SMS. Although specialist librarian support from Aston University confirmed search strategy suitability, significant, labour-intensive manual searching was still required. Whilst this limited the number of papers, this did allow for detailed checks of all reference lists despite minimal resources, to provide a level of assurance that the search and assessment were as thorough as possible.

The study selection process was fully described, and all publications were accounted for. Similar methodology has been used with success by other researchers undertaking systematic reviews which have covered related subject matter, such as Sanger, *et al.,* (2018), who used the same approach for their systematic review protocol for iatrogenic opioid dependence. The systematic review of POM opioid misuse in the prison setting by Bi-Mohammed, *et al.,* (2017), likewise used similar methodology and also found a very limited number of papers (n=10) for inclusion.

The final number of thirteen studies meant that the subsequent analysis was limited and only tentative generalisations to the wider population accessing SMS can be made, and especially for demographic characteristics such as gender and age. More papers could have been included if it had been possible to extract the data relating just to 18 years or over, or to individuals recruited from SMS rather than other services such as sexual health or homeless shelters. Restricting the publications to UK-only enabled more relevant findings, as in other countries different medicines are available and drug markets also vary. The finding that three studies referenced products that are no longer available in the UK (particularly temazepam capsules), was perhaps reflective of the age of some of the publications: however, the medication is still available, albeit in different formulations, and therefore they were still considered as being relevant for inclusion (BNF, 2024; Wilce, 2004).

Since all reviewers used the same data collection form, which was piloted for suitability of use, it enabled the data extraction process to be standardised. The heterogeneous nature of the extracted data, the lack of consistent datasets and small number of studies identified (as exemplified in ***Table 1***), resulted in the use of a narrative synthesis, because of the inability to conduct meta-analyses or smaller sub-analyses, or

identification of themes which would have enabled a thematic analysis. This led to the predetermined analysis and assessment tools not being applicable. Therefore, to consider the study limitations, the risk of bias and to provide an assessment of confidence in the review findings, the approach required reconsideration: the GRADE-CERQual criteria was therefore applied in conjunction with the MMAT (Hong, *et al.,* 2018; Lewin, *et al.,* 2018a; Lewin, *et al.,* 2018b) during the data extraction process.

CERQual identified a moderate limitation in the methodologies used, predominantly due to an absence of complete datasets and reporting of statistical analysis for some studies. Despite these limitations, as has been similarly described by Lewin, *et al.* (2018b), a high confidence in all the review findings was found, which provides a degree of assurance, though the subjective nature of these tools must also be considered. Having two individuals independently undertaking study selection, data extraction, assessment of risk bias and review findings, with support from a third person to resolve disagreements, strengthened the assurance process. Additionally, including all publications in the analysis allowed complete reporting of the dataset.

This approach of using mixed methods is increasingly being applied in evaluative research (CRD, 2009). However, there is no widely used method for undertaking mixed method systematic reviews which can be more challenging and resource intensive, for example because of the increased volume of publications involved, the interpretative process and the additional synthesis methods which are employed to cover qualitative, quantitative and both data types (Petticrew, 2013). This highlights the importance and strength of having a robust protocol from the outset (Gittins, *et al.,* 2021) and the use of the PRISMA checklist was also suitable for mixed methods systematic reviews (Page, *et al.,* 2021).

2.5.3. Implications for Clinicians, Policymakers and Researchers

The frequent mention of antihistamine misuse was unexpected because this medication type is not commonly observed in nationally reported trends; however an increase in their association with drug related deaths and other adverse events has been observed (Burns, 2021; Chiappini, *et al.,* 2021; Oyekan, *et al.,* 2021), suggesting the need for further research and increased vigilance for this amongst healthcare professionals. Although the level of detail provided about adverse consequences was often limited, due to the frequent mention of withdrawal symptoms, this highlights an important need for SMS to consider how associated approaches can be optimised to alleviate them. This also supports national guidance which outlines the need for proactive interventions to be prioritised to reduce drug related harms, especially relating to polypharmacy and co-occurring physical and mental health conditions (DHSC, 2021). Additionally, there was limited data relating to patterns of use, but when misuse occurred, they were associated with significant harms, which warrants further exploration.

The variety of sources used to obtain OTC/POM highlights that making changes to supplies from pharmacies or prescribing changes in isolation may be unlikely to completely ameliorate availability, especially where online sales and street dealing remains ongoing (Pearce, 2020). If supplies are restricted, care should be taken to avoid unintended consequences, such as people seeking unregulated alternatives (Caulkins, *et al.,* 2021). The frequency that the need for improvement in raising awareness of OTC/POM misuse and other

changes to healthcare provision was commented upon was notable. Despite the age of some of the publications, this is a continued issue, especially given the more recent national review by Marsden, *et al.,* (2019). This highlights the need for continued developments and a greater understanding of how best to undertake these required improvements, for example by creating greater awareness amongst the pharmacy profession (Jankovic, 2019; RCoA, 2017).

The heterogeneous and incomplete dataset made it difficult to meaningfully identify themes for demographic characteristics. Consequently, although men in their mid-twenties often featured, this cannot be stated with robust assurance about reliability. This, as well as the general limited number of studies identified, and lack of prevalence data, highlights the need for additional research to be conducted on this topic. As the predominant use of qualitative methodologies was identified, this demonstrates that their use, (especially interviews), to explore this subject area has been successful. Whilst questionnaires/surveys generated the largest datasets indicating the utility of this approach for further research, none of the studies were found to have used a validated questionnaire.

2.6. Conclusion

Completion of this systematic review highlights the need for additional research to be conducted because of a paucity of the current published evidence base relating to OTC/POM misuse by adults who are accessing SMS in the UK. Benzodiazepines, opioids, and antihistamines were most frequently cited as being misused, usually administered orally or by injection. Pattern of misuse varied significantly, and they were sourced from a variety of places, including online, from pharmacies/GPs, street dealers and friends/family. Adverse consequences were common, as was the use of other substances, with amphetamine, cannabis and opioids being most prevalent. Withdrawal symptoms were a notable issue and contributed to perpetuating misuse. Qualitative methodologies were used most frequently: the use of interviews predominated, though questionnaires/surveys generated the largest datasets. A limited number of relevant studies were identified which has consequent impact upon the strength of the analyses, associated findings, and generalisability.

3. Research Strategy and Design

The purpose of this chapter is to present an oversight of the potential methodologies which could have been employed to explore the misuse of OTC/POM by adults that are accessing community SMS. The rationale for why the selected methods for the four subsequent studies were chosen, including utilisation of findings from the systematic review ***(see Chapter 2 – Systematic Review)*** are also outlined.

This chapter considers the ethical, methodological, and practical challenges of undertaking research in community SMS, such as obtaining consent, Researcher reflexivity, undertaking participant recruitment and data management processes. It also highlights the added complications of the COVID-19 pandemic (including the national 'lockdown' and subsequent iterations) which inadvertently coincided with when this research was undertaken.

To avoid unnecessary duplication, where there are similarities in the methods which were employed, for example relating to the use of semi-structured interviews for service users, SMS staff and affected friend/family members, these are stated here, and further details for each study are then provided within specific chapters as appropriate ***(see Chapter 5 - Study 2: Service User Interviews, Chapter 6 - Study 3: Staff Interviews and Chapter 7 - Study 4: Friend/Family Interviews respectively)***.

3.1. Rationale for Selected Methodologies

As the systematic review identified ***(see Chapter 2 – Systematic Review)***, OTC/POM misuse may be detected and explored in a variety of ways, and there is a current paucity of published UK research which explores this in SMS. Findings from the systematic review outlined that a variety of different methods, including qualitative and quantitative data, had been employed by the published studies.

3.1.1. Quantitative Methodologies Overview

Quantitative methods can establish the associations and trends between different variables, and the extent to which the findings are generalisable to a wider population. As they provide a fixed, single set of data, they may be viewed as 'one-dimensional', as they do not allow for exploration of the relationship between different variables, or for changes following initial data capture (Driscoll,*et al.,* 2007). Often a hypothesis is generated and tested using quantitative methods, with the use of statistical analysis and a 'power' calculation to determine sample size (Bowling, 2002).

Quantitative data can be captured in the form of discrete, categorical, or continuous data, and in a variety of different ways. When exploring a topic such as the misuse of medication, quantitative data may be obtained from wastewater analysis and drug tests, capturing for example which medicines are present/absent in urine, and in what amounts (McNamara, *et al.,* 2015; Passik, *et al.,* 2000; Peles, *et al.,* 2015). However there are limitations to their use, such as requiring the ability to detect specific medicines, needing access to reference samples, knowledge of metabolites and stability in fluids: for example, OTC/POM may not be detectable or

may give false positive results on drug tests (Martinak, *et al.*, 2017; Schwartz, *et al.*, 2008; Wen, *et al.*, 2019). Analysing samples in isolation also does not allow for confirmation that the OTC/POM was actually being misused, or for exploration of confounding factors, or discussion with individuals regarding their reasons for use/misuse, experiences with them or any subsequent treatment needs.

Wastewater analysis requires highly specialist (and expensive) laboratory equipment and expertise to be able to implement. Furthermore, permissions from water companies/sewerage treatment works would also likely be required, which would be particularly difficult to obtain during the pandemic. Drug testing is also associated with notable cost and challenges to implement, and especially during COVID-19, when face-to-face interventions were deliberately restricted to minimise transmission risk. There would also be a need to carefully consider upskilling individuals to be able to collect samples, provision of appropriate facilities which maintain privacy and dignity of the participant, and infection control measures to ensure safe handling of body fluids/material which could be hazardous to health. At the beginning of the pandemic, personal protective equipment was not routinely available in SMS, and staffing levels/footfall in services was minimised to enable social distancing and shielding of vulnerable people. Therefore, these methods were not selected for use.

The use of closed questions (e.g., 'yes/no') and categories (e.g., gender, ethnicity), which are often used in surveys and occasionally also in interviews, can be used to generate quantitative data. This approach can also make data completion easier and quicker for the participant. The subsequent quantitative data can then be relatively easily analysed, making it preferable for larger samples. Quantitative, fixed datasets can also be similarly generated from clinical records such as those recorded for NDTMS, for example, substance/medication name, injecting, housing and employment status, and demographic data such as age, ethnicity and gender (PHE, 2020a). With the appropriate ethical approvals and data governance arrangements, this information is readily accessible in SMS systems, relatively cost-effective to obtain, and especially when automated reports can be used to extract the data.

The systematic review usefully identified where such approaches have been successfully used to obtain quantitative data relating to OTC/POM misuse in the UK SMS setting. Some had relatively large sample sizes, such as 71 patient records (Oyefeso, *et al.*, 1996), 297 interviews (Jaffe, *et al.*, 2004) and 208 surveys (Strang, *et al.*, 1994); albeit the information obtained was somewhat limited, for example in relation to demographic data ***(see Chapter 2 – Systematic Review)***.

3.1.2. Qualitative Methodologies Overview

Often qualitative research is used to explore more 'in-depth' views, and the methods are continually applied until a degree of data saturation is thought to have been achieved, which is where no new or relevant information is elicited (Bowling, 2002; Coyne, 1997). However, ascertaining when data saturation is achieved and the number of participants required for this can be difficult to determine a priori, so is usually determined when in-situ (Braun and Clarke, 2019; Reilly and Parker, 2012; Sim, *et al.*, 2018).

When an exploratory, inductive, pragmatic, grounded theory approach is taken, it enables hypothesis generation, which is especially useful to gain an understanding of participant actions, behaviours, attitudes, views and experiences from their perspective (Brod, *et al.,* 2009; Green and Thorogood, 2014; Lee and Cooper, 2019; Urquhart, 2013). Additionally, it is important to consider the potential impact of the Researcher(s), their perspective and self-awareness, to ensure reflexivity. This requires them to acknowledge from the outset their own 'world view', account for their position/role as a Researcher, and how their experiences/personal biases may subsequently impact upon how they undertake the research, such as the way in which questions are asked or responded to, the prism through which the results are analysed, and the subsequent influence on the findings (Morse, *et al.,* 2002; Sutton and Austin, 2015) ***(see 3.6.2. Researcher Reflexivity)***.

Qualitative data may be provided as single words, in lists, detailed prose or narrative, so the volume of data that is generated may therefore be copious, even from a small sample: consequent analyses can be time consuming and may have the added complexity of handwriting interpretation (Silverman, 2021). Data collection can also be burdensome on the participant, which may increase the risk of missing data and uninformative responses may result in unusable data. However, the use of open questions encourages more meaningful, comprehensive, unique, and richer answers from individuals, and uses their own words, rather than predetermined narrow answers. This means that open responses can provide essential insights into unexplored areas and highlight issues most relevant to participants, whilst reducing the likelihood of missing information.

Qualitative methodologies include surveys, interviews and focus groups (Bryman, 2012), and these approaches have been used with good effect to explore the topic of OTC/POM misuse (Fingleton, *et al.,* 2016; Inciardi, *et al.,* 2009; Kimergård, *et al.,* 2017; Orriols, *et al.,* 2009; Ramlagan, *et al.,* 2010; Van Hout, *et al.,* 2017). As demonstrated by the systematic review, interviews (Armstrong, 1992; Coombes and Cooper, 2019; Cooper, 2013a; Ruben and Morrison, 1992) and questionnaires/surveys (Baird, *et al.,* 2014; Strang, *et al.,* 1994), were especially successful for generating appropriate datasets in the SMS setting ***(see Chapter 2 – Systematic Review)***. Some novel netnographic approaches have been utilised (Lee and Cooper, 2019), including surveying websites and online forums such as 'Facebook' (Norman, *et al.,* 2014) and 'Twitter' (Guirguis, *et al.,* 2020b). However, this methodology requires individuals to have internet access which may not always be possible or desired by people who misuse OTC/POM, for example, if they are street homeless.

Focus groups can identify topics that are important for participants using their own language and terms. Unlike interviews, they allow for data collection from several (usually about six to eight) people, and can obtain a wide range of multiple perspectives in a relatively short time; however, there is a risk that group rather than individual views may be ascertained, and there may be hesitancy in expressing opposing views, especially in larger groups (Krueger and Casey, 2009; Stewart and Shamdasani, 2014). Additionally in a group situation individuals may be less likely to share sensitive or in-depth perspectives, due to feelings of shame and stigma (Robinson, 1999). To encourage group interactions and sharing of views and experiences, a facilitator usually utilises a semi-structured topic guide rather than a restricted set of questions (Barbour,

2010; Bryman, 2012). Skilled facilitators are required to manage group dynamics, and minimise the impact of group bias, particularly in the case of strong personalities and views. For this research, it was determined that focus groups would not be feasible because they were felt to be more challenging to organise and facilitate in the context of COVID-19.

3.1.3. Determining a Mixed Methods Approach

The findings from the systematic review ***(see Chapter 2 – Systematic Review)***, as well as the respective strengths and limitations of quantitative and qualitative approaches outlined above, were considered when determining the required research methods: the Researcher and the Supervisory Team therefore agreed that a mixed methods approach, where both approaches are used (Johnson, *et al.,* 2007) would be preferable.

The use of mixed methods is common in health services research where there are complex issues, to elaborate or explain or enhance the usefulness of findings, and to counterbalance and complement the limitations of different datasets (Barbour, 1999; Bryman, 2006; Hong, *et al.,* 2020; Johnson and Onwuegbuzie, 2004; O'Cathain, *et al.,* 2007). A mixed methods approach therefore allows for both qualitative and quantitative data to be used concurrently: for example, qualitative data can be used to explore the quantitative findings, and quantitative data can be used to enable broader generalisation and establish trends from the qualitative findings (Pluye and Hong, 2014).

For this research, a pragmatic worldview has been taken, in that both qualitative and quantitative approaches were utilised within the same studies, and a practical research philosophy was applied, which is real-world and practice orientated (Creswell and Plano Clark, 2017; Tashakkori and Teddlie, 2010). Furthermore, as described by Brierley (2017), adopting a flexible approach to the application of mixed methods research *"by conducting it within the pragmatic paradigm"* also means that the research would not be not impacted by ontological or epistemological restrictions.

As the need for both qualitative and quantitative approaches was determined and planned from the outset, a fixed mixed methods design was utilised, rather than an emergent design where a second approach is applied after the research has already commenced when the first method was found to be inadequate (Creswell and Plano Clark, 2017). An initial inductive approach was utilised, and whilst the individual studies were planned to be sequential, for practical reasons (including managing time and resources due to COVID-19), the data capture was undertaken simultaneously, though the data was analysed in sequence (Morse and Niehaus, 2009). Additionally, the approach taken enabled an exploration of an area (OTC/POM misuse in SMS) that has not been previously studied in depth: therefore, whilst there are various types of mixed methods research designs, such as convergent parallel, exploratory sequential, embedded, transformative and multi-phase (Hanson, *et al.,* 2005; Sharma, *et al.,* 2023), this study may be best described as qualitative-dominant, explanatory sequential (George, 2023; Hanson, *et al.,* 2005). Indeed, Schoonenboom and Johnson (2017) have similarly outlined the need to consider different mixed method design dimensions and that this should be constructed to fit each unique research situation.

When considering the different methods which may be employed, it was important to consider that in the context of OTC/POM misuse, individuals may not always be open or honest about what they are misusing; although if drug testing is used as a collaborative tool, self-reports are more likely to be corroborated (Hamid, *et al.,* 1999). Even in the case of complete transparency, findings may still differ, for example because illicitly sourced formulations may not always contain the expected substance, due to memory impairment or inability to recollect what was consumed whilst intoxicated. Observational studies (from which both data types may be obtained), may allow for a direct comparison between what people say and do, but were not thought to be feasible due to the context of COVID-19, made more complex by the administration of potentially illicit substances in the person's own (uncontrolled) environment. This approach is also resource-intense, cannot be covert and carries notable risk to the Researcher, so was not felt to be feasible.

As an alternative, the use of resource logs such as 'drug diaries' (RCGP, 2014b), were considered for use to capture information relating to what was being misused, when, and consequent impact on wellbeing. They are commonly used in SMS, may improve recall bias, and reduce missing data, as events are recorded as they occur (Marques, *et al.,* 2013). However, this approach is more intensive for participants to complete, whereas alternative methods such as a questionnaire is usually only undertaken once. Qualitative and quantitative data relating to OTC/POM misuse can also be obtained from prescribing data, post-marketing surveillance, pharmacovigilance studies and electronic medication dispensing systems (Küfner and Rösner, 2008; Schifano, *et al.,* 2019). However, such methodologies, similar to analyses of drug testing data, would also be unlikely to contain the required information pertaining to exploring the person's experiences and perspectives. The Researcher also did not have access to appropriate systems to be able to utilise such approaches. However, the Researcher could obtain information from SMS clinical records, and this approach has been used by other researchers such as Nielsen, *et al.,* (2015b) to conduct case reviews.

Clinical records are also not without their limitations: for example, they are only applicable to people who access SMS for treatment, and not those who access anonymised parts of the service such as NSP. Furthermore, documentation has been found to be incomplete (Walley, *et al.,* 2009), and may not capture all the salient information required, because the person may not make full disclosures due to concerns about the potential impact on their care, and as routine data collected for NDTMS purposes (which is also stored in clinical records), only reports up to the person's tertiary drug of choice (PHE, 2020a). These limitations could be somewhat overcome by incorporating the concomitant use of interviews, and the systematic review ***(see Chapter 2 – Systematic Review)***, identified that a similar approach had been undertaken in UK SMS by Seivewright and Dougal (1993).

After much consideration and discussion with the Supervisory Team, the Researcher felt that questionnaires and individual interviews (supplemented with clinical records for people who are receiving treatment from SMS), would be the selected methods. Interviews and questionnaires were preferred as they were identified in the systematic review as generating the most amounts of data specifically relating to this subject matter ***(see Chapter 2 – Systematic Review)***. Furthermore, Noble, *et al.,* (2012) identified that the most complete

(82%) datasets are found for interviews, and whilst the response rate can often be relatively low for questionnaires, self-completed questionnaires were associated with high completion rates.

These approaches were also thought to be feasible (though dissemination/participation was still expected to be limited), during the pandemic restrictions. It was planned that the questionnaires would be self-completed, implemented first and distributed only to SMS service users, and the information from these would inform the consequent interview questions. It was thought that the interviews would allow for an additional, more in depth exploration, building upon the findings relating to the reasons for OTC/POM misuse identified from the questionnaires, and would enable individuals to disclose more detailed and personal experiences, for example relating to the impact upon other substances used and physical/mental wellbeing.

Clinical records were used to obtain quantitative data relating to service user demographic characteristics, including their age, sex, primary drug (such as benzodiazepines, opioids, cannabis, and alcohol), employment, housing, and injecting status. This data was regularly inputted and updated by SMS staff, and the information was obtained directly from the service user during their treatment reviews for the purposes of NDTMS reporting (PHE, 2020a). It was also planned from the outset that SMS staff would be interviewed, and the intention was to include staff in a variety of front-line roles and with differing levels of experience. It was only after the frequent mention of friends/family by both SMS staff and people accessing the services that the research was extended to incorporate this group too.

This approach to data triangulation, where different methods and incorporating the perspectives of various key informants to create a more comprehensive dataset (Kuper, *et al.,* 2008; Tonkin-Crine, *et al.,* 2016), should also *"ensure the 'trustworthiness' of the findings"* (Noble and Smith, 2015). This approach has also been used by researchers such as Ramlagan, *et al.,* (2010), who obtained both data types from national datasets, questionnaires, focus groups and interviews with a variety of different key informants across a variety of South African SMS sites. Furthermore, the Consolidated Criteria for Reporting Qualitative Research checklist was used to report on the qualitative data to provide assurance of rigour, and to ensure complete and transparent reporting of the findings (Tong, *et al.,* 2007).

3.2. Questionnaire Design

A questionnaire may assist with more objectively measuring subjective views, and there are some questionnaires which exist that are related to the misuse of OTC/POM. Examples include the Pain Medication Questionnaire (Holmes, *et al.,* 2006) and the Prescription Opioid Misuse Index (Knisely, *et al.,* 2008), which are specific only to opioids and are designed for use in the primary care (rather than SMS) setting. Unfortunately, a suitable, good quality questionnaire that would be relevant to the research topic had to be created: none were identified via the systematic review ***(see Chapter 2 – Systematic Review)***; a search of the Core Outcome Measures in Effectiveness Trials database (2021); Database of Instruments for Resource Use Measurement (2021); by the stakeholders involved in development/piloting process; raised during the ethical review process; or known to the Researcher who has worked in the sector for many years.

As previously outlined, a combination of quantitative and qualitative data can be collected via questionnaires: a purely qualitative approach would be difficult to enable collation of data amongst many participants, and a larger number of respondents increases the ability to generalise the findings to the wider population. The questionnaire ***(see Appendix 3 - Questionnaire)*** which was created, collated both quantitative and qualitative data from service users who had misused OTC/POM in the preceding month. As the questionnaire did not require the rating of the different domains being explored, it was felt that a Delphi approach (Murphy, *et al.,* 2017) was not indicated, but may be considered as a future development.

An anonymous self-completed questionnaire was selected, as it avoids interviewer bias and risk of coercion, and is relatively inexpensive and easy to administer. Whilst this approach is known to be associated with more complete datasets (Noble, *et al.,* 2012), and encourages participants to provide accurate information more freely, it prohibits checks for completeness prior to submission, verification of which individuals have completed it, subsequent assertive follow up and the provision of incentives to enable a higher response rate ***(see 3.6.1. Ethical Issues)***. Additionally, if participants subsequently decide to withdraw their submission this would not be possible because of the inability to identify which response was attributable to them: it was therefore essential that this was made explicit in the Participant Information Sheets (PIS) ***(see Appendix 4 - Service User Participant Information Sheet, Appendix 5 - Staff Participant Information Sheet and Appendix 6 – Friends/Family Participant Information Sheet)***.

Stakeholder review and piloting the questionnaire ***(see 3.4. Patient and Public Involvement)*** helped to ensure that the questions covered all the relevant issues, since the questionnaire must be comprehensive, specific to the respondent group and exclude any irrelevant items (Brod, *et al.,* 2009; Patrick, *et al.,* 2011a; Patrick, *et al.,* 2011b). It also confirmed that any inappropriate abbreviations, acronyms, jargon, and technical terms were avoided. This is important to limit ambiguity, the possibility of misunderstanding or missing items, and to ensure the acceptability of the questionnaire (McColl, 2001). The layout and format to aid navigation was carefully considered: simple, clear, concise, appropriate, familiar wording and phrasing was used, with clear instructions about what information to provide (McColl, 2001). The questionnaire format used tables to help guide the person to complete the required sections and had sufficient open space for responses to open-ended questions (McColl, 2001).

A paper version was favoured rather than an online tool, because SMS have more experience in distributing this format. Where the list of OTC/POM response categories was too long to fit on a single page, the question was repeated on the next page. Since no notable visual impairment was anticipated, font size 10 was used, which is generally considered to be the minimum permitted size within the SMS organisational style guide. Printing on white paper enhances legibility, with bold and italic formats added to focus the respondent's attention where applicable (Edwards, 2010). Standard size A4 paper stapled together with single sided printing reduced the risk of the pages becoming detached and minimised the risk of the person missing a page when turning over (Edwards, 2010).

A web-based data entry tool, where the participant completes the questionnaire online, needed to be considered due to COVID-19 restrictions, where service sites were closed, potential participants were self-isolating, and interventions were being provided remotely to reduce the risk of virus transmission. Therefore, an online version was created using the Joint Information Systems Committee online survey system, because it intrinsically met all data protection requirements, the use of the system was endorsed by Aston University, and it also enabled online questionnaire design, distribution and analysis in real-time (JISC, 2023). Additionally, the online version was freely accessible to participants regardless of their device and location. This was preferable to direct data entry methods where information is inputted into the system for analysis, which can also involve the need for encryption, the additional expense of data entry devices, and may feel overwhelming to some participants.

Having the option of an online version was also thought to be desirable given widespread internet access, ease of transferring data to a MS Excel® spreadsheet in the required format, and as there were no additional hardware or data entry costs. Additionally, online tools are thought to be quicker to complete, are associated with reduced data entry errors and are cheaper to distribute than more traditional approaches, for example by eliminating postage and other administrative costs, such as printing/photocopying and paper use. However, their full response rates may be lower, and especially if the person has received a lower level of education (Heiervang and Goodman, 2011). This was an important consideration given the known issues with educational levels in this population (Nielsen, *et al.,* 2011; Ramlagan, *et al.,* 2010). Therefore, the online tool utilised automated filter questions and branching options to ease navigation. Although digital approaches are thought to be well received amongst people who use substances, problems with digital poverty are known to affect people accessing SMS (Ashford, *et al.,* 2018; Perri, *et al.,* 2021), and are more likely if the individual is street homeless. Therefore, this approach offered an additional opportunity for individuals who do have digital access and are information technology literate enough to be able to engage, potentially enabling a larger population to participate and offering greater anonymity.

3.3. Interview Design

The interviews were designed to be explorative, with a modified grounded theory approach (Brod, *et al.,* 2009; Silverman, 2021). Individual interviews allowed for greater privacy when compared to other methods such as focus groups (Bowling, 2002): they are better suited to more sensitive topics, and to exploring knowledge in poorly understood or complex areas (Green and Thorogood, 2014; Urquhart, 2013). Although they require gaining of trust and building rapport with individuals so that they feel able to express in-depth personal views, such approaches have been successful, for example regarding the use of new psychoactive substances (Gittins, *et al.,* 2018a; Van Amsterdam, 2015; Van Hout and Bingham, 2012; Van Hout and Brennan, 2011) as well as OTC/POM misuse (Lyndon, *et al.,* 2017). Furthermore, other researchers have been able to analyse both quantitative and qualitative data obtained from semi-structured interviews to explore OTC/POM misuse (Lankenau, *et al.,* 2012).

Interviews are usually either structured, semi-structured or unstructured. Iterative semi-structured interviews were felt to be most appropriate for this research, and the systematic review ***(see Chapter 2 – Systematic Review)*** identified that similar approaches have been used by other researchers exploring OTC/POM misuse in the UK SMS setting (Coombes and Cooper, 2019). They allow the interviewer to flex to the participants' responses, follow up on ideas, and standardised responses to potential issues may be prepared in advance. This approach was preferred since an overly structured format would have been too rigid to accommodate the required level of flexibility needed to explore the research topic. Conversely, in-depth, unstructured interviews would have allowed for a deeper and richer insight, enabling a fully free-flowing conversation (Edwards and Holland, 2013). A semi-structured approach was therefore selected to allow for some level of consistency between interviews, whilst ensuring that all salient points would be covered (Jensen and Laurie, 2016).

The use of an interview guide ***(see Appendix 7 - Service User Semi-structured Interview Guide, Appendix 8 – Staff Semi-structured Interview Guide and Appendix 9 – Friends/Family Semi-structured Interview Guide)***, supported the Researcher, and provided consistency with an outline of the key areas to be covered, whilst allowing flexibility to explore issues that had not been anticipated and which may be sensitive (DeJonckheere and Vaughn, 2019). Stakeholder review and piloting the interview questions ***(see 3.4. Patient and Public Involvement)***, helped to ensure that the questions were appropriately phrased and covered all the relevant issues. To ensure they also did this in an efficient way was additionally important because interviews are resource intensive: transcriptions and analysis are time consuming and require expertise. Piloting of each of the interview guides suggested that the interviews should not usually take more than thirty minutes to complete (either face-to-face or virtual due to COVID-19 restrictions), and the duration that the resultant transcript would cover was likely to be significantly less if the introduction/consenting process and final part of the closing statement was not included in the recording. The iterative process also meant that after each interview the findings were reviewed and informed the approach in subsequent interviews (Brod, *et al.,* 2009). The changes made to the interview guides for service users and friends/family following this process were denoted by red text ***(see Appendix 7 - Service User Semi-structured Interview Guide, and Appendix 9 – Friends/Family Semi-structured Interview Guide)***.

Where internet connectivity was difficult, for example in rural locations, or due to digital poverty, facilitation via telephone was offered. When conducted face-to-face, this was at their usual SMS. All the interviews were conducted by the same Researcher, with the participant as the only other person knowingly present. The presence of non-participants such as the person's Recovery Coordinator would have been permitted if requested. Repeat interviews with the same individuals could support inter-rater reliability and member-checking/respondent validation may assist by ensuring that the findings corresponded with the participants' recollection and perspectives (Long and Johnson, 2000; Noble and Smith, 2015). However, this was difficult to implement in the SMS setting, and especially in the context of a pandemic.

3.4. Patient and Public Involvement

Patient and Public Involvement (PPI) was important to ensure that expert views were captured, and the suitability of language and terms used, since respondents may otherwise interpret questions differently to researchers, and they can also provide different perspectives (Adamson, *et al.,* 2004). Consequently, PPI improved the quality and relevance of the research, and in this context, PPI included people who had, or currently were, or could potentially use SMS, their friends/family/carers, SMS staff and organisations that represent people who use SMS (INVOLVE, 2012a). As part of the initial scoping process, forums and conversations on social media could have also been checked for views from the wider public, individuals may have been more formally part of the research team from the outset, or more formal arrangements with advocacy groups or other key stakeholders could have been considered (Sense about Science & NIHR, 2017), such as seeking the involvement of SMS commissioners or organisations like Adfam (2023a).

As it is essential to include key informant opinions (Streiner and Norman, 2004), to ensure question suitability and layout, staff and people with lived experience reviewed the questionnaire ***(see Appendix 3 - Questionnaire)***. They also reviewed the PIS ***(see Appendix 4 - Service User Participant Information Sheet, Appendix 5 - Staff Participant Information Sheet and Appendix 6 – Friends/Family Participant Information Sheet)***, and semi-structured interview guides for service users, staff and friends/family ***(see Appendix 7 - Service User Semi-structured Interview Guide, Appendix 8 – Staff Semi-structured Interview Guide and Appendix 9 – Friends/Family Semi-structured Interview Guide respectively)***.

Minor amendments were made to the documents after the initial stakeholder consultation, which included multiple staff meetings and discussions at service user/peer forums. For example, in the online version of the questionnaire, *'prefer not to state'* was added for ethnicity following strong feedback from a Recovery Coordinator from an ethnic minority background. It was important to ensure that the methodologies and associated findings were translatable and accounted for cultural differences and inclusion of minority groups. Subsequent piloting of these documents with at least one person in each of the groups to be studied, confirmed that the potential participants were likely to understand the questions as intended, and individuals also provided constructive feedback on their experience of participating. Improvements were again minor and included pinpointing where poor responses occurred and reflections upon how to improve this, to help ensure that the views of *"hard to reach"* groups were captured (Boynton, *et al.*, 2004).

The PPI engagement process used networks and conduits for communication and venues that the Researcher knew already existed and were readily available (INVOLVE, 2012b). The Researcher was not able to attend all of the relevant meetings (such as confidential forums led by peers or staff meetings led by local management teams) due to logistical challenges. It was unknown how many people actually attended them because this information was not ordinarily recorded and people were known to not always attend for the full duration, or they were sometimes rearranged/postponed with limited prior notice. Whilst there was a minor concern that the feedback would be reliable, the facilitators of these meetings were experienced in eliciting and communicating relevant and sensitive information in a group setting, and this was also thought

to be of benefit given that they had pre-existing trusting relationships with the attendees, increasing the opportunity to engage "*seldom-heard people in research"* (INVOLVE, 2012b).

Three individuals with lived experience and at different stages of recovery (one internal and two external), formally reviewed the documents in notable detail. In line with National Institute for Health Research (NIHR) guidance (2020a), it was important to appropriately remunerate these individuals for their time. Therefore, they were paid with shopping vouchers at rates commensurate with current best practice (NIHR, 2020b). During their involvement, these individuals were supported by the Researcher as and when required: two had an existing professional relationship with the Researcher, as they had collaborated when undertaking similar work previously.

Had budgets, timing and pandemic restrictions allowed, the PPI would have been more extensive, for example by including more people from the different potential participant groups in a more structured way, perhaps facilitated by an interactive workshop (Sense about Science & NIHR, 2017), and with a particular focus on friends and family. To further ensure greater consideration of diversity and inclusivity, deliberate PPI of people with digital poverty, disabilities, a broader range of protected characteristics, literacy issues and more complex active use of substances may have been incorporated (INVOLVE, 2012b). However, in the SMS context and with the pandemic restrictions this would have been difficult to implement.

Whilst there were limitations to the PPI approach used in this research, the Researcher also needed to be pragmatic and realistic about what was feasible, and the NHS Health Research Authority (2020) similarly recognised the additional challenges of COVID-19, outlining that whilst PPI remains important, "*it needs to be rapid and proportionate, so that studies can begin as quickly as possible*" and acknowledged the challenge and relatively lower rate of PPI as a consequence.

PPI engagement in the dissemination of findings was also important (Sense about Science & NIHR, 2017), therefore a wide range of activities were undertaken to share the findings and to create awareness of this work, including media articles, presentations at conferences and publication in international peer reviewed journals ***(see Appendix 1: Summary of Publications/Contributions)***. This was additionally important to ensure transparency, as this work was funded using public monies (INVOLVE, 2012a) using a Research Award from PRUK and the CMHP (PRUK, 2021; CMHP, 2021).

3.5. Sampling and Data Collection

The approach to sampling was carefully considered, especially given the SMS context in which this research was undertaken. To maximise the opportunity for participant inclusion, a variety of techniques were used (convenience, purposive and snowball). Random sampling was not feasible due to the way that SMS operates: the actual number of potential people that SMS may have contact with, as well as their identification or the details of their friends/family is not always known (for example, when people access confidential NSP where their identifying details are not recorded). Furthermore, as the data collection occurred during the

unexpected COVID-19 pandemic, had this approach been used for SMS staff, it was likely to negatively affect participation rate, as the capacity for their involvement was extremely limited at that time.

The data collection took place at SMS operated by Humankind, one of the UK's largest national third sector specialist SMS providers. The charity joined with Exeter Drugs Project (EDP) in April 2020 via a subsidiary model (where they receive organisational support and governance from Humankind), and at the time when the research was conducted, was estimated to have a total of over 1,300 staff and approximately 100 volunteers providing services for over 85,000 people (Humankind, 2021). This organisation was also selected for practical reasons, as when the research was undertaken, the Researcher was employed by Humankind, and therefore had existing knowledge of the associated clinical systems and how to connect with key stakeholders to ensure appropriate PPI and participant recruitment approaches.

Humankind works with people regardless of the substance(s) which they have a problem with, including OTC/POM misuse and affected friends/family. They operate low threshold services (including NSP), so do not necessitate any 'minimum' requirements or any other prerequisites, except that the person must be aged at least 18 years. The organisation operated numerous integrated community SMS across England, and was the contract holder (the 'prime') for the following services where data was collected from:

- Barnsley Recovery Steps (BRS): a metropolitan borough of South Yorkshire based in Barnsley.
- Calderdale Recovery Steps (CRS): a metropolitan borough of West Yorkshire based in Halifax.
- Forward Leeds (FL): a busy city centre and the second biggest UK SMS with hubs in Armley, Kirkgate and Seacroft.
- North Yorkshire Horizons (NYH): a rural SMS across North Yorkshire with hubs in Harrogate, Northallerton, Skipton, Selby, and Scarborough.
- REACH: operated via EDP in Dorset, a rural county on the South coast with hubs in Christchurch, Gillingham, and Weymouth.
- Staffordshire Treatment and Recovery Service (STARS): a predominantly rural county in the West Midlands with hubs in Newcastle-under-Lyme, Stafford, and Burton.
- TOGETHER: operated via EDP in Devon, with hubs in Barnstaple, Exeter, and Newton Abbot.

Enabling all eligible individuals to be invited to participate from all of these SMS enabled a range of relevant views to be obtained (Brod, *et al.,* 2009; Green and Thorogood, 2014). Recruitment of participants was planned to be kept internal to Humankind, given the geographical spread and the variety of services included. This approach had the additional potential to apply the findings (such as identification of service development needs) to the same organisation which (at least in theory), should be utilising standardised approaches to care delivery. It also enabled additional support to be provided to individuals which would not be possible, for example if recruitment occurred via social media platforms. Had this been extended to other SMS (including beyond England), this would have perhaps enabled greater generalisability of the findings, due to increased participation; however, it would have also necessitated greater logistical challenges, more ethical approvals (especially via NHS conduits), and data sharing agreements which can be time consuming and complicated to implement.

The intention was to undertake approximately twenty interviews for each group (SMS staff, service users and friends/family), to achieve likely data saturation; however, previous research suggests that as few as eleven or twelve may be required (Guest, *et al.,* 2006; Van Hout and Bingham, 2012). Indeed, Gittins, *et al.,* (2018a) found that twelve was sufficient when exploring similarly sensitive issues in SMS and the systematic review identified that Coombes and Cooper (2019), only required fifteen ***(see Chapter 2 – Systematic Review)***.

Interviews were digitally recorded using an encrypted voice recorder (Dictaphone®), which was activated once the participant provided informed consent and had agreed to the interview commencing. There was scope for field notes to be made during the interview, and these were used if there were any difficulties in understanding the audio-recordings. Audio recordings also allowed for more complete data and detailed transcriptions than relying on memory or field notes alone. As soon as possible, the recording was checked for audibility, uploaded to the secure online platform, and then deleted from the Dictaphone®. All recordings were fully transcribed verbatim and separately, by an independent transcriber (Brod, *et al.,* 2009). The transcriber was an experienced administrator who usually worked in NHS healthcare settings and was familiar with the associated data governance arrangements and requirements of the Data Protection Act (National Archives, 2024b). Once received, the transcripts from the interviews were checked by the Researcher to ensure completeness. The transcriber highlighted any words where they struggled with the audibility/clarity, allowing the Researcher to particularly focus on these areas. During the transcription accuracy checking process, words which the transcriber was not familiar with such as the names of some medicines were corrected.

3.6. Ethical Considerations and Risk Management

The questionnaire and interview methodologies were reviewed and approved by Humankind/EDP and Aston University's Life and Health Sciences Ethics Committees (ID#1655), which were revised to include friends/family. Evidence of the associated approvals can be found in ***Appendix 11 – Ethical Approvals***. How the research was to be conducted, and mitigation of potential risks were considered, and the final version of the Risk Assessment with relevant risk-management plans can be found in ***Appendix 12 - Risk Assessment***.

3.6.1. Ethical Issues

Consideration was given to avoid any potential coercion. Incentives may facilitate response rates and money which is provided unconditionally may be the most impactful (Roberts, *et al.,* 2000). However, monetary incentives bring ethical and logistical considerations, especially amongst people who are actively using substances. There are mixed views about providing people in recovery with money or vouchers which could be used for the purchase of alcohol or other substances, and especially when the value is of a large amount; however, the evidence for the risk of harm from this, including so called 'windfall payments' is conflicting (Rosen, 2012). Additionally, remuneration could not easily be implemented given the anonymity of the questionnaires, the use of virtual methods and COVID-19 restrictions: consequently, no incentives were provided for individuals to participate for any research components, with the exception of formal PPI involvement ***(see 3.4. Patient and Public Involvement)***.

The individual must have access to written information to make an informed decision about participation and they must not feel under pressure or coerced in any way. Separate PIS were therefore produced for service users ***(see Appendix 4 - Service User Participant Information Sheet)***, staff ***(see Appendix 5 - Staff Participant Information Sheet)*** and friends/family ***(see Appendix 6 – Friends/Family Participant Information Sheet)***: these covered both questionnaires (for service users only) and interviews. The PIS structure was reviewed by key stakeholders ***(see 3.4. Patient and Public Involvement)***, but ultimately determined by Aston University requirements. They contained the title, organisational logos, the purpose of the research, the question type that was asked, why they were being invited to participate, what was expected of them, what would happen to their data and contact details in case of any questions or concerns.

All potential participants were treated equally, and the PIS outlined how the participants may have potentially benefitted or have come to harm (such as psychological distress) because of their involvement, and action which would be taken should this occur. Although the participants would have been able to withdraw or refuse to answer questions at any time and without reason, and potential risks were thought to be relatively easily mitigated ***(see Appendix 12 - Risk Assessment)***, they warranted careful consideration. The Researcher had support from the Supervisory Team who had notable qualitative methodology experience, including in the mental health setting, and access to supportive line management in the research setting. As the research was conducted in SMS regulated by the Care Quality Commission (CQC, 2024) and the Researcher was a pharmacist registered with the GPhC, any issues which required escalation, including safeguarding concerns would have been managed in accordance with Humankind and Aston University's relevant policies and procedures, GPhC standards (GPhC, 2024b) and the Health and Social Care Act (PHE, 2020c).

If potential participants were interested in taking part, they were given a copy of the relevant PIS, either in person or via post or email. For all interviews, after initial consent to be contacted was given, at least 48 hours was permitted before further contact was made, to allow sufficient time for PIS review. Follow up contact was provided at a mutually convenient time, and eligibility to participate and informed consent (DCA, 2007) for their involvement was obtained by the Researcher immediately prior to the interview commencing. Whilst a follow up strategy can increase response rates, this could not be utilised for questionnaires due to their anonymised distribution; however, this was possible for interviews. Participants were therefore contacted up to two further attempts if they did not respond at the original pre-agreed mutually convenient time. This was restricted to avoid the participant feeling under pressure to respond and to avoid any perception of coercion.

Capacity to provide informed consent for the interviews was assessed by the Researcher who was experienced in checking that people do not have any difficulties in understanding, retaining and using information (including perceived risks and benefits) to weigh up the decision about participation (DCA, 2007; GPhC, 2018). This was checked by asking the person questions, providing them with sufficient time and information tailored to their needs, and by answering any of their queries. Care was taken if the person was thought to have a disability, mental health problem or may have been under the influence of substances, which is likely when conducting research in SMS.

Due to COVID-19 restrictions (and for all virtual interviews), interview participants were not asked to complete a consent form. Instead, the Researcher completed and signed the consent checklist found on each of the interview guides ***(see Appendix 7 - Service User Semi-structured Interview Guide, Appendix 8 – Staff Semi-structured Interview Guide and Appendix 9 – Friends/Family Semi-structured Interview Guide)***, to confirm that verbal informed consent was obtained, and in an appropriate and consistent way (DCA, 2007; GPhC, 2018).

3.6.2. Researcher Reflexivity

The data collection from electronic clinical records, conducting of interviews, collation of questionnaire data and associated analyses was all undertaken by one Researcher, a White British female Pharmacist in her mid-thirties. As the Researcher defined the approaches taken, it was important to outline their perspectives (Klein and Myers, 1999): she was experienced in the management of substance use having worked in the sector for about a decade and in mental health services before this. She was employed full time by Humankind as their Director of Pharmacy and was the only pharmacy professional in the organisation when this research was conducted. During this time, she was also actively involved with other advocacy work and professional organisations, such as involvement with the CMHP and Drug Science ***(see Appendix 1: Summary of Publications/Contributions)***.

The Researcher also had prior research experience, and qualifications included MRPharmS (Hons) MSc CertPsychPharm MCMHP IP. To achieve these postnominals, the Researcher had to complete training and apply the learning relating to various research methods and associated data analyses. Furthermore, during the research period she completed short courses on qualitative research at Bristol University, NIHR Data Quality in Research e-learning, and was part of other research collaborations ***(see Appendix 1: Summary of Publications/Contributions)***. She was familiar with responding to acute risk issues, language (and jargon) used in SMS, and as a GPhC registered pharmacist since 2008, utilising strong communication skills and a holistic, person-centred care approach was core to her professional practice (Barnett, 2018; GPhC, 2024b). Due to her associated personal (conscious or unconscious) biases and subjectivity, it was important that these were made explicit from the outset, and where possible the impact of them also mitigated (Sutton and Austin, 2015).

Except for some SMS staff, the Researcher was not known to any of the participants prior to study commencement. Whilst this may have facilitated a degree of objectivity, this may have also created challenges to participants feeling able to disclose their sensitive personal views and experiences. Despite this, she was able to build rapport quickly because of her prior experience of working in SMS and psychiatry. Without an ability to routinely impact on the individual's care or employment, it was anticipated that this would increase the likelihood of participants sharing personal views and experiences, and the sensitive disclosures made confirm this.

The Researcher was especially mindful of the impact that she may have, for example should the participant feel inclined to give responses which may be ‘pleasing’, and especially given her senior role in Humankind.

Such challenges are well-established in qualitative interviewing (Richards and Emslie, 2000), and the Researcher remained cognisant of this, so she introduced herself as the 'Researcher and the organisation's pharmacist', and this was not further expanded upon unless specifically asked. Her experience of working in SMS was felt to particularly enable a greater understanding of the perspectives of SMS staff.

Whilst a formal reflexive diary was not kept, the Researcher acknowledged the emotional impact that participants personal disclosures sometimes had on her mindset. This was perhaps most notable for the interviews conducted with friends/family, perhaps because of her own experiences of supporting loved ones with problematic substance use and mental health issues. Therefore, the time gap between the interviews being transcribed and then analysed allowed for the impact of this to be diminished. It was therefore imperative to incorporate the views of others ***(see 3.4. Patient and Public Involvement)***, including SMS colleagues and the more objective views of the Supervisory Team, and the latter especially for the qualitative data analysis processes (Sandelowski, 1993).

3.6.3. Data Management and Analysis

Safe and secure data management, including maintenance of anonymity/confidentiality was ensured by anonymising all data at the earliest opportunity. For example, any potentially identifying information was deleted by the Researcher, and identification numbers were used to identify participants from the point of the transcription checks. Alongside participant contact details, identification numbers were kept completely separately with restricted access only to the Researcher. The data was used for the sole purpose of this research and in line with ethical approval, stored on a secure server which was automatically backed up in line with organisational processes and accessed via encrypted devices by authorised individuals. The use of a secure online password protected platform facilitated ease of collaborative working, and enabled the Researcher, independent transcriber, and Supervisory Team to receive information in a timely way. The Researcher was responsible for ensuring that all identifiable data, field notes, transcripts and recordings were appropriately destroyed after study completion.

When not in use, paper copies of the completed questionnaire and interview guides were stored in a locked cupboard in a secure office accessible only to the Researcher. Results of the questionnaire and quantitative data from the interviews were captured in a MS Excel® spreadsheet so that the integrity of the recorded data could be maintained and easily digitally backed up. This required indirect data entry due to the need for manual processing, which was labour intensive and time consuming, but enabled full control over the data collection process. To minimise the risk of errors, the completed paper responses were checked at least twice by the Researcher prior to destruction to ensure that the information was correctly recorded. Optical character recognition, (for example where questionnaire responses are scanned) may have enabled quicker and more accurate data transposition; however, it was not utilised because of the anticipated volume of free text which can be problematic for technology to interpret correctly (Wahi, *et al.*, 2008).

Thematic analysis can generate unanticipated insights from the data and is ideal for exploring individuals' experiences and perspectives and the factors which influence them (Braun and Clarke, 2006). Therefore the

qualitative datasets from the interviews were analysed using a six stage approach to thematic analysis (Braun and Clarke, 2006; Clarke and Braun, 2013; Naeem, *et al.,* 2023), which has been used by others who have explored OTC/POM misuse (Coombes and Cooper, 2019). First, familiarisation with the qualitative data was undertaken by repeated re-reading of the text, and for the interviews this was also undertaken whilst listening to the audio recording and reviewing field notes to capture any additional observations or nuances such as changes in intonation (Braun and Clarke, 2006; Gibbs, 2002). Then key words/phrases were identified using an inductive approach to generate initial codes from the data. This inductive approach was derived from the Researchers' observations of the participants views (Braun and Clarke, 2006; Naeem, *et al.,* 2023). The codes were selected and combined into themes, which were then further reviewed, refined, and developed (Clarke and Braun, 2013). Before the findings were reported in a descriptive account supported by illustrative quotes, the themes which emerged from the data were interpreted and their significance determined (Clarke and Braun, 2013). All transcripts were then actively searched for results which contradicted the key conclusions. The Research Supervisor (IM) reviewed all analyses and associated findings: all disagreements were discussed, and a third person, Roya Vaziri (RV), who was Humankind's Executive Medical Director, was available to resolve any disagreements if a consensus could not be reached.

This exploratory, inductive (data-driven) approach to the thematic analysis provided greater trustworthiness in the findings (Lin, 1998); and was preferred to a deductive (theory-driven) approach (Naeem, *et al.,* 2023). Frequent re-review of the codes and associated themes and re-comparing them to the original data, provided further reassurance of this, and enabled flexibility in the researchers approach as new ideas and themes emerged and evolved (Naeem, *et al.,* 2023). Allowing for codes to change and iterative development during the analysis process also enabled a deeper understanding of the data, as semantic (surface level, explicit) and latent (underlying, implicit) codes could then be captured (Braun and Clarke, 2006). This continued back and forth approach is established in the literature (Bernard, 2006), and ongoing critical reflection also allowed for opportunities to ensure that data collection and subsequent analyses had been sufficient (Sandelowski, 1993). Although it was time consuming to implement, the richness of the original data was retained, and it was feasible to be implemented by one individual. This less structured approach was also felt to be preferable for exploring OTC/POM misuse rather than applying pre-determined codes with a deductive framework analysis, which may be better suited to more voluminous datasets, where much about the research topic is already known, and a larger team are involved in the analysis process (Gale, *et al.,* 2013).

Computer assisted qualitative data analysis software arranges data in one place, provides a structure for organising data and facilitates ease of subsequent searching, coding, retrieval, exploration and collaboration at relative pace, especially for large volumes of data (Jackson and Bazeley, 2019; Lee and Fielding, 1991; Lewins and Silver, 2009). There are several different software packages available; however, NVivo® (version 12) was utilised as it is an intuitive package and notable support was available to ensure appropriate use, because it is preferred by Aston University and supported by internal technical services. Whilst NVivo® facilitates ease of identifying relevant quotations, subsequent data handling and analysis, manual rather than inbuilt NVivo® analysis was used to help ensure that no nuances were missed (Creswell, 2013; Gibbs, 2002).

4. Study 1: Questionnaires

This chapter presents findings from the anonymous questionnaires that were completed by service users accessing Humankind SMS, who had experience of misusing OTC/POM. The purpose was to identify the types of medication involved, use of other substances and associated characteristics. To avoid unnecessary duplication, further details of the methods (including rationale for the selected methodological approach) are provided in the previous chapter ***(see Chapter 3 - Research Strategy and Design)***.

The questionnaire design was informed by findings from the systematic review, and consideration of approaches undertaken by other researchers who have explored OTC/POM misuse, and in the broader literature ***(see Chapter 1 - Introduction, Chapter 2 – Systematic Review and Chapter 3 - Research Strategy and Design)***. In turn, the findings from this study were used to inform the interviews utilised in the subsequent studies. They have also been shared at international conferences ***(see Appendix 1: Summary of Publications/Contributions)*** and an abstract from a poster presentation of the initial findings was published in an international peer reviewed journal:
Gittins R, Maidment I. 2022. Exploring Over the Counter and Prescription Only Medication misuse amongst adults accessing specialist treatment services: A survey during COVID-19. Int J Pharm Pract. 30(s1): i23–4. doi: 10.1093/ijpp/riac019.032.

The complete findings have also been published:
Gittins R, Vaziri R, Maidment I. 2022d. Surveying Over the Counter and Prescription Only Medication Misuse in Treatment Services During COVID-19. Subst Abuse. 16: 11782218221135875. doi: 10.1177/11782218221135875.

4.1. Aim and Objectives

To explore OTC/POM misuse amongst adults accessing SMS in England, using an anonymous questionnaire to identify the types of medication, use of other substances and associated characteristics.

4.2. Method

The rationale for the chosen methodology and more details about the methods used (including data sampling, collection, management and analysis, PPI, ethical considerations, and risk management) are outlined in ***Chapter 3 - Research Strategy and Design.***

To obtain quantitative and qualitative data, a novel questionnaire was created, piloted, and implemented ***(see Appendix 3 - Questionnaire)***. Questions about medication currently prescribed for dependency, the use of alcohol, tobacco, vape/e-cigarettes, traditional illicit substances, and changes during COVID-19 were incorporated into the questionnaire. There is no consensus on what the best time frame to capture use of substances is, though 28 days is similarly used by NDTMS (PHE, 2020a): longer durations may give rise to

an increase in recall bias and may not reflect current drug-taking trends, especially in the context of COVID-19. Basic demographic details including age, gender, ethnicity, and associated SMS were also collected. Additionally, individuals had an opportunity to provide any further comments and their thoughts about potential SMS development. Open questions were strategically used at the end of the questionnaire to optimise data quality and analysis processes (O'Cathain and Thomas, 2004).

To be eligible for inclusion, the service user had to be at least 18 years old and have capacity to consent. The potential participant had to be currently receiving either pharmacological and/or PSI from a Humankind community SMS and have self-reported OTC/POM misuse within the last month. Participants were excluded if their additional needs could not be met (for example if they required an interpreter because they were a non-English speaker, and the SMS was unable to facilitate), or if they presented with significant risk issues (after assessment by their Recovery Coordinator/Prescriber). Consent forms were not required for the questionnaires since individuals' self-consented by opting to complete them.

Distribution of the questionnaire required communication with SMS staff: potential service user participants were informed about the research and invited to participate by front-line SMS staff at their next scheduled appointment or other contact with the SMS. Exemplar invitation wording which had ethical approval was issued to Humankind staff to facilitate recruitment ***(see Appendix 10 – Invitation Wording Guide)***. If service users wanted to complete the questionnaire, then a paper copy of the PIS ***(see Appendix 4 - Service User Participant Information Sheet)*** or the online link to an electronic version was provided. A copy of the PIS was also attached to the front of each questionnaire (either on paper or on the front screen of the online version). Where individuals wished to post their completed paper questionnaires, pre-addressed and stamped envelopes were available to encourage return rates (Edwards, *et al.,* 2002).

If requested by the service user, the questionnaire would have been posted to them too. Although posting out to all potential participants from the outset could have covered a wide geographical area, this was not undertaken because SMS service users have not consented for use of their contact data in this way, the cost of postage would have been significant, and as postal-only approaches are associated with lower response rates and offer no opportunities to support the accurate completion of the questionnaire (Boynton, 2004; Boynton and Greenhalgh, 2004; Oppenheim, 1992). Additionally, some people who access SMS may not have a postal address, for example if they are street homeless, which would have inappropriately excluded them.

These approaches enabled individuals to complete the questionnaire in their desired format, in their own time, whilst waiting for their appointment or at an alternative place of their choosing. As literacy issues are known to be an issue amongst people accessing SMS, if the service user required assistance, such as a translator, or to read out the question, then this would have been facilitated by SMS staff. Piloting suggested that the questionnaire in either format, would take no longer than ten minutes for the participant to complete. The larger the response rate the more generalisable the findings may have been, but it was difficult to calculate a precise sample size because some interventions are provided by SMS in an anonymous and

undocumented way, and potential participant interactions with SMS was further complicated by the context of the pandemic. However, the systematic review ***(see Chapter 2 – Systematic Review)***, identified that three surveys/questionnaires conducted in UK SMS relating to OTC/POM misuse generated between 79 and 208 responses (Baird, *et al.,* 2014; Perera, *et al.,* 1987*;* Strang, *et al.,* 1994).

Questionnaire results from both paper and online versions were captured and amalgamated into the same MS Excel® spreadsheet, so they could be jointly analysed. Statistical Package for the Social Sciences statistics software version 26 (SPSS®) was used to analyse the quantitative data, and this software has been similarly used by other researchers, including for data from questionnaires covering OTC/POM misuse (Foley, *et al.,* 2018; Ramlagan, *et al.,* 2010; Wright, *et al.,* 2016). A data dictionary with exclusive and exhaustive coding was developed and consistently applied at the point of analysis (for example, No=0; Not applicable=1; Not stated=2; Yes=3). It was anticipated that Pearson Chi-square, χ^2 (for categorical variables) or t-test (for continuous variables) would be applied (Field, 2018).

Content analysis (the process of applying a standardised coding frame to free-format responses to consistently classify them into meaningful categories and facilitate analyses), was planned for the associated qualitative data (Fink, 2003). All qualitative responses were included in the analysis out of responsibility to the participants for their contributions. However, due to the anonymous nature of the questionnaire, if there were missing, incomplete or unclear data entries, it was not possible to follow up with the participant and therefore these results were excluded to minimise the risk or errors and associated bias (Sterne, *et al.,* 2009). The findings were verified by the Research Supervisor (IM) and another reviewer (RV), was available to resolve any disagreements if a consensus could not be reached.

4.3. Results

Data collection occurred during the COVID-19 pandemic, from August 2020 to August 2021. A total of 80 questionnaires were received (15 online, 65 paper), though after preliminary screening, questionnaires were eliminated if they did not meet the inclusion criteria: 12 were from prison SMS and 12 did not capture OTC/POM misuse in the last month. Fifty-six questionnaires were included in the analyses and all answers were included; however, where answers were not given (i.e., left blank), these were captured as *'unknown'* to ensure completeness of the dataset. As the volume of qualitative data was limited, this was provided as a narrative to supplement and help explain the findings from the quantitative data.

4.3.1. Demographic Characteristics

The demographic characteristics of respondents are outlined in ***Table 4*** and ***Table 5***: all were White (94.6% British), aged between 18 and 61 years. The majority identified as male (58.9%) and accessed the STARS service (56.6%).

Table 4: *Summary of age, ethnicity, and gender data for questionnaire respondents*

		Gender		Total
		Female	Male	
Number of respondents		23 (41.1%)	33 (58.9%)	56
Mean age (years)		38	40	39
Age range (years)		22-61	18-61	18-61
Ethnicity	White - British	20 (35.7%)	33 (58.9%)	53 (94.6%)
	White - Irish	2 (3.6%)	0 (0.0%)	2 (3.6%)
	White - Other	1 (1.8%)	0 (0.0%)	1 (1.8%)

Table 5: *Summary of SMS location data for questionnaire respondents*

Service Name	Number of respondents	UK Region
BRS	2 (3.6%)	Yorkshire (28.6%)
CRS	7 (12.5%)	
FL	7 (12.5%)	
STARS	33 (58.9%)	Midlands (58.9%)
TOGETHER	2 (3.6%)	South West (12.5%)
REACH	5 (8.9%)	

4.3.2. OTC/POM Characteristics

Table 6 outlines the different OTC/POM misused by respondents in the preceding month: twenty-one (37.5%) reported misusing more than one OTC/POM, and 79.5% were taken orally. It is important to note that as some people misused more than one medicine, the total (117) is greater than the number of participants. Where stated, 48% were legally sourced (i.e., bought OTC/via prescription intended for their use). All participants who misused gabapentin also misused pregabalin and accessed the STARS SMS.

Ease of availability contributed to misuse, and sources included the internet, over the counter from pharmacies, on prescription, via street dealers and friends:

"How easy it is to get hold of it – in the past I have found it so easy and told different stories to access codeine liquid and tablets" #006

"It's easy to pick up diazepam and pregabalin…Buying through someone I know who is prescribed it" #009

Concerns about availability, especially via GPs and community pharmacies, and the need for improved education were subsequently expressed:

"They need to stop giving opioids out like sweets – I didn't realise what I was taking and medication kept getting thrown at me" #001

However, when legally sourced, prescribed supplies ceased, some participants described their OTC/POM misuse escalated and use of alternative, sometimes unregulated illicit sources commenced:

"Buying dihydrocodeine off the street as no longer prescribed…can get it online" #005

This included when changes to prescribing were made without a shared decision-making approach and on occasions, polypharmacy was involved:

"When I said to the GP that I am abusing zopiclone he stopped prescribing without telling me and that's why I turned to over the counter medication" #012

"GP is reducing me off my meds so I am buying eastern European benzos, gabapentin and pregabs" #031

Table 6: *Summary of different OTC/POM and routes of administration in the preceding month*

Route of Administration				Oral	Inject	Snort	Not Stated	Total
OTC/POM being misused	Antidepressants	Amitriptyline		1	0	0	1	2 (1.7%)
		Mirtazapine		3	0	0	0	3 (2.6%)
	Anabolic steroids (e.g. testosterone)			1	0	0	0	1 (0.9%)
	Antihistamine			3	0	0	0	3 (2.6%)
	Baclofen			1	0	0	0	1 (0.9%)
	Hypnotics	Benzodiazepines		26	0	0	0	26 (22.2%)
		Zopiclone		6	0	0	1	7 (6.0%)
	Gabapentinoids		Gabapentin	3	1	0	1	5 (4.3%)
			Pregabalin	14	0	0	3	17 (14.5%)
	Opioids	Buprenorphine		2	0	0	0	2 (1.7%)
		Codeine	Non-combination product	9	0	0	7	16 (13.7%)
			Combination product	13	0	0	7	20 (17.1%)
		Fentanyl		0	1	0	0	1 (0.9%)
		Dihydrocodeine		1	0	0	0	1 (0.9%)
		Methadone		4	0	0	0	4 (3.4%)
		Morphine		1	1	0	0	2 (1.7%)
		Tramadol		3	0	1	0	4 (3.4%)
	Quetiapine			2	0	0	0	2 (1.7%)
Total				93 (79.5%)	3 (2.6%)	1 (0.9%)	20 (17.1%)	117

4.3.3. Use of Other Substances

Figure 5 summarises the different illicit substances used by respondents: a total of 33 (58.9%) used illicit substances on-top (51.5% of these used daily), and 59.3% (predominantly cannabis) of on-top substances were smoked, though injecting was prevalent (13.0%). The only 'other' substance stated was 'monkey dust': a new psychoactive substance, and all of these participants accessed STARS SMS. In the preceding month 25 participants (44.6%) used alcohol (52% of these used daily, up to an estimated 788 units/week), and 41 individuals (73.2%) used tobacco/vaped (all used daily, up to a reported 45 times a day).

Participants also outlined how their use of substances had improved because of their positive experiences with SMS, and involvement with other sources of support, such as Alcoholics Anonymous (AA):

"No longer drinking alcohol through the support of AA and [SMS]…Spot on, wouldn't change anything, I've found it comfortable and easier working with someone that understands me and addiction" #006

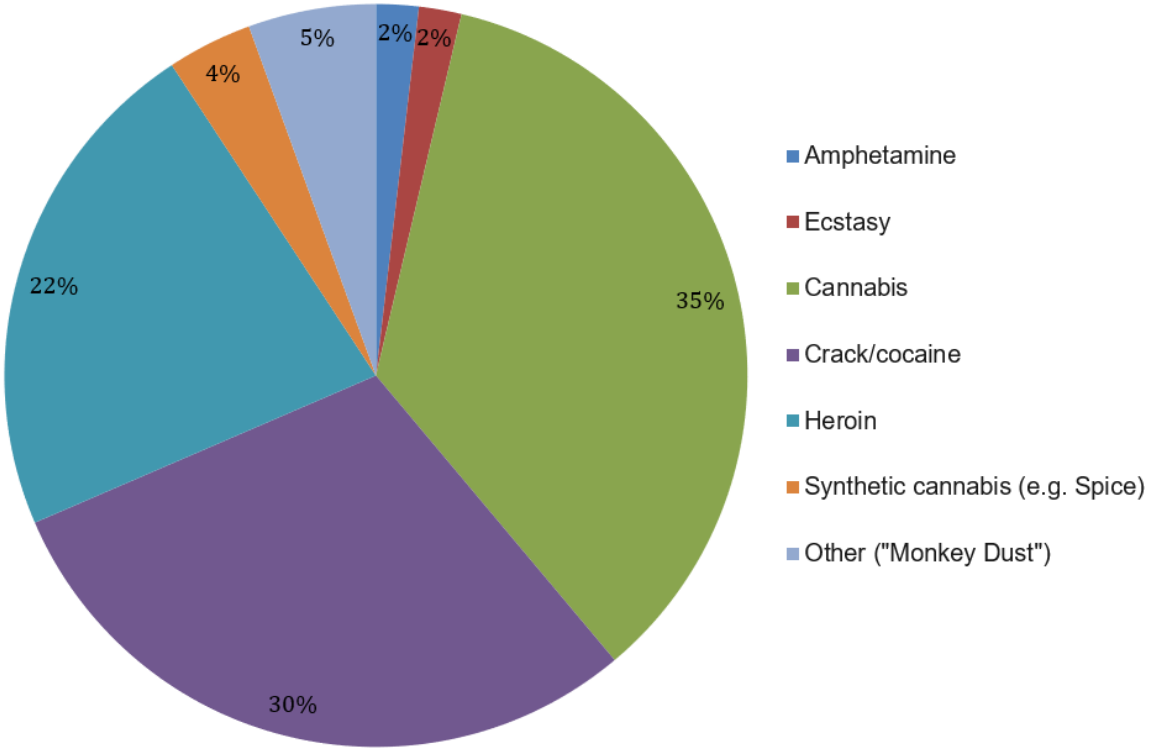

Figure 5: *Summary of illicit substances used by participants in the preceding month*

4.3.4. Concomitant Prescribed Interventions

Forty of the 56 respondents (71.4%) were in receipt of prescribed interventions for SMS. A summary of the medication being prescribed, with adjunctive use of other substances is provided in ***Table 7***. All prescribed interventions were oral formulations. Three people (all prescribed methadone) reported using their medication differently to how the prescriber intended, giving an adherence rate of 92.5%. Where used differently, they were all prescribed oral methadone solution and the rationale provided was that they preferred to split their dose throughout the day, saved up supplies for when they needed it, or to deliberately misuse by taking excessive quantities.

Some participants identified that SMS could improve the range of prescribed substitution treatment interventions that were available:

"Prescribe benzos on a controlled reducing prescription, same for pregabalin" #044

There was also an 'ask' for alternatives to prescribed interventions (such as OST) to be explored, with a particular focus on the management of withdrawal symptoms and discontinuation of medication:

"Need more help with withdrawal. Not interested in OST for getting off codeine…Want better support for coming off medication" #008

Table 7: *Summary of prescribed interventions provided by SMS*

Type of medication	Relapse prevention		OST			Benzodiazepine	Unknown
Medication Name	**Acamprosate tablets**	**Naltrexone tablets**	**Buprenorphine-naloxone sublingual tablets (generic/ Suboxone®)**	**Buprenorphine/ sublingual tablets (generic/ Subutex®)**	**Methadone oral solution (generic/ Physeptone®)**	**Diazepam tablet**	**Not Stated**
Number of respondents	2 (5%)	1 (2.5%)	2 (5%)	10 (25%)	23 (57.5%)	1 (2.5%)	1 (2.5%)
Number on supervised consumption	0 (0%)	0 (0%)	0 (0%)	0 (0%) *[1 (2.5%) not stated]*	10 (25%)	0 (0%)	1 (2.5%)
Number taking medication differently to how prescribed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (7.5%)	0 (0%)	0 (0%)
Number using alcohol on-top	2 (5%)	1 (2.5%)	1 (2.5%)	2 (5%)	9 (22.5%)	1 (2.5%)	1 (2.5%)
Number using tobacco/ vaping on-top	1 (2.5%)	1 (2.5%)	2 (5%)	7 (17.5%)	18 (45%)	1 (2.5%)	1 (2.5%)
Number using illicit substances on-top	2 (5%)	0 (0%)	1 (2.5%)	2 (5%)	17 (42.5%)	1 (2.5%)	1 (2.5%)

Percentages are given as a proportion of the total (n=40) who were in receipt of SMS prescribed interventions

4.3.5. Changes during COVID-19

Thirty-three (58.9%) of the 56 participants reported their use of OTC/POM changed in some way during COVID-19. Fourteen (56%) of them *[2 (8%) not stated]* reported changes in alcohol consumption during COVID-19: 12 of these 14 (85.7%) increased their use. Four (9.8%) of the 56 respondents reported increases in their tobacco use/vaping. Ten of the 33 (30.3%) reported changes to their use of illicit substances during COVID-19; only two reported their use reduced and the remainder reported increases.

COVID-19 related changes were reportedly due to alterations in access/money to afford supplies/opportunity to use or when switching between different substances/to manage withdrawal symptoms. Increases were predominantly to manage COVID-19 related stress/boredom/loneliness/mental health symptoms and because of traumatic life events/experiences that occurred/increased due to COVID-19 (such as loss of employment, domestic violence, bereavement, or sex working):
"Changed [increased] as sex working has been busier during COVID" #028

Consequently, reductions were reported when lockdowns eased (and some returned to work/college):
"Increased [codeine combination products] but reduced when lockdown eased so using a bit less but still more than before lockdown" #011

Fourteen of 40 individuals (35%) experienced prescription changes during COVID-19: they were either prescribed medication for relapse prevention or OST (nine were on methadone oral solution). The qualitative analysis identified that the predominant rationale for changes were in response to dynamic risk assessment and mitigation strategies relating to pharmacy provision, drug testing, dose optimisation safe storage and liberalisation of dispensing arrangements which were overwhelmingly positively regarded:
"Was changed to once every 2 weeks at first but now back to once a week. I was happy for the support in keeping me safe" #007
"Much better this way as not going to the chemist every day. OK with storing safely" #018

4.3.6. Association Between Categories

A low probability (p) value of <0.005 was selected given the relatively small sample size, to provide greater assurance of statistical significance of the findings (Field, 2018). Given the vast number of tests that were undertaken because of the number of different combinations of variables being tested, only those of note where statistical significance was identified are reported in ***Table 8***.

A statistically significant association was found between changes in OTC/POM misuse and illicit substance use during COVID-19 [χ^2 (2, n=56) = 18.07, p = .000]. ***Table 8*** also shows that there was a significant relationship between the person attending the STARS service and their misuse of codeine only (all product types) [χ^2 (1, n=56) = 10.85, p = .002] and benzodiazepines [χ^2 (1, N=56) = 13.23, p = .000]. Of the participants that attended STARS, 9.1% misused codeine only (all products) and 66.7% misused benzodiazepines, and STARS accounted for 21.4% and 84.6% of their misuse across all services respectively.

Statistically significant associations were identified between the type of OST prescribed and the misuse of benzodiazepines and codeine products (for combination only, all products and all codeine product type only). Furthermore, statistically significant associations were also identified between the misuse of benzodiazepines (in isolation and in combination with other OTC/POM misuse) and the misuse of codeine, except in the case of non-combination codeine products (n=16) and non-combination codeine products only (n=2). On-top heroin use in the last month was statistically associated with OST being prescribed [χ^2 (1, n=56) = 9.16, p = .005] and the use of supervised consumption [χ^2 (3, n=56) = 22.68, p = .000]. Since SMS may mitigate risks associated with on-top use at the same time as receiving OST by using supervised consumption, the relationship between supervised consumption, OST type and the misuse of benzodiazepines and codeine products was explored further in ***Table 9***. Of those who were prescribed buprenorphine, 91.7% misused codeine: no participant who was prescribed OST and reported codeine misuse was known to be on supervised consumption.

Table 8: *Summary of statistically significant (p<0.005) Pearson chi-square tests and likelihood ratios*

Categories Tested		Pearson Chi-square (χ^2)			Likelihood ratio		
Category 1	**Category 2**	**Value**	**df**	**Exact Significance (2-sided)**	**Value**	**df**	**Exact Significance (2-sided)**
Changes to illicit use during COVID-19	Changes to OTC/POM misuse during COVID-19	18.074	2	.000	21.832	2	.000
Used heroin in the last month	On supervised consumption for prescribed intervention	22.678	3	.000	22.335	3	.000
Used heroin in the last month	On OST for prescribed intervention	9.164	1	.005	13.189	1	.002
Codeine (all types) only misused	Benzodiazepines misused	16.178	1	.000	21.526	1	.000
Codeine (all types) misused	Benzodiazepines only misused	9.130	1	.003	12.803	1	.002
Codeine (combination products) misused	Benzodiazepines misused	16.599	1	.000	18.514	1	.000
Codeine (all types) misused	Benzodiazepines misused	14.957	1	.000	15.970	1	.000
Codeine (combination products) misused	On methadone for prescribed intervention	12.410	1	.001	13.932	1	.001
Codeine (all types) misused	On methadone for prescribed intervention	10.336	1	.002	10.980	1	.002
Codeine (all types) only misused	On methadone for prescribed intervention	8.878	1	.004	10.503	1	.004
Codeine (combination products) misused	On buprenorphine for prescribed intervention	10.267	1	.002	10.015	1	.005
Codeine (all types) only misused	On buprenorphine for prescribed intervention	14.141	1	.001	12.654	1	.001
Codeine (all types) misused	On buprenorphine for prescribed intervention	14.857	1	.000	16.189	1	.000
Benzodiazepines misused	On methadone for prescribed intervention	15.901	1	.000	16.707	1	.000
Benzodiazepines misused	On buprenorphine for prescribed intervention	13.236	1	.000	17.812	1	.000
Codeine (all product types) only misused	STARS SMS accessed	10.846	1	.002	11.034	1	.002
Benzodiazepines misused	STARS SMS accessed	13.231	1	.000	14.083	1	.000

Table 9: *Summary of OTC/POM misuse where OST and supervised consumption was provided*

OST type	OTC/POM Type Misused (% on Supervised Consumption)								
	Anabolic steroids	Antihistamines	Antidepressants (mirtazapine)	Benzodiazepines	Codeine products (all types)	Gabapentinoids	POM opioids (buprenorphine, dihydrocodeine. fentanyl, methadone, morphine, tramadol)	Antipsychotics (quetiapine)	Z-drugs (zopiclone)
Methadone oral solution	0 (0)	1 (100)	2 (50)	18 (44.4)	4 (100)	12 (58.3)	6 (33.3)	2 (100)	2 (100)
Buprenorphine oral product	1 (0)	0 (0)	0 (0)	0 (0)	12 (0*)	2 (0)	1 (0)	0 (0)	1 (0)

*1 not stated

4.4. Discussion

4.4.1. Key Findings

The demographic characteristics of respondents were broadly typical of national English datasets; for example, the mean age of 39 years, White British men predominated and the prevalent use of cannabis, crack/cocaine, and heroin (OHID, 2023). Given most responses (56.6%) were from the STARS SMS this may have influenced the findings of a statistically significant association between codeine and benzodiazepine misuse, and their level of representation when compared to other services. The reason for the over-representation of STARS is unknown, but it is likely that the staff team were perhaps more proactively engaged with the questionnaire distribution process.

Although the numbers were limited, no OTC/POM were identified as being misused that had not already been identified in the literature. Indeed, the results were similar to other studies, such as recent comparative analyses by Iwanicki, *et al.,* (2020) and Cassidy, *et al.,* (2015), who respectively identified that tramadol misuse was infrequent in comparison to other opioids, and that POM stimulant misuse was low when compared to other OTC/POM types. Oral administration predominated and a variety of legal and illicit sources were used to obtain the desired medicines, which has been similarly identified in the systematic review ***(see Chapter 2 – Systematic Review)*** and by others around the world, including outside of the SMS setting (Cassidy, *et al.,* 2015, Dada, *et al.,* 2015; Gossop and Moos, 2008; Rosenblum, *et al.,* 2007).

The notable level of OTC/POM polypharmacy (37.5%) and the concomitant use of other substances (58.9% illicit substances, 44.6% alcohol, 73.2% tobacco/vapes), which increase the risk of health issues, including accidental overdose, was also identified in the systematic review ***(see Chapter 2 – Systematic Review)***. However, unlike the systematic review, this study found that crack-cocaine rather than amphetamine, featured in the top three most used illicit substances (alongside cannabis and heroin). This was perhaps to be expected given that the latest national SMS data indicates opiates, crack-cocaine/cocaine, and cannabis, are the most prevalent substances being used (50%, 27%/12% and 20% respectively) (OHID, 2023). Furthermore, SMS have historically focused on opiate and crack-cocaine interventions because these substances have dominated the British drug market (PHE, 2014). The reports of 'monkey dust' reported in STARS SMS was not unexpected as it was a well-known, local geographical issue (Matthews-King, 2018). Indeed, in recent years concerns about this substance have grown and has even resulted in the SMS receiving additional funding to provide support for the people using it (Staffordshire University, 2023).

The self-reported adherence rate of 92.5% to prescribed interventions was notable, as generally, only about half of people take their medication as prescribed (Nieuwlaat, *et al.,* 2014). The limited data suggests that methadone may be more likely to be associated with suboptimal adherence and in SMS, this is not unusual when considering the potential risk of medicines misuse in this population (Haskew, *et al.,* 2008), and the context of a pandemic. The high rates of concomitant OTC/POM misuse and prescribed interventions for SMS, most notably medicines, which are associated with increased risk of sedation, respiratory depression and therefore accidental overdose is of concern, and has been the subject of national alerts (MHRA, 2020).

This may be further compounded by the use of illicit substances and alcohol (Gossop and Moos, 2008), and especially where daily, dependent, high levels of use occur.

Perhaps fewer people than expected reported changes to their use of illicit substances, given the reports on changes to the illicit drug market reported by others (Crew, 2021). A statistically significant association between changes in OTC/POM misuse and illicit substance use were identified, but in comparison to illicit substance use, notably more changes were reported in OTC/POM misuse. The nature of the relationship and the rationale for this was not possible to analyse further since data saturation was not felt to have been achieved and more in-depth questioning was required, suggesting the need for future research to explore this further. The reports of trauma perpetuating OTC/POM misuse and problematic substance use are widely acknowledged (Dube, *et al.,* 2003), so the reasons that were provided for pandemic-related changes, such as increased stress due to loss of employment, boredom, loneliness, heightened anxiety and other mental health issues were perhaps to be expected, and have been reported elsewhere, such as the Living Under Coronavirus and Injecting Drugs in Bristol (LUCID-B) study (Kesten, *et al.,* 2021).

4.4.2. Strengths and Weaknesses

The number of completed questionnaires received was lower than the amount stated in publications identified by the systematic review; however, the amount that could be included in the final analysis (n=56) was not too dissimilar to the those received (n=79) by Perera, *et al.* (1987) ***(see Chapter 2 – Systematic Review)***. Questionnaire/survey response rates can be notoriously poor (Noble, *et al.,* 2012), especially in SMS. The low numbers also highlight the challenges of conducting research during the COVID-19 pandemic, given the notable reduction in footfall at the services, infection control issues, pressures on staff limiting their capacity to distribute the questionnaires in person, and reliance upon telephone consultations which reduced opportunities for sharing the online versions.

Due to the limited sample size, it was difficult to conduct sensitivity analyses or generalise the findings. Whilst it was not possible to calculate the response rate because SMS attendance is unplanned and often not documented (e.g. anonymous drop-in clinics), Zhao, *et al.,* (2009), found a low response rate of only 47% in the 2004 Canadian Addictions Survey, and outlined that non-response bias is a notable problem in this population. The preference (81.3%) for paper completions was perhaps to be expected given the known digital poverty in this service user population (Perri, *et al.,* 2021), and the lack of SMS staff familiarity with distributing online equivalents. If data had been permitted which captured OTC/POM misuse over a longer period than the previous month, this would have permitted more completed questionnaires to have been included: however, their relevance to that point in time (and the context of the pandemic) may have reduced. Providing service users with digital devices and permitting staff to collate the data for example during telephone consultations, may have additionally increased responses, but the latter may have limited the information that the service users provided.

For the quantitative data, similar approaches regarding the use of SPSS®, descriptive frequencies and χ^2 tests of association have been used by Wright, *et al.,* (2016), to analyse the findings of questionnaires relating

to OTC/POM misuse. All available data was included in the analyses: only the χ^2 test rather than the t-test was used because only categorical variables were identified (Field, 2018). However, the χ^2 test does not provide information on the strength of the association or on whether the relationship was causal (Schober and Vetter, 2019). This highlights the need for qualitative interviews with service users to enable a more detailed exploration regarding such associations, and enable triangulation to assess the validity of the findings (Tonkin-Crine, *et al.,* 2016) ***(see Chapter 5 - Study 2: Service User Interviews)***. Such methodology is common in health services research where there are complex issues, to elaborate or explain or enhance the usefulness of findings, and to counterbalance and complement the limitations of the different datasets (Barbour, 1999; Bryman, 2006; Johnson and Onwuegbuzie, 2004; O'Cathain, *et al.,* 2007).

As the volume of data was limited, the qualitative data was provided as a narrative to supplement and help explain the findings from the quantitative data because the planned content analysis could not be used in a meaningful way (Fink, 2003). The appreciation of SMS during the pandemic has been similarly identified by Kesten, *et al.,* (2021); however, as there was a lack of confidence in data saturation being reached for qualitative data, the findings should be interpreted with caution.

The Researcher demonstrated reflexivity by being mindful of their personal preconceptions and perspectives whilst interpreting the data ***(see 3.6.2. Researcher Reflexivity)***. For example, generally, respondents were complimentary about SMS; whilst the questionnaire was anonymous and some negative views were expressed indicating that some participants felt comfortable sharing their honest opinions, it was also possible that positive views predominated because SMS staff distributed the questionnaire and the Researcher was employed by Humankind, so the participants may have thought that such responses may be more desirable for submission. Due to their senior role in the organisation and oversight of prescribing practices, the Researcher may also have been more sensitive to data which indicated that prescribed interventions were not being appropriately used, demonstrating the strength in involving others in reviewing the findings.

The data was also collected over a year of the pandemic where several changes in COVID-19 restrictions were experienced in England; therefore, perhaps repeating at different time periods during the pandemic and post-COVID-19, may allow for comparisons and an understanding if there are correlations between OTC/POM misuse at different stages of the pandemic. Additionally, as Humankind is a national organisation, this facilitated data collection from a wide geography, with established infrastructure to enable additional support to be provided to individuals which would not be possible, for example if recruitment had occurred via social media platforms. However, only six of the seven potential SMS provided responses, and collating more data to facilitate comparison across other SMS internal and external to Humankind should be considered, especially as this may enable a larger geographical reach and a higher number of responses. Although an invitation wording guide should have standardised the approach to engaging with participants and given the SMS staff confidence in undertaking this ***(see Appendix 10 – Invitation Wording Guide)***, had there been resources to involve non-SMS staff in distributing the questionnaires, then this may have further optimised response numbers.

Since the questionnaire was self-administered and could be completed at a time of the participants choosing, it was hoped that the impact of bias would be limited. The questionnaire has not been validated for use, but perhaps validity could be further refined by engaging a diverse range of key informants in cognitive interviews, where they are observed and asked to share their thoughts during completion in repeated rounds to redraft and refine questions, reduce response burden and improve data quality (Murphy, *et al.,* 2018; Willis, 2005). Whilst follow up of participants and member-checking was not feasible due to anonymity, this may also have provided greater confidence in the findings (Long and Johnson, 2000); though in doing so, people may be less likely to make such detailed disclosures.

4.4.3. Implications for Clinicians, Policymakers and Researchers

Whilst a cautious approach was required when interpreting the data due to the limited number of responses received, the tentative findings suggest that there are relevant implications for clinicians, policymakers, and researchers. For example, there may be a need for increased vigilance for sex working, because an unexpected increase was reported (albeit by a minority of participants), and this was reportedly and perhaps unsurprisingly, associated with an increase in the use of substances as well as OTC/POM misuse. The need for increased vigilance by SMS and other providers during COVID-19 was also important since the reports of increased interpersonal violence has also been noted nationally (Ivandić, *et al.,* 2020). Additionally, since there were reports of switching between different medicines/substances for example in response to changes in accessibility, availability and cost of supplies, there must be ongoing vigilance for associated trends, risks to service users and potential changes in SMS delivery needs.

Where COVID-related changes in substance use such as alcohol consumption were reported (Kilian, *et al.,* 2021), the majority increased their use, reflecting national reports which have outlined associated morbidity and mortality (PHE, 2021c; PHE, 2021d). This further highlights the likely need for SMS, commissioners and other health and social care providers such as acute secondary care services to respond to this post-pandemic. Similarly, every respondent who reported changes in tobacco/vaping also found their use increased, suggesting the need for additional likely requirement for associated smoking cessation and respiratory disease interventions. This is especially salient as people who misuse OTC/POM are also more likely to use tobacco (Fong, *et al.,* 2015).

Limited data suggested that reductions in OTC/POM misuse was associated with pandemic lockdowns easing, and mitigation of risks associated with prescribed interventions were well-received, such as changes to the liberalisation of dispensing regimens (Amram, *et al.,* 2021). Indeed, the statistically significant association between on-top heroin use with the use of supervised consumption and OST, is likely to indicate appropriate clinical practice because the two tended to be co-occurring. This is safer than on-top use occurring where there is a greater degree of liberalisation because of the increased risk of an accidental overdose. However, somewhat inconsistently the misuse of codeine appeared to be managed rather differently, as indicated by the absence of any supervised consumption, and especially in the context of buprenorphine, given the high rates (91.7%) of people reporting misusing codeine. This warrants further

investigation, such as undertaking a larger scale survey and a review of current SMS prescribing practices. It also indicates a potential training and education need amongst SMS prescribers.

Whilst it is important that the benefits to liberalised OST dispensing arrangements made during the pandemic are not lost (Brothers, *et al.,* 2021; Kesten, *et al.,* 2021), there has been an increase in drug (including methadone) related deaths (Friedman and Akre, 2021; ONS, 2023a; PHE, 2021b), and the national guidance has since been rescinded which had supported SMS to liberalise OST to a greater extent (PHE, 2021a). It is therefore important that monitoring changes in national prescribing practices, and review of the approaches to supervised consumption or other restrictive dispensing arrangements, and the consequent evaluation of its impact remain ongoing.

The challenges in managing withdrawal symptoms which initiate, escalate and perpetuate OTC/POM misuse, have been similarly highlighted in the systematic review ***(see Chapter 2 – Systematic Review)****,* and are not to be underestimated, for example in response to a self-reduction, dropping off prescribed interventions or having access to supplies curtailed. The latter was especially in response to what participants expressed as being a predominantly primary care issue, reactionary and conducted without a shared decision-making approach. The need for improved education of health care professionals, especially GPs and community pharmacy staff may therefore be required, though the need for this is not a new concept (Brown, *et al.,* 2012; Foley, *et al.,* 2016): the requirement for improvements in training and education with a psychologically informed approach, have already been raised at a national level (DHSC, 2022a), using resources such as 'Addiction TO Medication - Improving Care' (ATOMIC, 2022).

Given the reports of sourcing OTC/POM using unregulated online sources, individuals may also benefit from being educated about the risks of doing so, and how they can take steps to protect themselves (Alwon, *et al.,* 2015; GPhC, 2024a). Whilst some participants requested the widening of the range of SMS prescribed interventions and greater focus on OST discontinuation/withdrawal management approaches, there remains a paucity of evidence, commissioning pathways and funding to support the expansion of SMS prescribing formularies and organisational prescribing practices to routinely provide the medicines being misused.

Where there continue to be steps taken to limit access to medicines which may be misused, for example by rescheduling products and tightening up on prescribing practices, these should be implemented with care to avoid unintended consequences, such as people seeking unregulated alternatives (Caulkins, *et al.,* 2021). However, such measures may also be well received by some individuals who expressed concern at the ease of availability, and where supplies were sourced via diverted POM. Such issues highlight the pertinence of the ongoing debate about whether to regulate such medicines differently, for example by changing all UK OTC codeine products to POM (Pearce, 2020; Robinson, 2023). However, given the variety of sources used to obtain OTC/POM and the diversion of legally sourced POM, simply making changes to OTC products or prescribing practices in isolation, would be unlikely to resolve the situation (Caulkins, *et al.,* 2021; Saloner, *et al.,* 2018).

Further exploration of OTC/POM misuse, for example using qualitative interviews ***(see Chapter 5 - Study 2: Service User Interviews)***, may allow for triangulation of these findings (Kuper, *et al.,* 2008), and an improved understanding to support SMS developments. Improving an understanding of the statistically significant associations identified, for example between OST, the misuse of benzodiazepines and codeine, is important to gain a better understanding of how SMS can best respond to this. Additionally, exploring why more changes in OTC/POM misuse than the use of other substances was reported during the pandemic may enable SMS to consider how they continue to adapt post-COVID-19. As all participants identified as White men, and as this ethnicity and gender is known to be over-represented in SMS and associated research (Ramlagan, *et al.,* 2010), this highlights the need for further exploration amongst other genders and different ethnicities. This is important as there may be unique racial/ethnic profiles associated with differences in OTC/POM misuse (Ford and Rigg, 2015; Harrell and Broman, 2009), and as females may be more likely to misuse OTC/POM (Simoni-Wastila, 2000).

4.5. Conclusion

OTC/POM misuse, including polypharmacy and the concomitant use of other substances by community SMS service users was common. This continued during COVID-19, though the misuse of medicines/substances changed for some people. Oral benzodiazepines, pregabalin and codeine products predominated, and they were procured from both legal and illegal sources. SMS need to be vigilant for these issues and mitigate the associated risks, for example by ensuring appropriate provision of health, overdose prevention and safeguarding interventions.

Conducting research during the COVID-19 pandemic was challenging, and consequent limited sample size impacted upon the strength of the findings and generalisability. Where people had their OST dispensing regimens liberalised, this was generally well received, and an unusually high level of adherence was reported. However, the misuse of codeine on-top of buprenorphine provided via supervised consumption warrants further investigation.

Future questionnaires should involve more participants and include other SMS providers. This may facilitate further opportunity for gaining an understanding of associated demographic characteristics (especially gender and ethnicity), as the participants were typical of national English SMS datasets (middle-aged White men). Further research, such as the use of qualitative interviews with service users, may enable exploration of the issues identified, and triangulation of these findings.

5. Study 2: Service User Interviews

This chapter presents findings from the confidential semi-structured interviews that were conducted with adult service users accessing Humankind SMS. The purpose was to identify the characteristics of the OTC/POM being misused, the characteristics of the participants, and to explore their associated experiences. To avoid unnecessary duplication, further details of the methods (including rationale for the selected methodological approach) are provided in a previous chapter ***(see Chapter 3 - Research Strategy and Design)***.

The interview design was informed by findings from the systematic review, the service user questionnaires, and consideration of approaches undertaken by other researchers who have explored OTC/POM misuse in the broader literature ***(see Chapter 1 - Introduction, Chapter 2 – Systematic Review, Chapter 3 - Research Strategy and Design and Chapter 4 – Study 1 Questionnaires)***. In turn, the findings from this study were used to inform the interviews utilised in the subsequent studies. They have also been shared at international conferences ***(see Appendix 1: Summary of Publications/Contributions)***, and they are currently under peer review for publication in an international journal*:*
Gittins R, Vaziri R, Maidment I. 202X. "It were my best friend": the experiences of people in treatment misusing over the counter and prescription medication.

A case report which expanded upon the experiences of one of the participants involved in this study has also been published:
Gittins R, Cole S. 2021. Buprenorphine for the management of kratom dependency during covid-19: A case report. Drug Sci Policy Law. 7: 1-7. doi: 10.1177/20503245211021193.

5.1. Aim and Objectives

To explore the misuse of OTC/POM by adults accessing English SMS using confidential semi-structured interviews, to identify the characteristics of the OTC/POM being misused, and associated service user experiences.

5.2. Method

The rationale for the chosen methodology and more details about the methods used (including data sampling, collection, management and analysis, PPI, ethical considerations, and risk management) are outlined in ***Chapter 3 - Research Strategy and Design.***

Participants were excluded if their additional needs could not be met (for example if they required an interpreter because they were a non-English speaker and the service was unable to facilitate), or if they presented with significant risk issues (after assessment by their Recovery Coordinator/Prescriber), or were known in a clinical or personal capacity by the Researcher. Individuals were considered eligible if they had experience of misusing OTC/POM, were at least 18 years of age, able to provide informed consent and currently receiving community pharmacological/PSI interventions from a Humankind SMS.

Potential service user participants were informed about the research and invited to participate by front-line SMS staff at their next scheduled appointment or visit to the SMS. Exemplar invitation wording which had ethical approval, was issued to Humankind staff as they facilitated recruitment ***(see Appendix 10 – Invitation Wording Guide)***. If service users were interested in participating, then a paper copy of the PIS ***(see Appendix 4 - Service User Participant Information Sheet)*** or the online link to an electronic version was provided. If they wished to proceed or wanted more information, they verbally consented to their name, contact details and desired time to be contacted being relayed to the Researcher. During the interviews, informed consent was also obtained to access their electronic clinical records.

'HALO' and 'Systm1' were the electronic clinical record systems utilised by EDP's and Humankind's SMS respectively, and they were used to collate the latest quantitative data regarding the participants age, sex, employment, housing, injecting status and predominant substances used (such as opioids, cannabis and alcohol), as this was where the associated data for the NDTMS were captured (PHE, 2020a). All qualitative responses from the interview ***(see Appendix 7 - Service User Semi-structured Interview Guide)***, were included in the analysis out of responsibility to the participants for their contributions.

5.3. Results

5.3.1. Summary of Interviews

Twenty-four interviews took place between November 2020 and March 2022. Due to COVID-19 restrictions and participant preference, they were all undertaken remotely via telephone. Often, they were challenging to arrange, for example because participants were pre-occupied by drug-seeking behaviours, childcare issues, or difficulty in finding confidential space. On occasions, the interviews were also rescheduled/cancelled because the participants telephone was no longer in use, or the individual was assessed as intoxicated and lacking capacity to consent.

Interviews had a mean duration of 20 minutes 23 seconds (with a range of 7min 26 secs to 57min 17secs). No participants had additional needs which required support during the interviews. Repeat interviews with the same participants were not possible due to time constraints and logistical challenges. Despite attempts to undertake more, member-checking was only successfully implemented for one participant and resulted in no changes being made to the transcript or the associated analysis.

5.3.2. Characteristics of Participants

Demographic particulars and their NDTMS data obtained from HALO/Systm1 are summarised in ***Table 10***, which outlines that participants were accessing interventions from a range of Humankind community SMS:

Table 10: *Summary of participants demographic/NDTMS information obtained from HALO/Systm1*

Participant ID	Service	Age (years)	Sex	Primary substance	Secondary substance	Tertiary substance	Prescribed intervention for substance dependence	Injecting status (number of days injected in last 28 days)	Currently Employed	Housing Problem	Did NDTMS data match interview OTC/POM misuse medicines(s) type?
1	CRS	35	Female	Codeine	Cannabis	None	Buprenorphine sublingual tablets, 8mg once daily, unsupervised	None	No	No	Yes
2	STARS	42	Male	Heroin	Crack Cocaine	Alcohol	Physeptone® 1mg/ml sugar free liquid, 50ml once daily, supervised	28	No	Homeless	No
3	STARS	39	Male	Heroin	Crack Cocaine	Cannabis	Physeptone® 1mg/ml sugar free liquid, 70ml once daily, unsupervised	None	No	No	No
4	STARS	62	Female	Heroin	Crack Cocaine	None	Physeptone® 1mg/ml sugar free liquid, 90ml once daily, unsupervised	None	No	No	No
5	STARS	42	Male	Heroin	Benzodiazepines	Cannabis	Physeptone® 1mg/ml sugar free liquid, 85ml once daily, unsupervised	None	No	No	No
6	STARS	47	Male	Heroin	Alcohol	None	Physeptone® 1mg/ml sugar free liquid, 55ml once daily, unsupervised	None	No	No	No
7	STARS	41	Female	Heroin	None	None	Physeptone® 1mg/ml sugar free liquid, 55ml once daily, unsupervised	None	No	No	No
8	CRS	28	Male	Codeine	None	None	Buprenorphine/naloxone sublingual tablets, 16/4mg once daily, unsupervised	None	No	No	Yes
9	CRS	32	Female	Pregabalin	Codeine	Tramadol	Buprenorphine sublingual tablets, 16mg once daily, unsupervised	None	No	No	Yes
10	CRS	51	Male	Baclofen	None	None	None	None	No	No	Yes
11	REACH	33	Female	Sedatives unspecified (Sleepeze®)	None	None	None	None	No	No	No
12	REACH	45	Female	Codeine	None	None	Buprenorphine sublingual tablets, 16mg once daily, unsupervised	None	No	No	No
13	CRS	24	Female	Codeine	None	None	None	None	Yes	No	Yes
14	TOGETHER	58	Male	Dihydrocodeine	None	None	Buprenorphine tablets, 15.6mg once daily, unsupervised	None	No	No	No
15	TOGETHER	42	Female	Opiates unspecified (Kratom)	None	None	Subutex® sublingual tablets, 24mg once daily, unsupervised	None	Yes	No	No
16	FL	49	Female	Oxycodone	None	None	Methadone 1mg/ml sugar free liquid, 70ml once daily, unsupervised	None	No	No	No
17	FL	35	Male	Heroin	Cannabis	None	Methadone 1mg/ml sugar free liquid, 75ml once daily, supervised	None	Yes	No	No

18	FL	43	Male	Codeine	None	None	Buprenorphine sublingual tablets, 16mg once daily, supervised	None	No	No	No
19	STARS	44	Male	Heroin	Cannabis	Benzodiazepines	Diazepam tablets, 10mg once daily, unsupervised Physeptone 1mg/ml SF liquid, 60ml daily, not supervised	None	No	No	No
20	FL	61	Male	Heroin	Alcohol	Crack cocaine	Methadone 1mg/ml sugar free liquid, 60ml once daily, supervised	None	No	No	No
21	NYH	34	Male	Tramadol	Benzodiazepines	None	None	None	No	No	Yes
22	BRS	33	Male	Heroin	Alcohol	Crack cocaine	Methadone 1mg/ml liquid, 50ml once daily, supervised	10	No	No	No
23	BRS	48	Male	Codeine	Cocaine	Tramadol	Buprenorphine sublingual tablets, 8mg once daily, supervised	None	No	No	No
24	BRS	45	Female	Codeine	Alcohol	None	Zopiclone tablets, 7.5mg at night, unsupervised	None	Yes	No	No

58.3% were male, mean 42 years (range 24-62 years). One person (4.2%) had a known housing problem, four (16.7%) were employed and two (8.3%) were actively injecting. The majority (83.3%) of participants were in receipt of pharmacological interventions. Polypharmacy based upon NDTMS data was notable: heroin (41.7%) and codeine (29.2%) were the most common primary substances. The OTC/POM misuse reported in the interviews only matched the medicines stated in the NDTMS data in six instances (25%): either more were being misused or the medicines were not recorded at all, and even when there was space to do so, under 'secondary/tertiary substance'.

Many participants disclosed insight into their OTC/POM misuse and described being affected by traumatic life events such as loss of employment, bereavement, incarceration, significant health events and relationship problems. Iatrogenic dependence featured heavily, following treatment for a range of acute and chronic health conditions, including dental issues, sciatica, arthritis, migraines, neuropathy, and anxiety. Some participants did not use any other substances, due to their perceptions of them (especially in the case of familial dependence). These participants reported receiving SMS interventions alongside people using other substances without any issues. For those that did use other substances, a wide range, varying patterns, and routes of administration beyond just oral were described.

As well as prescribed interventions for substance use ***(see Table 10)***, most people were taking at least one other medicine for different physical/mental health conditions, and a variety of different types were named. Concomitant medicines were predominantly antidepressants (amitriptyline, citalopram, fluoxetine, mirtazapine, sertraline, venlafaxine) as well as propranolol, risperidone, topiramate, quetiapine and zopiclone for mental health conditions, and levothyroxine, lansoprazole, pantoprazole, vitamins, metoclopramide, naproxen, and acetazolamide for physical health issues. Where there was co-existing anxiety/depression, antidepressants were cited as helpful, but their adherence and effectiveness were sometimes affected by OTC/POM misuse-related interactions.

5.3.3. Thematic Analysis Findings

Thematic analysis enabled further explorations of the data and identified sub-themes (Braun and Clarke, 2006; Green and Thorogood, 2014), and no discrepancies were found when the transcripts were independently reviewed. Three overarching themes were identified: OTC/POM characteristics, positive experiences, and negative experiences:

5.3.3.1. OTC/POM Characteristics

Four sub-themes were identified relating to the characteristics of OTC/POM which were being misused: type of medication; patterns of misuse; route of administration; and sources used to obtain them:

- **Type of Medication**

  Medicines with sedating profiles predominated: the gabapentinoids (mostly pregabalin), benzodiazepines (mainly diazepam) and codeine (including combination products) were cited most often: other opioids (dihydrocodeine, dipipanone, tramadol, morphine, methadone, and oxycodone), zopiclone, baclofen,

mirtazapine and sedating antihistamines were also mentioned. In some cases, only one medication was being misused, but usually polypharmacy occured, and the use of different products changed over time:
"Benzos…diazepam and temazepam…pregabalin and gabapentin…[morphine] I was misusing that" #005
"It started off with just co-codamol…then…tramadol…after a few years…pregabalin…I was taking promethazine every single day" #009

The type of medication used was also affected by affordability, accessibility, and relative cost:
"Sometimes pregabs are cheaper or easier to get them. It's what comes up at the time" #019

- **Pattern of Misuse**

  The amount and frequency of misuse varied: some described ad hoc/ 'binge' use, for example on 'payday' or when they could source them, though for the majority, daily use indicative of dependence was described. In these cases, significant quantities were usually being misused, and for many, they had experienced gradual increases in consumption which had then continued for many years:
  "Just basically when somebody's had some and…would give me a few…as and when…It was sporadic. Once in a blue moon…it wasn't a regular thing" #006
  "I were taking 10 in the morning and 10 in the afternoon…doubling up all the time…[then] I was taking 200, 300, 400 at a time…I'd been on them for years and years" #023

  Subsequent problems with a lack of control over misuse behaviours were also outlined, and awareness of this risk led some participants to express careful self-regulation of their pattern of misuse:
  "*Sometimes I'd take half a tab…if I took a whole one of them, I'd get used to them quickly" #018*

  For some, their OTC/POM misuse was long-standing and had first commenced in their teenage years:
  "It started when I were say 15 or 17, that's when it started to get bad. It's gone on a long time" #013

- **Route of Administration**

  Overwhelmingly, participants described that their route of administration was oral, even when they took other substances via other routes. Swallowing was viewed as being 'normal' and contributed to views of their misuse being legitimised:
  "Swallowing. I've sometimes heard of those who've snorted it…with me it was always swallowing. I acted as if the doctor prescribed mine" #018

  An adversity or 'distrust' of injecting paraphernalia explained why for some, injecting was actively avoided:
  "[Swallow only] … I don't trust needles" #020

  However, occasionally participants described over time progressing to injecting. In each case, this was alongside the injecting of other substances. There were also reports of manipulating products to make them more palatable, and smaller solid oral formulations and liquids enabled larger amounts to be taken:
  "When I was doing the extracting, it was over a 100 tablets [all at once] into about a pint of liquid" #014

- **Sources Used**

  Participants stated that they sourced supplies from street dealers, GPs, hospitals, online pharmacies, unregulated websites, and social media sites such as 'Instagram'. Some stated they used deceptive behaviours (such as stealing from family), and 'all available means' to source supplies. Some also resorted to alternative supplies (usually unregulated and from illicit sources or codeine combination products associated with greater risks), when they could not legally procure them ***(see 5.3.3.3. Negative Experiences – Problematic Withdrawal Symptoms)***:

  "*I used to get them on prescriptions, I also used to steal it off family…I would ring the doctors and lie and say that my bag got stolen and they were in my bag so I needed more…any way of getting them, I would get them…When I couldn't get hold of proper codeine, I used to buy co-codamol tablets" #001*

  Participants also involved friends/family, including young people and elderly relatives in sourcing supplies:
  "I just ended up getting my friends and family doing it...often my gran and my son have to get them" #011

  Additionally, community pharmacies were used, and in a strategic way to avoid detection. Participants also reported becoming increasingly aware of what they needed to say and do, to obtain supplies:
  "Used to go around 6 or 7 pharmacies and then kind of make a note of where I'd been. Just to make sure no one really questioned…I think I was kind of quite good at talking them round" #014

  However, some also described how a lack of recognition of potential misuse behaviours, such as early requests for repeat medication, and inadequate questioning or reviews by healthcare professionals, enabled greater access to regulated supplies:
  "The doctors couldn't be bothered with any, you know, backlash or asking questions because they didn't have time to ask questions…Could be weeks early and they'd give you them. They wouldn't even question it…pharmacists…they'd just give it to you…" #008

  Where participants were accessing unregulated supplies, some described their concern over the unknown content, and had experienced adverse effects from 'bad batches':
  "I kept getting bad batches where I'd be ill for a few days at a time" #015

5.3.3.2. Positive Experiences

Participants purported various positive experiences, which were categorised into three sub-themes: altered mental state; physical health effects; and impact on other substance use:

- **Altered Mental State**

  All participants reported misusing OTC/POM for their desired impact on mental state, such as feelings of euphoria, relaxation, reduced anxiety, increased energy and mood, or conversely improved sleep:
  "It were my best friend. It enabled me to feel happy, I could take on the world, nothing would phase me. It was better than any antidepressants…It got me through the day…It just helped" #016

However, over time, many described problems with tolerance and needing to resort to taking increasingly larger amounts to feel the same effects:
"When I first took it…I was like 'wow, this feels amazing' but I quickly got used to it" #009

Participants with greater insight into their own behaviours acknowledged that they were likely self-medicating for underlying mental health issues and recognised this as a maladaptive coping strategy. This was particularly pertinent in the case of familial substance use:
"I would continue to ignore my feelings because I would use medication and put them in a box and ignore them, rather than facing them…My mum had been an alcoholic when I was growing up so I recognised the similar traits and coping mechanisms" #009

- **Physical Health Effects**

  Improvements upon pain management and appetite were reported, with a minority stating that OTC/POM misuse had no negative effects upon their functioning:
  "They took away the pain so I thought they were the best thing ever. I thought they were so wonderful…gave me a fantastic appetite, they were great…I did function quite good on them" #024

  One participant (#009) reported that their OTC/POM misuse facilitated their eating disorder due to appetite depressant and laxative effects, which they chose to view as a positive for reducing their purging behaviours. However, this then became a barrier to their OTC/POM misuse recovery:
  "I would always have an upset stomach so I didn't need to worry about taking laxatives… would make me feel a bit queasy which meant I didn't eat…if I make myself sick…I'll lose the tablets that I've taken…tramadol put off hunger pangs…I just was appreciative that it meant that I didn't eat…One of my biggest fears when I was trying to get clean was that I would end up putting on loads of weight" #009

- **Impact on Other Substance Use**

  Several participants reported the benefits of OTC/POM misuse on their use of other substances. Typically, this was to potentiate the desired effects or to otherwise manage withdrawals or side-effects:
  "Taking benzos, have them first then use heroin on-top of the benzos, you get a lot more effect off the heroin…Afterwards would be to help with the come down and just to try and mellow it out a little bit so I wasn't so wired" #005

  A preference for OTC/POM misuse over other substances was expressed due to their perceived better effects, lessened side-effects, undetectability via drug tests, and as they facilitated the reduced use of illicit substances and alcohol:
  "They don't find them on the drug tests…they don't make me slur my words…I stopped taking a handful of [illicit] benzos at a time and swap for a couple of [prescribed] pregabs" #005
  "I started taking painkillers and I preferred the high that I got. So I stopped drinking, like straight away. I stopped almost instantly" #009

Indeed, for some the desire to be free from other substances was what precipitated OTC/POM misuse:
"I was feeling pretty anxious and I wanted to stop myself from drinking so I took baclofen instead…It's much easier to titrate down on baclofen than it is alcohol" #010

5.3.3.3. Negative Experiences

Various and more numerous negative effects were outlined, which were categorised into five sub-themes: physical side-effects; problematic withdrawal symptoms; impact on daily life; relationships; and finances:

- **Physical Side-effects**

  A range of physical adverse effects were noted, especially for codeine combination products and long-term OTC/POM misuse. They varied in degree of severity, and included nausea and vomiting, gastric ulcers and bleeds, paracetamol toxicity, hepatic and renal impairment, seizures, ataxia, falls, bruising and blood pressure problems, as well as the need for surgical procedures and ongoing problems due to the chronic damage that had been caused:
  "I stand up too quick and my blood pressure drops...unconscious before I hit the floor…blackouts and seizures…" #005
  "I ended up being rushed into hospital when they had to take a bit of my small intestine away and I had a stoma for a year" #012

  For participants without a known underlying eating disorder, the impact of these physical side-effects upon weight loss was negatively viewed:
  "I was incredibly ill. Vomiting every day about 10 times…Didn't really have any appetite…I think I lost 2 stone over about a month…I was just slipping away" #014

  To minimise the risks of physical side-effects, participants outlined a variety of harm reduction strategies, such as avoiding polypharmacy, and undergoing proactive health checks including organ function tests:
  "As soon as I started taking painkillers regularly, I didn't take anything else because I didn't dare mix…I had a full liver count blood test…my renal function seems ok…" #009

  Participants taking co-codamol were especially vigilant for possible paracetamol overdoses, and where possible minimised their use of paracetamol-containing products:
  "I wasn't filling my body full of paracetamol…might be only one day that I'd have to take these co-codamol before I then found another [codeine only] source" #001

  To minimise physical side-effects, other harm reduction approaches included seeking prompt medical attention, having their paracetamol levels checked, and using self-taught cold-water extraction techniques, though there were frequent reports of adverse effects associated with the latter:
  "Purifying it with a cold-water extraction…I had to go to the hospital a few times to be tested for paracetamol overdose…I found out about it online years ago" #014

- **Impact on Daily Life**

Participants outlined negative psychological effects, including low mood, cognitive impairment, memory problems (which also affected medicines adherence), impaired sleep, excessive sedation and tiredness, lack of motivation, irritability, increased anxiety, and impulsiveness, which impacted upon their daily lives:
"I was just a bit like a zombie…Really lethargic. Tired all the time…It was destroying my life…I wasn't able to function. I wasn't able to get up in the morning and do things" #014

Negative effects on daily living also included having contact with the police and hospitalisation:
"I stopped taking them because I were getting into trouble with the police" #017

Sometimes polypharmacy was avoided to minimise the impact on activities such as looking after children:
"Very very rarely I would take them both [codeine and pregabalin] because I don't like being tired and grouchy and slouchy…I've got a son to look after" #018

Individuals described wanting to 'return to normal' once they noticed changes in their self-care, improved mental wellbeing, and ability to return to work following improvements in their misuse:
"I'm so glad that I've levelled now…I'm just leading a normal life now, go to work…" #023

Where prescribed interventions were provided, some valued the structure and motivation involved in attending their community pharmacy. However, to minimise the impact on their daily lives, flexible appointment availability, child-friendly facilities and more liberalised dispensing arrangements were required:
"I couldn't go to a specific [SMS] appointment for my prescription because I look after my grandson…I wasn't prepared to bring my grandson into [SMS], just in case anything happened" #016
"I've still got to go to the chemist every day…It's an inconvenience" #018

- **Problematic Withdrawal Symptoms**

A variety of withdrawal symptoms were described, such as sweating, tremor, headaches, lacrimation, rhinorrhoea, sleep disturbance, impaired concentration, mood lability, depression, suicidality, leg cramps, hallucinations, nausea and vomiting, apathy, inertia, appetite suppression, restlessness, severe stomach cramps and diarrhoea, often with severe impairment upon their functioning. For many, anxiety predominated, and participants became preoccupied with sourcing further supplies:
"I couldn't function in life if I didn't have them…I'd just panic more…sweats, sleep, my mood was up and down, my anxiety used to be bad…fidgety…can't concentrate on anything other than…where am I going to get the next lot of codeine from?" #001

This preoccupation with alleviation of withdrawal symptoms also led to problematic behaviours and affected their relationships:
"It was hard work trying to get them…it was interfering with me life big time…they say you'll take the last cent off your grandma – they will. Just to get rid of that rattle" #023

Withdrawal symptoms were routinely expected, either following a 'binge', or when the participant knew that their next dose was due, leading them to 'clock-watch', to ensure they did not miss a dose so that they would not feel unwell:
"I'd time it with my phone. If I didn't take them, I'd start to feel ill...I'd forgotten to take them a few times and you really know about it. Three hours after your dosage time you start to feel pretty sick" #010

The management of withdrawal symptoms was most problematic when OTC/POM supplies suddenly ceased, for example when reactive cessation of prescribing or OTC sales occurred, or OST doses were forcibly missed:
"I said to the doctor I want to come off them and basically they stopped the medication.…I did do a detox on my own…and it nearly killed me…and then I relapsed. I was back to square one again" #023

Consequently, withdrawal symptoms perpetuated OTC/POM misuse:
"After a while you start to realise that you need to take them or you don't feel great and then you start withdrawals and then once you know it's withdrawals involved, that's when you don't want that to happen. So you just keep taking them and taking them and taking them so you don't feel that way" #013

Participants used illicit or 'herbal' substances to self-manage withdrawal symptoms, and resorted to using polypharmacy or large amounts of less potent codeine combination products associated with greater risk of adverse effects:
"The heroin and crack cocaine come in because I couldn't find any tramadol…Pregabs or anything. Codeine…perhaps buying 32 co-codamol, take them all at once…they just kept the rattle away" #023

Participants also reported that gradual reductions with SMS support, prescribed interventions and PSI were helpful to manage problematic withdrawal symptoms. Good adherence to OST was typically noted and concomitant use of PSI were especially useful where issues with cravings and emotional dysregulation remained ongoing:
"I don't mess about with the methadone. I don't take more than I should… I don't save it or sell it…The methadone has helped" #005
"I get really, really, really, really bad cravings…I don't have any physical withdrawal symptoms [on OST] getting a lot more intrusive [obsessive compulsive disorder-related] images due to like not knowing how to suddenly deal with the fact that I was like feeling anxiety rather than masking it" #009

- **Impact on Relationships**

Participants were cognisant of the negative impact that their OTC/POM misuse was having on their loved ones, especially on their anxieties and mental wellbeing. The negative impact on relationships was typically due to behaviours whilst under the influence of the OTC/POM, and how these were perceived by others:
"Everyone hates being around when I'm high…Me mum's scared…She's got a spare key and she's terrified of knocking, getting no answer, letting herself in and finding me dead" #003

Participant inability and lack of willingness to engage in meaningful contact due to their OTC/POM misuse taking priority and/or subsequent introversion, also impacted on their relationships:
"I've lost out on friendships. There's been times where I've just been like intent in staying in my own little world like, using at home and not seeing anyone" #009

Consequently, participants described feelings of loneliness and isolation, and the lack of support was compounded for example by being an only child, or where there were long standing difficult relationships:
"Barely have any friends so I'm on my own all the time…I've got no brothers. I've got no sisters. I've got no dad. No grandma, no grandad…All I've got is my mum. A very complicated woman, so it's difficult…There's no support" #008

Sourcing supplies impacted upon their free time to spend with their loved ones, employment, daily life activities and finances ***(see 5.3.3.3. Negative Experiences – Impact on Daily Life and 5.3.3.3. Negative Experiences – Financial Impact)***. This further negatively impacted upon their relationships, especially due to the associated deceitful behaviours:
"Trying to get them…organising, paying for them, trying to pay for them. Hiding the fact that I was paying for them behind my wife. Doing extra work…The lies, deceitfulness" #023

However, where positive, open, and honest relationships with friends/family (and especially parents) existed, this provided opportunity for more supportive conversations, help with housing and facilitating access to SMS, OTC/POM supplies and finances:
"I'm living with my parents at the moment…they provide a lot of emotional support…" #014

Where these supportive relationships didn't exist, the importance of SMS creating opportunities to connect with new relationships by engaging with different social networks was also highlighted:
"I haven't got a job or like places to go where you like meet people... [at SMS] you're meeting different people" #019

- **Financial Impact**

Some sourced supplies for free, for example through legitimate access to (usually free) NHS prescriptions or diverting friends/family supplies, and then only spent money when these sources were exhausted. Many reported a notable negative financial impact due to lack of control over their misuse, (especially for OTC purchases), with some using monies from inheritance, redundancy payouts or working additional hours:
"I was constantly asking people to lend money…I'm constantly in money difficulties…I have that money from the redundancy pay. I also had a small amount of inheritance when my grandfather died" #009

Sometimes there was an inability to quantify the amount being misused, or because their use depended upon access to money, their typical expenditure and true financial impact was unknown:
"Could be £30/40 a day-ish. But then it could be a tenner another day if that's all I've got and then you know it could be £50 another day if I've got more money. It's difficult to quantify" #004

Expenditure also varied due to differing patterns of misuse and medication types involved: participants described spending up to £350/week or all the money they had access to. This resulted in financial difficulties and strained relationships with friends and family, usually due to reliance on them for money and dishonesty regarding how their money was being spent. Consequently, a focus on improved financial management, including repayment of associated debts and sometimes involvement of family members in managing finances, was an essential part of many participants recovery. One participant (#023) even resorted to going to jail when they were no longer able to afford their OTC/POM misuse:

"It got really expensive, that's how it got out of control…me and me wife fell out…wouldn't let me in the house because I was spending too much money…I'd run out of money and I knew that I'd be able to get medication in jail so I messed the injunction up…All my money now gets paid straight into my wife's bank account…so I can't go on a bender or anything like that…I'm a great believer in not owing people money…I went to work and paid all my debts off to everybody that I owed" #023

5.4. Discussion

5.4.1. Key Findings

The finding that middle-aged men presenting with problematic opioid use predominated, is typical of those accessing English SMS (OHID, 2023; UNODC, 2023). The other characteristics of individuals who were misusing OTC/POM, such as the use of other substances, experience of traumatic life events, having a familial history of substance use, a diagnosis of a mental health or chronic pain condition, (sometimes with associated iatrogenic dependence), are broadly comparable to the participants of other studies (Cooper, 2013a*;* Fischer, *et al.,* 2006; McCabe and Cranford, 2012; McHugh, *et al.,* 2016) and ***Chapter 4 – Study 1 Questionnaires***. The variety of sources (legal or otherwise, including friends/family) used to access OTC/POM are also well known (AOG, 2012; Fischer, *et al.,* 2006; Rosenblum, *et al.,* 2007; UNODC, 2011).

In keeping with national datasets (OHID, 2023), participants mainly used (OTC/POM/illicit) opioids, which also explains why most were in receipt of OST. Predominant oral administration and a lack of participants misusing stimulant-type OTC/POM was also identified by Cassidy, *et al.,* (2015). There were significant discrepancies (75% inaccurate) between OTC/POM misuse reported during the interviews and what was recorded on HALO/Systm1 for NDTMS reporting (PHE, 2020a). As found by Walley, *et al.,* (2009), this suggests that using clinical records in isolation would have been unreliable because of their lack of completeness, likely due to poor documentation by SMS staff, change in the participants misuse since their last NDTMS data review, or perhaps they had not been asked about or disclosed the information to SMS staff. Whilst patterns of misuse varied, long-term, daily dependent use was typically described. Other researchers have found that the pattern of misuse was affected by affordability, relative cost, and availability (Bi-Mohammed, *et al.,* 2017). This included when illegal drugs were not available, whereas Lessenger and Feinberg (2008), found the reverse.

The themes identified were similar to the findings of Van Hout, *et al.,* (2018), whose work in Ireland focused on people who have misused codeine. The preference for products due to their (perceived) relative better effects, side-effect profile and reduced likelihood of detection via drug tests, has also been found by others (Chiappini, *et al.,* 2020; Gittins, *et al.,* 2018a; UNODC, 2011; Van Hout and Brennan, 2011). Where perceived positive effects upon mental state were identified, polypharmacy often featured, and sometimes incorporated illicit substances to potentiate the effects of each other. This is perhaps to be more expected when people were in the early stages of their recovery journeys (Gittins, *et al.,* 2018a; Van Hout and Bingham, 2012). Whilst these effects were generally outweighed by the negative health impact over time, this is of particular concern given the use of sedating OTC/POM which are associated with the risk of fatal overdose (Robinson, 2017; UNODC, 2011).

As has been reported by others (Coombes and Cooper, 2019; Cooper, 2011), a wide range of physical and psychological adverse effects were identified. These were often significant, and impacted upon participants daily lives, and especially in relation to the physical health consequences of combination codeine products. To minimise them, a variety of harm reduction measures were outlined and desired by participants, including avoidance of polypharmacy and the proactive use of health checks.

The anticipation of withdrawal symptoms caused notable anxiety and they perpetuated misuse. By being preoccupied with sourcing further supplies to alleviate withdrawal symptoms, this also led to problematic behaviours and antagonised relationships with loved ones. Consequently, when participants had their supplies suddenly curtailed, withdrawal symptoms were more problematic and they were more likely to source alternatives, including illicit substances, unregulated products, or they would take significantly more combination codeine products, which put them at greater risk of adverse effects, such as accidental overdose. This was also identified in the systematic review and the previous study ***(see Chapter 2 – Systematic Review and Chapter 4 – Study 1 Questionnaires***).

The financial impact of OTC/POM misuse and the relatively low number of participants who had employment, supports the need for continued embedding of employment and benefit support services into SMS, and is also in keeping with national reports (DHSC, 2022a; OHID, 2024). The recognition amongst some participants that their 'self-medicating' was a maladaptive coping strategy is in keeping with the findings of others (Claffey, *et al.,* 2017; Fischer, *et al.,* 2006), and the positive impact of PSI, supports national treatment intervention guidance and the need for a trauma-informed approach (DHSC, 2017; DHSC, 2022a).

These findings also highlighted the importance of the role of friends/family and the need for improving their awareness, especially given their apparent involvement in providing support, facilitating access to treatment, and reducing feelings of loneliness and isolation. The need to improve this, for example by providing group PSI and interventions such as family therapy, has been similarly raised in national guidance (NICE, 2022; PHE, 2020b) and charities such as Adfam (2023a).

5.4.2. Strengths and Weaknesses

The approach taken in this study, and with a similar number of service user interviews combined with data from clinical records, has been successfully used by Seivewright and Dougal (1993). This study has built on the findings from ***Chapter 4 – Study 1 Questionnaires***, as it has allowed for further exploration of what OTC/POM are being misused by service users. Participants represented a geographical range of community English SMS, and all seven of the potential Humankind services were represented. Despite the challenges of conducting research during pandemic restrictions, and in SMS where people were prioritising their substance use, due to the rich and relevant data obtained, the methodology and sampling approach was thought to have been appropriate (Brod, *et al.,* 2009; Green and Thorogood, 2014; Guest, *et al.,* 2006). Similar has been found in related studies with around the same number, or indeed even fewer participants (Buttram, *et al.,* 2019; Coombes and Cooper, 2019; Cooper, 2013a; Ruben and Morrison, 1992) ***(see Chapter 2 – Systematic Review)***.

Whilst data saturation was felt to have been achieved, (Bowling, 2002; Green and Thorogood, 2014), additional information may have been elicited if further interviews had been undertaken, including in other SMS providers, which may also enable greater generalisability. Although repeat interviews were not implemented, when member-checking was undertaken, no discrepancies were identified; however, extending this further and adding repeat interviews may offer a greater degree of assurance in the findings. A degree of validity and reliability was suggested, as when transcripts and associated themes were reviewed, no differences were identified; however, the independent critique of the thematic analysis by the Research Supervisor proved important to challenge the Researchers views (Sandelowski, 1993), when they may have otherwise been overly critical of primary care.

Complete and detailed transcriptions were facilitated using audio recordings and field notes, and the full data set was analysed. Piloting, using standardised exemplar invitation wording and an interview guide, anonymising the findings ***(see Chapter 3 - Research Strategy and Design)***, the absence of chaperones and using a Researcher who has experience of working in this clinical area, but with no prior knowledge of the participants or direct input into their care, likely increased participants willingness to share their personal experiences despite the 'artificial' environment (Brod, *et al.,* 2009; Van Amsterdam, 2015; Van Hout and Brennan, 2011). Indeed, the Researcher's prior experience of working in psychiatry, including with people who use substances and the openness and sensitive details participants disclosed in their interview responses, indicates that rapport was quickly built. Additionally, use of an interview guide and utilising the same Researcher/reviewers, should have limited the variability between interviews and the analysis process. However, involving peers with lived experience, in undertaking recruitment and conducting the interviews rather than SMS staff, may have enabled more individuals to be involved or disclose further information.

5.4.3. Implications for Clinicians, Policymakers and Researchers

As some participants reported long-term OTC/POM misuse which sometimes commenced in teenage years, and changes in misuse (route, pattern of use, manipulation of products and medicine type) over time, healthcare professionals should be vigilant for, and regularly ask about, changes during regular reviews or at

the point when medication is being supplied (RCGP, 2014b). Due to disclosures about commencing misuse as a teenager, there is a potential need for further exploration and greater awareness amongst those working with young people (Sheridan, *et al.,* 2019). These findings also suggest the need for extra caution in the case of personal history or familial problematic use of substances or OTC/POM misuse.

Given that the patterns of misuse were affected by access and cost (Bi-Mohammed, *et al.,* 2017), this should be considered when healthcare professionals and policy makers are making decisions about enabling access to supplies (Lipanovic, 2023). As outlined in national guidance, there should be increased monitoring of repeat requests, regular reviews, checks for interactions and increased questioning for OTC/POM which are liable to misuse (NICE, 2022; RCGP, 2014a), and there may be a need for additional training to support healthcare professionals with this. The findings highlight the importance of SMS staff also routinely and specifically asking about OTC/POM misuse during assessments, even if there is a perception that other substance use dominates initial presentations. SMS may also wish to review their approach to drug testing, to ensure that they can facilitate tests for OTC/POM (Wen, *et al.,* 2019).

As some participants motivations for OTC/POM misuse included self-detoxification from other substances and to manage underlying physical/mental health conditions, healthcare professionals should be especially mindful of the potential misuse of OTC/POM in these circumstances. There were conflicting views about the effects of OTC/POM misuse on weight, which was generally explained by the presence of co-morbid eating disorders. As previously outlined by Gregorowski, *et al.,* (2013), people with an eating disorder may have poorer outcomes, and the concomitant use of other substances can be substantial. These findings tentatively suggest that this is also the case for OTC/POM misuse, and the need for improved awareness of eating disorders amongst SMS staff has been previously highlighted (Gittins, *et al.,* 2018a). Furthermore, polypharmacy to potentiate or otherwise alleviate the withdrawal effects of other substances has been noted by others (Lankenau, *et al.,* 2012; Lyndon, *et al.,* 2017). As OTC/POM misuse may also affect the adherence to other medicines such as antidepressants, this can also cause adverse effects (PHE, 2020b). All care providers should therefore ensure a shared decision-making approach, proactively question about withdrawal symptoms, and provide advice about how to manage them (NICE, 2022; RCGP, 2014b).

Despite calls for offering separate SMS for people who misuse OTC/POM rather than other substances (BMA, 2015; PHE, 2020b), as many participants also used other substances and those that didn't reported engaging effectively in SMS alongside people who used only illicit substances, this indicates that this may not be necessary. Due to the negative experiences of 'bad batches' when OTC/POM are sourced illicitly (CCENDU, 2021), these findings also indicate the potential utility of drug checking to reduce harms (Guirguis, *et al.,* 2020a). Ensuring other harm reduction provision, such as education and awareness of how to undertake cold water extraction also remains essential.

Whilst participants outlined difficulty in controlling their misuse, sometimes they managed their consumption, for example so that they felt that they could still parent effectively. This highlights potential safeguarding concerns and the need for healthcare professionals and SMS to remain vigilant for this. Indeed, in accordance

with standards for healthcare professionals (GMC, 2024; GPhC, 2024b; NMC, 2018), safeguarding issues should also be considered in situations where friends/family (and especially young or older people) become involved in sourcing or controlling OTC/POM supplies or finances, and SMS must assess their support needs too (Manthorpe, *et al.*, 2015). Given the impact upon friends/family that participants outlined, triangulation of these findings (Kuper, *et al.*, 2008; Tonkin-Crine, *et al.*, 2016), to explore their perspectives is important ***(see Chapter 7 - Study 4: Friend/Family Interviews)***.

To maximise engagement opportunities, and to minimise impact upon daily life, SMS should consider child-friendly facilities, and flexibility when providing appointments and pharmacological interventions. Therefore, future research should further explore treatment pathway development to gain a better understanding of barriers which may exist, and how engagement and treatment interventions may be improved. This also highlights the importance of exploring SMS staff views to additionally triangulate these findings (Noble and Smith, 2015) ***(see Chapter 6 - Study 3: Staff Interviews)***. Extending this work, may also enable comparisons and exploration if subsequent treatment needs change depending on different demographic characteristics such as geographical location/SMS provider (including beyond England), ethnicity and gender, as well as different OTC/POM types, and those which were not mentioned, such as image and performance enhancing drug (IPED) use (Hinde, 2019).

5.5. Conclusion

OTC/POM misuse (including long-term, daily dependent use and iatrogenic dependence) was prevalent, but highly variable amongst people who access SMS. They were associated with a range of socioeconomic, physical, and psychological health effects, and traumatic life events, physical and mental health issues were often co-existing. Oral administration of those with sedating profiles (especially opioids) predominated, and polypharmacy sometimes featured, including the use of other substances. OTC/POM are both legally and illicitly sourced, and misuse was impacted by cost and availability, so can change over time, and should be routinely enquired about. Due to their physical health consequences, harm reduction strategies are particularly pertinent for codeine combination products.

NDTMS data may not accurately reflect OTC/POM misuse, which can notably impact upon daily living. Associated SMS interventions and withdrawal symptoms can also affect daily activities, so healthcare professionals should proactively consider how their impact can be minimised. They also need to be vigilant for potential safeguarding issues relating to parenting, involvement of friends/family in sourcing supplies, and managing finances. Future research should therefore explore the experiences of SMS staff and friends/family from their own perspectives to triangulate these findings.

6. Study 3: Staff Interviews

This chapter presents findings from the confidential semi-structured interviews that were conducted with Humankind SMS staff. The purpose was to explore the experiences of community English SMS staff who have supported adults that have misused OTC/POM. To avoid unnecessary duplication, further details of the methods (including rationale for the selected methodological approach) are provided in a previous chapter ***(see Chapter 3 - Research Strategy and Design)***.

The interview design was informed by findings from the systematic review, the service user interviews and consideration of approaches undertaken by other researchers who have explored OTC/POM misuse in the broader literature ***(see Chapter 1 - Introduction, Chapter 2 – Systematic Review, Chapter 3 - Research Strategy and Design and Chapter 5 - Study 2: Service User Interviews)***. In turn, the findings from this study were used to inform the interviews utilised in the final study. They have also been shared at international conferences ***(see Appendix 1: Summary of Publications/Contributions)***, and they are currently under peer review for publication in an international journal*:*
Gittins R, Vaziri R, Maidment I. 202X. "The most high risk people are given the most high risk drugs in the most high risk way": experiences of treating problematic over the counter and prescription only medication use in substance misuse services.

6.1. Aim and Objectives

To use confidential semi-structured interviews, to explore the experiences of community English SMS staff who, through their employment, have supported adults that have misused OTC/POM.

6.2. Method

Participants were excluded if they were known in a personal capacity by the Researcher. Individuals were considered eligible if they had current experience of working in a service user facing (front-line) Humankind community SMS role and had experience of supporting adults who had misused OTC/POM. Due to the requirements of their employment, all SMS staff were at least 18 years of age, were able to provide informed consent and had good English-speaking skills.

The rationale for the chosen methodology and more details about the methods used (including data sampling, collection, management and analysis, PPI, ethical considerations, and risk management) were outlined in ***Chapter 3 - Research Strategy and Design***. All qualitative responses from the interviews ***(see Appendix 8 – Staff Semi-structured Interview Guide)*** were included in the analysis out of responsibility to the participants for their contributions.

Potential SMS staff participants self-identified as being eligible and interested in being included, by contacting the Researcher directly via telephone, email/Microsoft® Teams®, or in person during SMS visits. This occurred after the Researcher sent emails to relevant staff with copies of the PIS ***(see Appendix 5 - Staff Participant***

Information Sheet) attached. Paper copies were also provided if requested, and if participants wished to proceed or wanted more information, they liaised directly with the Researcher.

6.3. Results

6.3.1. Summary of Interviews

Data saturation was thought to have been achieved after twenty interviews, which were conducted between October 2020 and January 2021, with mean 18min 23 secs (range 7min 19 secs to 40min 15 secs). Organising time for the interviews was challenging due to staff operating busy clinics and managing additional pandemic-related work pressures. No participants had additional needs which required support during the interviews. Due to COVID-19 restrictions and logistical challenges, only six (30%) were conducted face-to-face: for the remaining, 13 (65%) were conducted via telephone and one (5%) via Microsoft® Teams®. Member-checking and repeat interviews with the same individuals were not possible due to time constraints and logistical challenges.

6.3.2. Characteristics of Participants

The majority were female (60%) and the different community SMS that they worked in and job titles are summarised in ***Figure 6*** and ***Figure 7*** respectively (this data has not been combined so as not to identify individuals, for example as each service had only one Clinical Director). Although the participants were not asked, four chose to divulge details of their own lived experience of OTC/POM misuse.

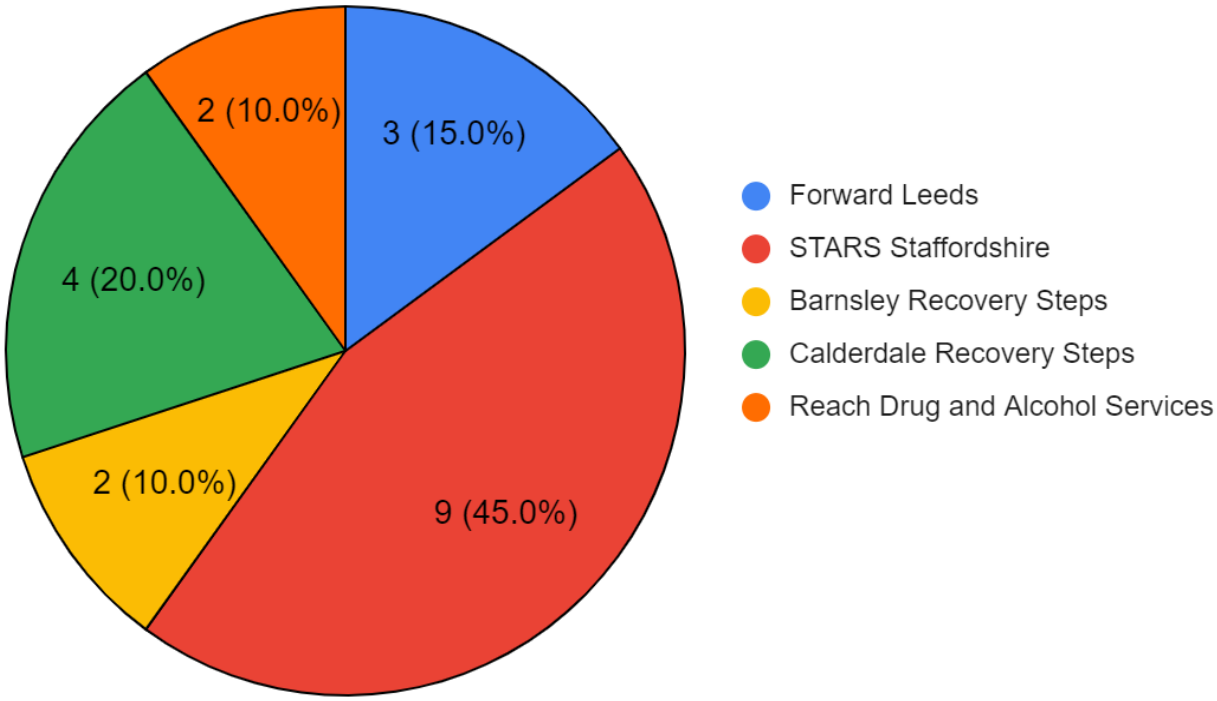

Figure 6: *Summary of community SMS where the participant worked*

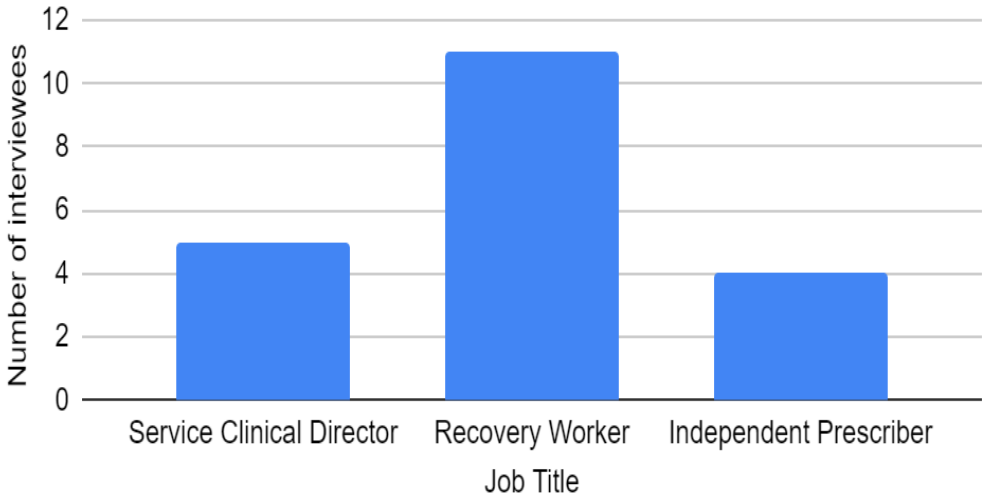

Figure 7: *Summary of different staff participant job titles*

Experience of working in SMS ranged from 14 months to thirty years, and many had worked in different roles and SMS: the registered healthcare professionals were doctors and nurses, and some had moved from Recovery staff roles to working as a qualified healthcare professional and vice versa.

6.3.3. Thematic Analysis Findings

When transcripts were independently reviewed for themes, their findings were discussed and no differences in the themes that emerged were identified. From the thematic analysis (Green and Thorogood, 2014; Silverman, 2021; Urquhart, 2013), three overarching themes were identified: characteristics of the OTC/POM misuse that the people they had provided support to presented with; different groups of people who misused OTC/POM; and associated negative experiences and concerns (with six sub-themes which emerged, relating to the lack of awareness of risk of harm; unmanaged health conditions; withdrawal symptoms; side-effects; problematic behaviours; and treatment pathways):

6.3.3.1. Characteristics of OTC/POM Misuse

Whilst participants acknowledged that a wide range of OTC/POM were misused, they predominantly described experience of supporting people who took three main medicine types: benzodiazepines, gabapentinoids and opioids (especially codeine-containing products). Staff reported that the administration of OTC/POM was usually by mouth, even when people were opting to take other substances by alternative routes, though occasional snorting, smoking, or injecting was reported:

"Codeine, all the way through the more serious opiates, the morphine derivatives, oxycodone, fentanyl, all forms of benzo: diazepam, temazepam, clonazepam…the Gaba drugs… those three groups at the moment. There are many others which are abused, right down to things like cyclizine and loperamide although not so commonly…Generally orally, but people do snort and inject on occasion, but mostly orally" #001

Sometimes the type of medication being misused was identified via drug tests, but for some SMS there was an alleged lack of availability for specific OTC/POM tests, and when used, there was a lack of consistency

and clarity about when to use them. Additionally, the need for improvements in obtaining prompt test results was outlined, due to reports of significant delays and the consequent impact on care delivery:
"Nothing was coming up on the urine screen so we had to send that away to the labs so that put his treatment back which didn't go down well because he was waiting about a month" #013

Participants described OTC/POM misuse as an ever-evolving issue, and some didn't come across it as often as the use of illicit substances. Consequently, staff described how their confidence had grown as they had been involved in more OTC/POM misuse situations, and utilised the knowledge of more experienced colleagues when they felt at their limit of professional confidence/competence:
"I didn't feel like I knew what I were dealing with. I felt a little bit out of my depth…about 3 years ago…I've seen a lot of people since…nervous to start with…I'd always run it by [SMS colleague]…said, I was thinking of doing this and she'd say 'oh have you thought of such and such'…we are all working side by side…if I don't feel confident, you know don't feel like I'm doing it right, I will ask somebody" #013

In their experience, a variety of sources were used to obtain supplies: friends/family, high street pharmacies, GPs, private practice, hospitals, online pharmacies, illegal websites, social media, the dark web, and street dealers. Additional suppliers were reportedly used when larger quantities were needed, and especially in the case of iatrogenic dependence:
"They're often initially prescribed and then obviously people start to take more and more…over the counter from various pharmacies. Or via the internet or via people who they know are prescribed them…. All sorts of sources" #006

To respond to concerns about supplies, some examples of collaborative working between SMS, secondary care and community pharmacies were provided:
"We liaised with [senior hospital clinician]…got him to come along to one of our training events…he has made it his mission to ensure that less people come out of hospital on absurd opiate and gaba regimes – that they get people off…before they get discharged" #001
"I'm actually quite impressed with the pharmacies locally. They tend to report it if somebody shows up quite regularly…saying this person's been a few times and been refused" #018

Some participants described friends/family involvement in enabling access to supplies, and the positive impact that friends/family had on OTC/POM misuse:
"Almost the whole family [involved in buying] the medication…she started reducing the medication because family doesn't really want to provide her with these meds, now they're trying to get her prescribed" #019

Some reported observing trends in misuse changing over time, impacted by ease of availability and increased awareness, (for example via social media), with geographical and age-related variations:
"It's all under 21's on codeine – quite a lot of codeine linctus type…it's very accessible from pharmacies…The power of social media. The words gets about…. Very easy to get hold of diazepam. Obviously Xanax® over here is relatively new…pregabalin and gabapentin which also seem to be on the rise" #017

Participants described supporting people with patterns of daily, dependent use with frequent re-dosing of large amounts, though frequency also varied in response to psychological stress:
"Throughout the day…in handfuls…every so many hours they'll be taking it. Closer and closer together, depending on their stress level…because they couldn't manage the day to day" #016

6.3.3.2. Different Groups

Participants indicated that in their experience there were two distinctly different groups of individuals who misuse OTC/POM. One group routinely misused OTC/POM in combination with illicit substances, and the other group only used legally sourced supplies (typically only OTC codeine products), and usually didn't use other substances:
"People are using codeine, from my experience so far, they are using just that…. [however] the benzodiazepines alongside the opiates" #011

The first group usually misused the OTC/POM to potentiate or otherwise to counteract the effects of illicit substances, and views were expressed that OTC/POM misuse may act as a 'gateway' to the use of other substances:
"You get a lot of like opiate users using [benzos]…quite a lot of stimulant users using [benzos] because either they help them come down or one of the side effects of stimulant use is anxiety and it helps with that…A lot of them got onto heroin through like prescription opiates or over the counter opiates" #002

The second group were often viewed as being more methodical in obtaining supplies and not having the 'appearance' of someone who required SMS, though they still presented with problematic behaviours. In this group, iatrogenic dependence was more likely, individuals were often described as younger, female, 'working-professional types', who could more readily afford the cost associated with OTC supplies. They were described as requiring more intensive psychological support, lacking in insight, and struggling the most during detoxification:
"We see professionals and career people managing their lives but are nevertheless battling with a serious issue…[they] have no contact with illicit substances at all…they have bona fide medical conditions or illness behaviours which legitimise the use of their substance…[to afford them] a fair expense. Which is why it is often something that is practised by professionals" #001
"Most of the people whom I see…women…when they come off it, they are the ones who struggle…especially young women…it is emotionally they are struggling…I think that is where it requires more work and psychological principles" #014

However, there were mixed views about how people in these different groups presented to SMS. Some felt that separate SMS that were specifically for those who misused OTC/POM only, and that they may encourage engagement where people did not want to use the same SMS as people who use illicit substances. Since this was likely due to stigma, some felt uncomfortable with separating people into 'categories', out of concern that this may further compound how people who use illicit substances were viewed:

"She was scared to come into the building, cos she was like, all the heroin addicts are going to be there and they're not in the same vein" #004
"I don't think separating people into different categories is the right thing to do. But…there's a group of people that would not entertain going to a group where there's people that do heroin, because they see themselves different…" #015

PSI were usually described as being the same for both groups or for people who only used other substances, such as drug diaries, motivational interviewing, advice about structured self-reductions, linking with other supporting agencies for crisis and contingency management and peer support, such as AA and narcotics anonymous (NA). In all cases, PSI were delivered via allocated Recovery staff, with a co-production approach, and group interventions were especially well regarded:
"Motivational interviewing, harm reduction, signposting to fellowships so NA, AA, all groups like that…Groups were fantastic…on a regular basis. Make friends groups, discuss experiences" #005

For non-opioids there was a higher threshold described for initiating prescribed interventions, primarily due to the perceived lack of evidence base and greater issues that this may create, as well as organisational systems restricting prescribing practices. However, there were potential inconsistencies in OST provision where only opioid OTC/POM were being misused:
"I kind of don't agree with all clients coming in and started on medication for over the counter medication…I'd rather get them off that than put them on OST…I think the withdrawal symptoms are for more intense on the OST…I agree with buprenorphine being prescribed for…codeine clients, if they are taking high amounts…but I think they need to be on daily supervised…not really keen on them being on methadone" #016

Overall, participants generally agreed that ultimately the interventions used need to be tailored to the individual, because everyone's OTC/POM misuse and circumstances can be different:
"One size doesn't fit all does it, with our cohort and our communities" #020

6.3.3.3. Negative Experiences and Concerns

Participants expressed having a range of negative experiences and concerns regarding OTC/POM misuse, with six sub-themes: lack of awareness of the risk of harms; unmanaged health conditions; withdrawal symptoms; side-effects; associated problematic behaviours; and treatment pathways:

- **Lack of Awareness of Risk of Harm**
  Due to the legal status and ease of availability OTC or as a POM, or their initial use for a genuine clinical reason, this led to participants having concerns about the lack of understanding of the potential harms amongst people misusing OTC/POM. Multiple participants articulated negative experiences of working with people who had a lack of awareness, especially regarding the relative potency of different products, and when compared to traditional illicit substances:

"What concerns me the most, that people don't really realise what codeine can do…'oh it's a prescription drug and they prescribe it to you and you get if from a doctor'…They don't think it's a problem because it's over the counter rather than going out on the streets to buy it" #004

As a result, one participant (#016) described needing to be 'stricter' with people, and opted to provide more assertive outreach when OTC/POM misuse featured:
"I am actually calling them throughout that week…you've got to be stricter with them because they deem it as being ok for them to take it, over the counter so they seem to think it's ok, it's been prescribed, or it's not that bad, it's not like heroin" #016

Participants had concerns about people who had been misusing for many years and had 'normalised' their OTC/POM misuse, despite the additional risks of harm due to their increasing age and associated co-morbidities:
"A lot of our service users are getting a bit older and they're a lot of the mindset 'oh, I've been doing this for years – I've got a really high tolerance. I can do a lot of stuff with no risk of harm' but you're probably more at risk now than you were previously, because you now have other issues with your health" #015

Participants also outlined the critical need to improve awareness of the potential risks amongst people accessing SMS and their significant others, though indicated that this would take time, required prioritisation, and needed a particular focus on how to access help and support:
"Raising the profile more within the service, posters and leaflets…tends to be lower on the list of priorities…You have to keep the conversation going so you kind of drip feed the messages" #007

- **Unmanaged Health Conditions**

  Participants outlined concerns that in their experience, individuals misused OTC/POM for the temporary alleviation of psychological or pain management issues, rather than addressing the underlying causes. This was more notable when the person was self-medicating whilst being unable to access the care they required:
  "[When] not being able to get into mental health services…to manage the way they feel…they're trying to self-medicate their anxiety" #002

  This was particularly observed during COVID-19, where sometimes misuse was thought to have escalated due to increased difficulty in accessing care, more anxiety and loneliness, issues with housing and reduced face-to-face SMS provision:
  "*Part of it is you're not fully there, face to face…housing has been a big part for a lot of clients…mental health has really gone down, struggling with mental health…[misusing to] manage mental health…being isolated as much as many of them are isolated in their day to day lives" #016*

  Staff described challenges in working with mental health and primary care services when trying to address additional healthcare needs. Long waiting lists or refusal to provide support if the person had

co-existing substance use (including OTC/POM misuse) was cited. Only one participant (#019) described positive working relationships with mental health services:
"Here the mental health team have been brilliant and they are supportive with the client. They got her this month with a psychiatrist so the support from that side is amazing" #019

Some participants expressed concern that consequent 'self-medication' may increase the risk of individuals becoming dependent where they had a likely susceptibility for this:
"Made it easier to get through the day so it seemed to be a benefit but that feeling is very dangerous in susceptible people…leads to the addiction cycle and escalation" #001

Due to concerns about the increased (and unmet) health needs that people who misuse OTC/POM presented with, one participant (#001), described feeling overwhelmed and thought that SMS was becoming saturated with clinical cases involving iatrogenic dependence or complexity that other services viewed as too difficult to manage:
"Complex people with multiple medical conditions and complex psychiatric conditions and substance misuse issues…the most high risk people are given the most high risk drugs in the most high risk way….It just seems to be getting relentlessly worse…There is a huge reservoir of people who are practically impossible to treat…'heart-sink' patients with multiple ailments, polypharmacy…makes me feel personally rather daunted by that task…[SMS] become a dumping ground for prescribing blunders" #001

- **Withdrawal Symptoms**

  Participants made multiple references to their concerns about withdrawal symptoms, due to their negative experiences of supporting people who misused OTC/POM that were struggling with symptoms. Sometimes withdrawal symptoms were directly because of OTC/POM misuse, or otherwise OTC/POM were being taken to alleviate withdrawal symptoms associated with missed doses of OST, or where illicit substances could not be sourced:
  "One thing that is quite common is you know 'one day I didn't have my methadone' or 'I couldn't get any heroin' but got gabapentin. Or they've come off their [OST] prescription…it's used to try and manage the withdrawal if people are off their prescription" #015

  Furthermore, when the person then underwent a reduction/detoxification, as with other substances, participants described concerns that this may become problematic as they may start to experience the underlying mental health condition or psychological trauma again. Therefore, there was a suggestion of the need for increased vigilance around the use of medication such as hypnotics when they were used for symptomatic relief during detoxification:
  "When it comes to detox time, we've got to be really, really careful of what we prescribe because I feel that a lot of medication clients enjoy benzos and zopiclone…we should be really wary of that…When you're withdrawing, you will take anything that's offered to you just to get away from the mental health and the physical withdrawal" #016

- **Side-effects**

  There were concerns about numerous possible side-effects, including addictive behaviours, dependence, accidental overdoses, and deaths. Participants were particularly concerned about the physical side-effects relating to combination codeine products, primarily due to the overdose risk associated with paracetamol and the gastrointestinal effects of ibuprofen:

  "Appallingly underweight, with appalling internal bleeding, bulimia, kidney damage, relentlessly pounding themselves to death with Nurofen Plus®…ingesting far larger [paracetamol] amounts than the liver is supposed to be able to handle…we have had some deaths…you wipe your liver out" #001

  Participants had increasing concerns when supplies were illicitly sourced, due to their unknown content and consequent unknown side-effect profiles. Staff described how their concerns became heightened when people were taking relatively high amounts of OTC/POM, or misusing them alongside illicit substances or OST, and especially when they were lacking in awareness of the risks they were taking. To mitigate this, participants encouraged additional health checks such as liver function tests, and provided harm reduction advice:

  "We would definitely encourage service users to go and get kind of LFTs done. Paracetamol toxicity tests done and things like that" #020

  To reduce the risk of adverse effects, participants wanted to offer more effective interventions and harm reduction advice. To be able to do this, the need for more research, protected training time, user-friendly 'at a glance' resources and further training was identified, for example relating to cold water extraction, OTC/POM misuse in pregnancy, reduction regimes, drug interactions and knowledge about 'newer' OTC/POM, so they were able to deliver the latest evidence-based care:

  "More research needs to go into the gabapentinoids…reductions and harm reduction and interventions that we can give…more evidence base for Recovery Workers to be providing those interventions" #020

  Some felt that increasing access to take home naloxone supplies was important for people who used OTC/POM opioids, or other OTC/POM in combination with other opioid substances to reduce the risk of accidental overdoses. To further reduce this risk, views were expressed that there should be more restrictions on OTC sales and reflected that formulations aimed to reduce diversion were associated with more harm, due to the difficulty of being able to extract the desired medication from combination codeine products. One participant (#001), outlined that medication should still be available for where there is genuine clinical need, but in a more controlled manner and with increased vigilance:

  "It used to be in a form that you could split very easily into a pink ibuprofen half and white codeine part and so abuse was safer…restrict the amount of codeine to doses that don't cause a high very easily and limit the amount that can be sold…pharmacy guidance and pharmacy watching closely...enables people with minor conditions to self-medicate and relieve the struggling primary care and A&E Services. If all these medicines were totally and utterly restricted…it would put even more of a drain on primary care. The trick is to be responding and picking up the signs when they are abused but also restricting the availability of the most likely doses to be abused" #001

- **Problematic Behaviours**

  Participants described negative experiences where people who misused OTC/POM presented with problematic behaviours that created concerns, and especially for prescribers and the wider multidisciplinary team. Concerns included repeated presentations, dishonest behaviours, using others to make purchases on their behalf, and spending notable time and money in travelling to different pharmacies:

  "The addictive behaviour starts to come out. Because if they are on a prescription, they are having to justify getting larger amounts than the prescriber is supposed to be giving so the scams about losing scripts, dropping medication down the toilet, needing the medications early because of going on a trip, all of those sort of subterfuges towards the prescribing organisations….Having to access 10 pharmacies a day to get the supplies they need and travelling really quite long distances" #001

  Some participants had concerns about how honest people were being about their OTC/POM misuse if it was perceived as negatively impacting on their SMS prescribed intervention or if it raised concerns about their ability to parent. There was also a sense that stigma and shame contributed to the lack of honesty and openness, and some highlighted the consequent need for SMS to constructively challenge people on their behaviour, and the importance of therapeutic rapport:

  "I will challenge…they can relate to what I'm saying…they become more open to telling the truth" #016

- **Treatment Pathways**

  Concerns were raised about the lack of clear treatment pathways which affected the experiences of people who misused OTC/POM, and the added challenge of how SMS are commissioned:

  "Either there isn't a clear pathway or they are not aware of a clear pathway…Having a consistent approach…[commissioning] consistency would help" #002

  Participants advocated for allocating the same staff members to the person for the duration of their recovery journey. This was especially important in the case of young people's services, where a robust transfer to adult services that incorporated consistency in consultation allocation, was viewed as critical for engagement:

  "They're getting lost in the caseload so they're coming in using codeine and you've got a caseload of 70 odd and you've got a majority of heroin users, it's so easy…to miss…I might keep my medication clients to one prescriber only so they're getting the same consistent support and they're not getting lost" #016

  Pathways that incorporated structured treatment plans, with regular and increased frequency of contact, using a consultation format that suited the persons care needs, was perceived as important when people presented with OTC/POM misuse. This was especially due to more virtual and altered frequency of consultations during pandemic restrictions, and some staff described having more positive ways of working due to COVID-19:

  "Since lockdown…I've been doing weekly telephone calls…prior to lockdown they would have had an appointment to come and see me face-to-face every 4 weeks so it's increased dramatically…there's

been so many changes that we've implemented, such as Zoom groups…it's been extremely beneficial. There are things that we are going to continue with into the future now" #018

Participants described negative experiences where SMS multidisciplinary team working was not cohesive enough to provide a joined-up approach or the required clarity in treatment pathways, and identified the potential need for training to improve this:
"The knee-jerk reaction is to put them straight forward to the clinical and that then I think gives the assumption that they are going to be prescribed...So we have identified training needs there" #006

The need for improved communication and partnership working across all settings was identified as key to improving treatment pathways. There was recognition of the compounding negative impact of COVID-19, improvements required to prescribing controls and practices, and the need for further training and raising awareness amongst all health and social care professionals:
"GP didn't seem to have any awareness that there might have been an issue with the co-prescribing of pregabalin…I followed it up with a letter and gave some recommendations and guidance on a tapering regime of gabapentinoids…Communication with GPs via letters and phone calls and the prescribing of these drugs has gone down…GPs aren't available…with COVID we don't seem to be getting [referrals] much at the moment…GPs are working remotely…" #007
"The difficulty is communication with other services. So having better relationships with GP surgeries, mental health services, pain management, those sorts of services, might aid a better experience and make me a little bit more confident in what I can offer" #011

6.4. Discussion

6.4.1. Key findings

Opioids (especially codeine products), benzodiazepines and gabapentinoids being reported as being misused most often, as well as the predominant oral administration and patterns of dependent and high levels of misuse, corroborate earlier findings ***(see Chapter 4 – Study 1 Questionnaires and Chapter 5 - Study 2: Service User Interviews)***, and is in keeping with national data sets and other studies (Marsden, *et al.,* 2019; OHID, 2023; PHE, 2020b).

Whilst the finding that a variety of sources were used to obtain supplies is well-documented by others (Cooper, 2011), as staff reported OTC/POM being identified and consequently monitored via drug testing, this emphasises the added value of such tests. This further supports their use as a harm reduction intervention, and their value in helping to raise awareness of potential harms when products are being illicitly sourced and have unknown contents (CCENDU, 2021).

Patterns of dependent and high levels of misuse, with frequency varying in response to psychological stressors, supports the views of Bagusat, *et al.,* (2018), who described the need for tailored resilience

interventions to avoid the misuse of medicines. This was further supported by the views expressed by participants that interventions require tailoring to individuals. Where polypharmacy occurred, for example for synergistic effects, this has also been previously found ***(see Chapter 4 – Study 1 Questionnaires and Chapter 5 - Study 2: Service User Interviews)***, and similarly reported by others as having negative effects (Jones, *et al.,* 2012). These findings also emphasise the importance of prioritising harm reduction interventions and the need to maximise take home naloxone provision (Burton, *et al.,* 2021; DHSC, 2019; Mercer, *et al.,* 2023; Schofield, *et al.,* 2021). Participant concerns about side-effects further supports this, especially in older age, where high doses or polypharmacy featured and the risk of overdose is greater (Chhatre, *et al.,* 2017; Gossop and Moos, 2008; Omenka and Greene, 2017; Satre, 2015), and in the case of codeine combination products, where paracetamol toxicity and gastrointestinal damage were more likely (Greene, *et al,* 2005).

These findings tentatively indicated that females who were employed, presented with iatrogenic dependence, and were misusing OTC medication, may require more intensive and specialised PSI, and especially when they were undergoing detoxification. In keeping with national guidance, the findings highlight that PSI remain the mainstay of effective treatment (DHSC, 2017; NICE, 2022), and the use of group interventions were particularly valued. The suggestion that there are two distinct groups of individuals, where other substances are either used or not, and with associated *"unique co-morbidities and psychosocial profiles"*, has been identified by Tkacz, *et al.,* (2012). Fingleton, *et al.,* (2019) have similarly highlighted that people who misuse OTC/POM may be perceived as different to people who use other substances, and more complex to treat due to comorbidities.

The need to increase awareness of OTC/POM misuse, including amongst the public and healthcare professionals has also been suggested by Coombes and Cooper (2019). Similarly, reports of iatrogenic dependence and self-medication with OTC/POM for underlying physical and mental health needs is also well-established (Chiappini, *et al.,* 2020; Fischer, *et al.,* 2006; Lipari, *et al.,* 2017), though highlights the importance of people being able to access holistic support (for example including housing and mental health services), and in a prompt manner.

The findings indicated that withdrawal symptoms perpetuated OTC/POM misuse, and predisposed individuals to sourcing illicit substances, unregulated supplies or larger amounts of combination codeine products associated with greater risks and perhaps with a gateway effect (Inciardi, *et al.,* 2009; Lankenau, *et al.,* 2012). Similarly, as people reportedly misused OTC/POM when unable to source their usual substance of choice (Lessenger and Feinberg, 2008), or to manage self-detoxification from them, this highlights the need for appropriate withdrawal symptom management, and echoes the findings of ***Chapter 5 - Study 2: Service User Interviews***. Additionally, increased vigilance is required at the point of discontinuing medication, which should be undertaken in a gradual way and with a shared decision-making approach (NICE, 2022). The findings also suggest that this is of particular importance when medication which is liable to misuse is being provided as symptomatic relief for withdrawal symptoms, and during detoxification where people may particularly struggle with their mental health.

6.4.2. Strengths and Weaknesses

Coombes and Cooper (2019) indicated that due to recruitment issues, their work, which they believed to be the first study to explore the views of English SMS staff about OTC/POM misuse, likely under-represented the view of staff working in the third sector, or their experiences of supporting people who concomitantly used other substances. Since this study only included SMS staff working for a third sector provider, where people were also using other substances, this was somewhat unique, and the findings will therefore add to the evidence base.

The interviews allowed twenty individuals to describe a wide range of experiences, from five of the potential seven SMS, despite the pressures of working during the COVID-19 pandemic. The inclusion of a broad range of staff roles who had different levels of experience, including in various SMS settings, indicates that a variety of views were likely sought. Data saturation was thought to have been achieved, and the number of participants was similar to the publications identified in the systematic review for Coombes and Cooper (2019) (n=15), Cooper (2013a) (n=25), and Ruben and Morrison (1992) (n=23) ***(see Chapter 2 – Systematic Review)***. As the qualitative data was relevant and suitably detailed, the methodology was thought to have been appropriate (Brod, *et al.,* 2009; Guest, *et al.,* 2006; Green and Thorogood, 2014). However, as staff were all employed by the same SMS provider, future research perhaps conducted by a researcher who is not a senior colleague, in SMS operated by other providers, and covering a wider geography, may enable more information to be shared, more participants to be recruited, and the results more generalisable.

Using digital audio recordings and field notes, a rich dataset was achieved and all the transcripts, and in their totality, were incorporated into the analysis. Whilst no differences were identified when transcripts were independently reviewed, as a future development, repeat interviews and member-checking may be considered to improve assurance in the findings. No participants were accompanied and the detailed responses and openness in their responses (including those who chose to disclose being in recovery), indicated that the Researcher built a good level of rapport, perhaps because of their own long-standing experience of working in SMS. This also suggests that the anonymisation, piloting of associated documents and use of an interview guide was effective ***(see Chapter 3 - Research Strategy and Design)***, as has been found in other studies (Gittins, *et al.,* 2018a; Van Amsterdam, 2015; Van Hout and Bingham, 2012; Van Hout and Brennan, 2011). As the same Researcher conducted all of the interviews, this limited variability in the way that interviews were conducted; however, it is important to note that interviews were delivered via three different methods (face-to-face, telephone and Microsoft® Teams®). Furthermore, the independent review of the themes by the Research Supervisor made the analysis process more robust (Sandelowski, 1993), and proved invaluable to ensure that the Researchers focus remained on how staff experiences related to those who were accessing SMS, rather than broader service delivery issues.

6.4.3. Implications for Employers, Clinicians, Policymakers and Researchers

Ensuring staff have access to continuing professional development opportunities is in keeping with current national drivers and government strategy to improve upon recruitment and retention (DHSC, 2022a; NHS, 2019; RCPsych, 2020). Retaining staff longer-term should optimise continuity of care and SMS engagement,

by enabling the same person to provide support to the same individuals for the duration of their recovery journey, and especially during transition from young people to adult SMS. Improvements in SMS education and training provision should also further develop internal collaborative working and staff confidence (McKeown, *et al.,* 2003; Sheridan and Barber, 1997). Enabling peer support and structured practice/clinical supervision to further develop staff knowledge and skills, should further optimise retention (Murphy, 2022; RCPsych, 2020), maintain and develop their confidence and competence, regarding OTC/POM misuse, and especially when people are new to working in the sector. There should be ongoing consideration of how this can be achieved, including protected time and different methods, such as access to quick reference resources, supportive peers, podcasts, virtual and workplace-based approaches. The findings indicate that future learning opportunities should incorporate the latest OTC/POM misuse trends, treatment options for special groups, cold water extraction and medication-specific interactions and side-effect profiles.

As staff disclosed that they were in recovery, this should further support a co-production approach to SMS developments (O'Connor, 2015; PHE, 2014; Welsh Government, 2014); however, there should be further consideration as to how their experiences can better influence service improvements, whilst being sensitive to their want for confidentiality, which may be particularly pertinent to those in senior clinical leadership roles (Akvardar*, et al.,* 2002). Whilst there is a significant strength to employing people with lived experience, it will be important to consider how best to mitigate any associated personal biases. Future research which formally captures if the staff participant has lived experience of OTC/POM misuse or other problematic substance use, as well as additional demographic characteristics such as their age and ethnicity, may allow for comparisons in how their views and experiences may vary too.

The dichotomous staff views about the need for separate SMS for people who do not use other substances requires further consideration. Whilst Coombes and Cooper (2019) indicated the need for the commissioning of new and specific services for OTC/POM misuse, the findings from this research do not wholly concur. Perhaps ultimately, the decision to offer separate SMS or more bespoke PSI should avoid further stigmatisation (Claffey, *et al.,* 2017; Goodyear and Chavanne, 2021), be determined by the needs of the individual, and would require appropriate resourcing, though may be advantageous when there is refusal to access usual SMS (Kmietowicz, 2016; NHSE, 2023), or for special groups such as young people. Similarly, the use of pharmacological interventions (especially for the illicit use of non-opioid OTC/POM), may require a more cautious approach and further exploration. Whilst buprenorphine may be favoured by staff for OTC/POM opioids (Van Hout, *et al.,* 2015), lower doses, for shorter durations and more restrictive dispensing arrangements may be necessary, and a more consistent approach may be required. This indicates that future research should explore if the treatment needs of individuals vary by their characteristics and/or the medication being misused.

As OTC/POM misuse was described as insipid for some people, healthcare professionals from all sectors, should routinely review the ongoing suitability of medication supplies, including OST and medication provided for symptomatic relief: they should be vigilant for behaviours that are indicative of likely OTC/POM misuse and promptly signpost to SMS where needed (Chiappini, *et al.,* 2020; Cooper, 2013b; Feldman and Everton,

2020; RCGP, 2014a; Wazaify, *et al.,* 2006). As suggested by other researchers (Coombes and Cooper, 2019; Fingleton, *et al.,* 2019), more specific national clinical guidelines and appropriately resourced care pathways are required. These should ensure the consistent provision of evidence-based interventions for the latest OTC/POM misuse trends. As participants outlined that some SMS did not use drug tests in a consistent manner and struggled to access them in a timely way, policymakers should also provide clarity regarding the use of drug tests, as well as the frequency of reviews and consultation styles (Wen, *et al.,* 2019). Additionally, the utilisation of physical health checks should be better defined, such as liver function tests and paracetamol levels when co-codamol is being misused, and this need has been similarly outlined by the findings from ***Chapter 5 - Study 2: Service User Interviews***.

This research also highlights the ongoing need for improved joint stakeholder working across all sectors, with a particular focus on improving awareness of OTC/POM misuse, associated training, medicines supply controls and communications with GPs, community pharmacies, psychiatry and hospitals (DHSC, 2017; RCGP, 2014a). To reduce the risk of misuse, changes to the formulation, legal status, and ease of availability of OTC/POM may be required, and should be considered by manufacturers and policymakers, whilst simultaneously ensuring that medication remains accessible for genuine clinical requirements. Given likely ongoing changes to OTC/POM availability (Pearce, 2020; Robinson, 2023), future research should identify if there are changes in experiences over time.

To encourage disclosures about OTC/POM misuse, and to aid identification of diversion and potential safeguarding concerns, the findings suggested that unnecessarily restrictive practices, (especially to the use of prescribed interventions), should be avoided (Inciardi, *et al.,* 2009). Furthermore, since participants highlighted the role of friends/family in sourcing supplies and facilitating access to SMS interventions, this requires further investigation and triangulation with the findings (Noble and Smith, 2015) from ***Chapter 5 - Study 2: Service User Interviews*** ***(see Chapter 7 - Study 4: Friend/Family Interviews)***.

6.5. Conclusion

This study had a unique focus on the experiences of third sector front-line SMS staff in England, who have supported people who have misused OTC/POM. Semi-structured interviews suggested that increased awareness of OTC/POM misuse is required amongst healthcare professionals and the general public. Training for SMS staff is important to ensure the delivery of the latest evidence based, treatment interventions, and SMS should sensitively consider how to incorporate the views of staff with lived experience into service delivery.

When SMS staff supported people who misused OTC/POM opioids (especially codeine products), benzodiazepines and gabapentinoids, they were usually taken orally and in a dependent way and polypharmacy and the use of other substances sometimes occurred. The need for different interventions and separate services for those who only misuse OTC/POM are unlikely required unless there are known issues with SMS engagement; however, this requires further exploration. There is a need for increased vigilance for

misuse and associated safeguarding issues when healthcare professionals are making decisions about safe supplies of medication, and when there are unmanaged health conditions, side-effects, problematic behaviours, or withdrawal symptoms.

Updated national guidance and well-resourced care pathways are likely required, which cover all OTC/POM types, to facilitate improvements in communication between care interfaces, greater clarity regarding tailoring holistic interventions, the use of drug tests, PSI, physical health checks, harm reduction, and prescribed interventions. Future research should include other SMS, capture staff characteristics such as age, lived experience and ethnicity, and identify if there are changes in experiences over time. If the treatment needs of individuals vary by their characteristics and/or the medication being misused, and the role of their friends/family, requires further investigation.

7. Study 4: Friend/Family Interviews

This chapter presents findings from the confidential semi-structured interviews that were conducted with friends/family of people who have misused OTC/POM. The purpose was to explore the experiences of friends/family whose loved ones were accessing community English SMS for OTC/POM misuse. To avoid unnecessary duplication, further details of the methods (including rationale for the selected methodological approach) are provided in a previous chapter ***(see Chapter 3 - Research Strategy and Design)***.

The interview design was informed by findings from the systematic review, the service user and SMS staff interviews, and consideration of approaches undertaken by other researchers who have explored OTC/POM misuse in the broader literature ***(see Chapter 1 - Introduction, Chapter 2 – Systematic Review, Chapter 3 - Research Strategy and Design, Chapter 5 - Study 2: Service User Interviews and Chapter 6 - Study 3: Staff Interviews)***. The findings from this study have been shared at international conferences ***(see Appendix 1: Summary of Publications/Contributions)*** and they have been published in an international journal*:*

Gittins R, Vaziri R, Maidment I. 2023. 'It's a horrible situation for everyone': The impact of over the counter and prescription medication misuse on friends and family. Drug Sci Policy Law. 9. doi: 10.1177/20503245231215407

7.1. Aim and Objectives

To use confidential semi-structured interviews, to explore the experiences of adults, who have supported friends/family that have misused OTC/POM and were accessing community English SMS.

7.2. Method

Participants were excluded if their additional needs could not be met (for example if they required an interpreter because they were a non-English speaker and the service was unable to facilitate), or if they were previously known to the Researcher. Individuals were considered eligible if they were at least 18 years of age and were able to provide informed consent. They were required to have experience of supporting a loved one who had misused OTC/POM and were currently accessing a community Humankind SMS.

The rationale for the chosen methodology and more details about the methods used (including data sampling, collection, management and analysis, PPI, ethical considerations, and risk management), are outlined in ***Chapter 3 - Research Strategy and Design.*** All qualitative responses from the interviews ***(see Appendix 9 – Friends/Family Semi-structured Interview Guide)*** were included in the analysis out of responsibility to the participants for their contributions.

Potential participants were identified by SMS staff, after receiving guidance on how to facilitate this by the Researcher, and were invited to participate using exemplar invitation wording which had ethical approval

(see Appendix 10 – Invitation Wording Guide); they were also identified via a snowball sampling approach, whereby the service users who participated in ***Chapter 5 - Study 2: Service User Interviews,*** were asked by the Researcher if they had a friend/family member who may be interested in participating. If friends/family were interested in participating, then a paper copy of the PIS ***(see Appendix 6 – Friends/Family Participant Information Sheet)***, or the online link to an electronic version was provided. If they wished to proceed or wanted more information, they verbally consented to their name, contact details and desired time to be contacted, to be relayed to the Researcher via SMS staff or their friend/family member.

7.3. Results

7.3.1. Summary of Interviews

Data collection occurred during the COVID-19 pandemic, between February 2021 and March 2022. All eight interviews were conducted via telephone, whilst the participant was in their own place of residence, with a mean of 16 min 49 secs (range 7 min 50 secs to 37 min 39 secs). No participants had additional needs which required support during the interviews, and for the complete duration of the interviews, all fully participated without other individuals knowingly present. The majority were female (62.5%), and the SMS that their friend/family was accessing, and the relationship type is summarised in ***Table 11***: #001 and #002 were the (divorced) parents of the same individual.

Table 11: *Friends/family relationship to their affected friend/family member misusing OTC/POM, and the SMS they were accessing*

Participant ID	Relationship		SMS
	Participant	Individual misusing OTC/POM	
#001	father	daughter	CRS
#002	mother	daughter	CRS
#003	son	mother	FL
#004	(female) friend	(female) friend	CRS
#005	son	mother	REACH
#006	mother	son	NYH
#007	mother	son	BRS
#008	wife	husband	BRS

Organising time for the interviews was generally more straightforward than for service staff or service users, especially during lockdown restrictions when they were less likely to be engaged in additional activities. However, conversely because of COVID-19 restrictions, this was also a more difficult group to recruit participants for, because the volume and frequency of support sessions for friends and family became more challenging so there were fewer opportunities for SMS staff to recruit potential participants. Repeat interviews with the same individuals were not possible due to time constraints and logistical challenges.

7.3.2. Characteristics of OTC/POM Misuse

Participants reported that their loved ones were misusing opioids (tramadol, oxycodone, and codeine products), pregabalin and benzodiazepines (diazepam and nitrazepam): tramadol and codeine products predominated. Where known, pattern of misuse was thought to be variable, sometimes reliant on what the individual was able to obtain, but generally described as daily and dependent, and often at concerning levels of misuse.

A variety of legal and illegal sources, often in combination when struggling to get hold of supplies, were reportedly used. Iatrogenic dependency, physical/mental health issues and underlying traumatic experiences, including adverse childhood experiences and familial substance use was described. In all cases, misuse had reportedly occurred for several years, and the OTC/POM product was always thought to have been swallowed. Polypharmacy was known to occur in most cases, though generally infrequent and minimal.

7.3.3. Thematic Analysis Findings

Thematic analysis (Green and Thorogood, 2014; Silverman, 2021; Urquhart, 2013) enabled exploration of the data; when transcripts were independently reviewed, no differences were identified. Five overarching themes emerged, relating to the negative impact of OTC/POM misuse on relationships, finances, personal wellbeing, side-effects/withdrawal symptoms and the role of healthcare interventions:

7.3.3.1. Impact on Relationships

Often it was due to the discovery of or problems in sourcing supplies, that led to friends/family identifying that problematic misuse was occurring. After the true level of misuse was revealed, the extent of 'hidden' behaviours and sometimes dishonesty, (including personal theft of their own supplies of medication) became more evident: participants reported that they were previously naive to these, and they were shocked by their discovery. This created negative impact on their relationships, caused challenging dynamics and led to arguments:

"That's when I found out…and that's when it got heated" #003

"I really really noticed when we went on holiday…I said 'you really need to get this sorted now because it's ruining our lives'...We were arguing…It were just a nightmare, an absolute nightmare" #008

Relationships (especially family dynamics and the impact on others) were strained, often due to a lack of trust or irritation, usually associated with dishonest behaviours:

"I don't know whether she did get migraines really…I would get cross…she'd stolen [POM] from me…She'd come up with all these weird and wonderful stories…the behaviour becomes deceitful…[husband] got really irritated with her…and then it got to the point where if she didn't move out, he was going to move out" #002

Trust issues were particularly pronounced where children were affected:

"[Son] still got trust issues…He's put an app on his phone where he can see where his dad is at all times…to make sure he's coming back…" #008

The negative impact on relationships was also described as going beyond immediate family/close friendships:
"When he was going through his bad times, his friends sort of backed off. They didn't want to know…" #008

For many, challenging family dynamics, communication and trust issues continued, indicating the long-lasting changes in their relationships because of the OTC/POM misuse:
"We fall out regularly but that's the nature of it" #001
"An addiction's an addiction and he doesn't care what he's saying to me and he doesn't care how he's going to get these tablets, as long as he get them and all I want is my son back…" #006

The impact on relationships varied, for example, in one case (#005), the participant had contrasting views regarding how OTC/POM misuse affected parenting; however, even as a young person they were also engaged with sourcing parental OTC/POM supplies:
"When I was like 15…It was like go and get it for her…When I was in school…she was a normal mother. You wouldn't have known. No one knew, no one and she would always do the gardening, take me out – for days out like she was a normal mother. It never affected her bringing me up whatsoever" #005

Positive relationships where there was greater honesty, trust, openness, and empathy, reduced the negative impact of OTC/POM misuse, by enabling more support provision and greater advocacy by friends/family, which was driven by a desire to help:
"She's been fairly open with me and her dad…I used to say to her 'please just be honest with me' and I think I was the first one that she told…she knew that I wouldn't be mad…I would want to help…I am sort of the one that [daughter] thinks has got her back. Which I have…I will never, never, never, ever not be there for her…I contact her every day. I speak to her, I try to see her as much as I can, even if it's just for a walk" #002
"When I ask him a question he doesn't lie. He tells me and then he was telling me how much he'd actually taken…then other things came out…I do try and get him the help…I don't judge…help the best I can…involved anybody I could" #006

This was particularly notable where the participant had their own lived experience, or otherwise an understanding of underlying trauma/mental health issues:
"I know that the lengths that you will go to, to get your fix and how you get deeper into an addiction. How it rules your life more and more…" #002

Indeed, the more educated about OTC/POM misuse that participants were, the more they felt able to empathise and advocate for their friend/family. Participants without this knowledge or where they held negative personal opinions about the use of medication more generally, indicated that they held stigmatising views and a lack of empathy:
"I don't know what the long-term side-effects of tramadol are…I don't know whether [support for self is] available…I had a [negative] perception at first and probably still have some prejudice now" #001

7.3.3.2. Impact on Finances

Participants rarely knew exactly what their friends/family were spending on OTC/POM misuse, though many acknowledged that notable amounts of money were required to afford the OTC/POM, or that financial support was needed due to the consequences of misuse, such as the inability to work. Friends/family often personally felt the financial impact by providing the required financial support, for example, to enable access to private healthcare:

"She's got a very, very part time job so she's totally dependent financially on us…I'm supporting her 100% financially…pay [for her to] speak to a therapist once a week" #001

"I'm pretty sure most [money] had gone on, you know, internet codeine…fortunately, her dad can pick up the tab [for talking therapy] …maybe I do end up supporting her financially…if she's run out of money" #002

For their friend/family to be able to afford OTC/POM misuse, participants also experienced personal theft of their own money or medication supplies:

"He would take the last £30/40 out of my bag just to stock up for a week" #008

To reduce the risk of personal theft, or to alleviate their anxieties about their friends/family finances, participants sought increased security arrangements or forcibly took control of their finances:

"The lengths that she went to were quite extraordinary to get my tramadol…In the end, I got a safe" #002

"I took the cash card off him. I weren't giving him any money so he couldn't do owt like that" #006

7.3.3.3. Impact on Wellbeing

OTC/POM misuse was described as having negative consequences, not just for the person but for their friends/family too:

"It's a horrible situation for everyone…It's not just the person…whose life is ruined, it's the family around them as well" #008

Participants expressed a sense of helpless acceptance of their situation, with ongoing notable impact on their work-life and psychological wellbeing:

"Sort of tipped me – as a father – over the edge…85% of [worries] are [daughter] all the time. It's just the way it is" #001

"I have the occasional meltdown at work when I get really upset about her…Two periods off work with stress and [daughter] has been part of that stress" #002

There was notable variation in participants receiving personal wellbeing support. Some participants described a lack of support and awareness and struggled trying to manage in isolation, especially due to the psychological impact:

"There's times when I've been at my wit's end…they forget about parents that are struggling…depressed with it and just want to sit and cry…I've had no support whatsoever and I don't tell anybody. I deal with it on my own…There's not a lot of people that knows about what's going on" #006

However, others viewed themselves as self-sufficient, without the need for personal interventions, had a lack of expectation of support being provided, or articulated that if assistance had been required, they already knew where to access it:
"I've not been provided with support, and I suppose I didn't expect it…I haven't felt I've needed it really" #001
"I was fine…I'd have probably spoken to [friends] support worker…I'd have just got advice from there" #004

When participants did receive wellbeing support, it was often sought via their existing personal support network or related to holistic concerns such as involvement from social services or support with housing. In some cases, notable personal psychological interventions were needed, and participants described obtaining these of their own volition, typically requiring them for long durations to reduce the significant impact on their mental health and the wellbeing of affected children too:
"Nobody [NHS/SMS] provides me with any support…my work family if you like, are really lovely…I am [accessing via private healthcare] a counsellor" #002
"It were more me and the kids that needed a bit of support…We got there. We're getting there…Social services wanted to close the case now, but I said I'm not ready" #008

When there were reports of SMS engagement by the participant and their friend/family member, wellbeing support was well received and led to positive changes in wellbeing and parenting:
"Since he's been on this [SMS medication] reduction…he's interacting with me. He's a much better person. He's happy you know, he's chatty, he's sleeping well" #006
"[SMS] are absolutely outstanding. They're brilliant, totally brilliant…If I've got any concerns, just to give them a ring…I'd recommend anybody going to [SMS] or owt like that…The bond between them [father and son] is absolutely fantastic now [since SMS engagement]" #008

The positive impact of connecting with people who had similar experiences and the importance of improving motivation and maintaining hope and optimism was described:
"Another mum said to me…it can happen, and you can get your boy back. Hopefully in the future, I can be one of these mums that says to another mum…You know, is there light at the end of the tunnel.…it can be done…" #006

To mitigate their concerns about the impact of OTC/POM misuse on their affected friend/family members' wellbeing and ability to effectively parent, participants ensured appropriate support was in place through other routes too, such as social services, schools, and widening their personal support network (including involving others in childcare arrangements):
"When people found out how bad it were, a lot of people stepped in…taking her children to school, looking after her children" #004
"[Son] seeing a psychologist once a week at school…I had the social services involved. So they've always been a good support…we have meetings once or twice a month with them and school" #008

7.3.3.4. Side-effects/Withdrawal Symptoms

Participants stated that negative moods due to withdrawal symptoms added to relationship dynamics, and sometimes alternative sources (including illicit substances), were sought to alleviate them. This escalated participant concerns and created more negativity due to associated behaviour, such as absence from the family home:

"He wasn't a happy person because obviously he were withdrawing…he were horrible, so it was making a really big impact on us…he wouldn't stop at home… And if [friends] haven't got [access to tramadol via prescriptions], then that's when he were turning to other substances…[crack and cocaine]…He'd disappear for days…that made a big impact on me and my son because obviously we didn't know what he were doing. We didn't know if he was ok…" #008

Participants also reported concerns about side-effects which added to their worries, especially relating to escalating use with loss of control and worsening mental health issues:

"Before we knew it, it were totally out of control…He got into a more and more depressive state as the day went on…he was feeling suicidal" #006

The physiological effects of combination codeine products were a particular worry for participants, due to the risk of paracetamol overdose, gastrointestinal damage, and tolerance to opioid analgesics:

"She would be overdosing on paracetamol and ibuprofen in order to get the more amount of codeine…I worry, not just about the addiction but the fact that she's damaged her body…can no longer have any kind of opioid pain relief" #002

Therefore, having reassurance of regular monitoring and reviews such as liver function tests helped alleviate participants' anxiety about side-effects:

"She was taking serious amounts [tramadol and co-codamol] enough for me to think, oh my God, what about her liver…I remember being quite relieved when she said she'd had a check and her liver was ok" #001

Some consequently described a need to improve their own knowledge, so that they may have been able to support in minimising side-effect risk, and provide better advocacy:

"We just thought it was a painkiller…I didn't realise how addictive it was…if I'd have realised how addictive they were in the first place, I would have said, you know 'give him something else'…" #006

7.3.3.5. Healthcare Interventions

Overwhelmingly, participants expressed concerns about healthcare professional awareness of how to manage the risks and consequent emergence of OTC/POM misuse (especially relating to primary care prescribing practices and lack of prescribing controls), and the long-term impact this had on engagement with healthcare professionals:

"They just stopped his prescription…He was feeling really, really poorly…The doctors were absolutely useless with him and it's still hard to this day. If he's really poorly, he never goes to the doctors because he lost all faith in them" #008

Reported deficient clinical practice had an impact: it caused friends/family to experience anger and frustration, and they had concerns that more should have been done and earlier, and especially during COVID-19 where access to POM was felt to have become easier:
"My concern is the ease with…how [daughter] was able to do this tactic of getting prescriptions early and starting to build stocks…giving out prescriptions like sweeties…Through COVID…the ability for you to get your normal prescription drugs that you need easily has increased dramatically" #001

Additionally, when specialist services were found to be lacking (predominantly related to responsiveness and tailoring the type and frequency of contact), participants described the increased impact this had on them, especially when they had personal anxieties about mental health needs not being met:
"Services for all psychiatry and psychological issues are all so stretched…I found her curled up on the bed sobbing, with a knife…waited for months and months and months for anybody to contact her…[SMS] doesn't get back to her for a few days or even a week…when you are struggling with anxiety and you're trying to get in touch with somebody and then you can't, that makes it even worse…heightens your anxiety even more" #002

Participants described helpful responses from healthcare professionals, such as having appropriate boundaries, supporting gradual reductions and being empathetic:
"I'd rung [GP] and I told him what were going on…he's trying to do a reduction with [SMS]…the GP has put his foot down and said 'right, this is it now. You're not getting any more tramadol. This is what we're going to do'…" #006

To improve this further, the need for monitoring access to medication supplies was highlighted:
"[POM] needs to be monitored because it's absolutely disgusting…[GPs] need to monitor things a lot more closely" #008

Whilst participants were positive about PSI and prescribed interventions such as OST, they had anxieties about how discontinuation of treatment would occur, and indicated the need for robust relapse prevention planning:
"Worried about when she's off [SMS medication] and what happens at that point…the potential for her to go straight back on prescription medication is a huge risk. Huge…" #001

Participants also expressed less worry when they felt that there was more time for interventions to be delivered (especially during COVID-19), and outlined their role in supporting the delivery of these interventions too:
"He doesn't have to go out and do [exercise]. We can do in room and put it on the television" #006
"With COVID it took a lot longer for him to come off his medication, so he's had a lot longer on it, which has done him a world of good" #008

7.4. Discussion

7.4.1. Key Findings

The interviews allowed eight individuals to describe a wide range of experiences: oral opioids (especially codeine products), benzodiazepines and pregabalin were reported by participants as being misused most often by their loved one. Co-existing health issues, traumatic life events, variable patterns of misuse (including long-term, iatrogenic, daily, dependent and high levels), impacted by access to the OTC/POM procured from a variety of sources, corroborate earlier findings ***(see Chapter 4 – Study 1 Questionnaires, Chapter 5 - Study 2: Service User Interviews and Chapter 6 - Study 3: Staff Interviews)***. This is also in keeping with national data sets and other researchers (Marsden, *et al.,* 2019; OHID, 2023; PHE, 2020b); however, in this study the reports of polypharmacy were not thought to be as notable.

Overwhelmingly, the consequences of OTC/POM misuse were viewed as negative, wide-ranging (including concerns about their own personal wellbeing, their loved one's health, relationships, and finances) and long-standing. This has been found by others (Coombes and Cooper, 2019; Cooper, 2011), and subsequently, a variety of longer-term interventions to mitigate the impact were likely needed. Whilst a wide range of different relationships were described, it is worth noting that most participants were female, which may be indicative of women more commonly offering a 'carer' role (Sharma, *et al.,* 2016).

The finding that meaningful engagement with SMS has a positive impact upon relationships, including parenting, is perhaps of no surprise. The pertinent need for this in familial (including parental) substance use disorders has been similarly reported by others (Cheng and Lo, 2012; Vertava Health, 2018). Lander, *et al.,* (2013) and Cooper and Nielsen (2017), also acknowledged the invaluable support that can be accessed through alternative sources to SMS, such as school pastoral care, counselling services, social or housing services or existing personal support networks. Recently published national guidance (PHE, 2021e) also highlights the importance of mutual peer to peer support, and these findings outline that SMS may have a valuable role to play in facilitating opportunities for friends/family to be better connected to affected others, in order to share their experiences and galvanise optimism.

The lack of knowledge about how much money was being spent on OTC/POM misuse (and potential for reduced reporting of substance use/OTC/POM misuse) was to be expected given the secretive behaviours and involvement in illicit activities, compounded by relationship issues associated with honesty and openness (Cooper, 2011). Friends/family cited experiencing personal financial impact, by providing direct financial support or experiencing theft: this issue has been previously raised by advocacy charities such as Adfam (2023b). Therefore, raising friends/family awareness of financial support services and enabling them access to safe storage facilities may facilitate a reduction in this burden. The need for greater awareness of OTC/POM misuse has also been raised by numerous researchers (Coombes and Cooper, 2019; Cooper, 2013a; Marsden, *et al.,* 2019), in several international reports (ACMD, 2016; AOG, 2012; PHE, 2020b; UNODC, 2011), and in UK national guidance (NICE, 2022).

Whilst the number of participants was relatively small, the findings have the potential to add to the published literature, outlining that further improvements to monitoring access to medication by healthcare providers is needed (DHSC, 2021; PHE, 2020b; Van Hout, 2018), as it adds to the negative impact on their psychological burden. There were particular concerns relating to prescribing practices in primary care and service responsiveness in specialist mental health and SMS. However, anxieties and frustrations were alleviated when healthcare professionals promptly responded with a tailored empathetic approach, facilitated gradual supportive reductions, and put in place appropriate boundaries and relapse prevention plans.

7.4.2. Strengths and Weaknesses

Although only eight interviews were conducted, as they were recorded using a Dictaphone® and supportive field notes were used, a rich dataset was still obtained and themes were identified; indeed Guest, *et al.,* (2006) have indicated that the *"basic elements for metathemes"* may occur with just six interviews. Additionally, such approaches with limited sample sizes have been successful in sensitive subject matters such as this (Buttram, *et al.,* 2019; Claffey, *et al.,* 2017; Fingleton, *et al.,* 2019; Gittins, *et al.,* 2018a) and the challenges in recruitment during the pandemic have been similarly reported (Kesten, *et al.,* 2021) and outlined in previous chapters ***(see Chapter 5 - Study 2: Service User Interviews and Chapter 6 - Study 3: Staff Interviews)***.

However, a major limitation remains that the participant numbers were likely too low and limited in the volume of each relationship type (for example, only one husband-wife), and were all recruited via the same national SMS provider, to have fully achieved data saturation and enable generalisability. Greater assurance in the findings may also have been achieved if repeat interviews and member-checking were implemented, and this could be considered as a future development to strengthen data reliability and validity. This may have been further improved if the person undertaking the data analysis had been blinded; however, when transcripts were independently reviewed by the Research Supervisor (Sandelowski, 1993), no differences were identified.

The use of a semi-structured interview guide which incorporated the use of open questions, encouraged more comprehensive, relevant, and unique answers from participants, and stakeholder review and piloting the forms ***(see Chapter 3 - Research Strategy and Design)***, also helped to ensure suitability (Brod, *et al.,* 2009). The use of an interview guide supported the Researcher and provided consistency in how the interviews were undertaken, as they provided an outline of the key areas to be covered, whilst also allowing flexibility to explore issues that had not been anticipated. The use of the complete transcripts in the analysis and the same Researcher/reviewers should have further limited variability between interview approach and the analysis process. This methodology has been found to be similarly effective for exploring sensitive substance use issues (Gittins, *et al.,* 2018a; Van Amsterdam, 2015; Van Hout and Bingham, 2012; Van Hout and Brennan, 2011). However, since participants were also asked to share their experiences in an artificial environment and the Researcher was employed by the SMS provider, this may lead to limited disclosure of information.

To mitigate this, the Researcher was not known to any of the participants prior to study commencement and they had no ability to routinely impact on individual SMS care. By participating virtually, in a confidential way, and on a one-to-one basis, participants were more likely to share personal experiences since individual interviews allow for greater privacy and building of rapport. Furthermore, the Researcher was experienced in SMS delivery and speaking to people about the use of substances, which enabled rapport to be quickly built. However, they needed to ensure that sufficient timing was allowed between conducting interviews and other tasks because of the tendency for the interviews to sometimes be quite emotionally draining.

7.4.3. Implications for Clinicians, Policymakers and Researchers

Whilst the findings remain tentative due to the relatively small number of participants, OTC/POM misuse appears to negatively impact upon friends/family, indicating that further research is therefore required before determining the appropriate action that may be required. For example, the poor management of withdrawal symptoms created issues not just for the individuals, but also for their affected friends/family, and especially when problematic behaviours escalated, which added to anxieties, frustration with prescribers and caused individuals to seek alternative/excess supplies, leading to greater impact upon finances and relationship dynamics. This tentatively suggests that there are implications for prescribers and policymakers who may take steps to restrict access to supplies, which may cause unintended consequences such as people switching to using illicit substances (Clements, *et al.,* 2016; Lankenau, *et al.,* 2012). Therefore, perhaps healthcare professionals should not reactively cease prescribing upon the identification of misuse, and should have increasing vigilance for and provide, optimal management of withdrawal symptoms. Indeed, ensuring a shared decision-making approach is in line with national guidance (NICE, 2022). However, there may also be implications for SMS capacity and resources if this resulted in significant referrals from primary care without appropriate gatekeeping.

As highlighted by organisations such as the Alcohol and Families Alliance, providing early intervention and ongoing support to address the mental wellbeing needs of friends/family is of particular importance, and especially in the case of children, to avoid childhood trauma and perpetuation of OTC/POM misuse or other substance use disorders in future generations (AFA, 2018; PHE, 2021e). Indeed, the emotional challenges, trust issues and associated relationship dynamics may be alleviated by increasing the delivery of psychological interventions such as structured family therapy sessions, and this approach is supported by the new government strategy (DHSC, 2022a). Advocacy and support organisations such as Adfam (2023a) also champion such an approach, including raising awareness, as a mechanism to help challenge stigma (Adfam, 2012). Whilst some friends/family may not feel that they need or want personal support, these findings indicate the likely need to raise awareness of availability, and proactively provide interventions for friends/family via SMS. This is supported by Adfam's recent survey (2023a), that estimated only 21% of people accessing local SMS have a family member receiving any type of support, and there may also be scope to further develop peer-to peer provision.

Participants outlined particular concerns about GPs supplying medication; therefore, consideration should be given to removing medicines which are known to be liable to misuse from pre-authorised repeat prescription

requests, and improve monitoring prior to issuing further supplies in accordance with guidance from the RCGP (2014a). Similarly, ensuring that shared decision-making occurs in the context of the persons social environment, and in conjunction with friends/family (where appropriate and with consent) is important, as the findings indicated that they facilitate prompt access to supportive services, as well as directly providing support themselves. Indeed, such approaches are highlighted in recent NICE guidance (2022), and improved engagement may also alleviate friends/family feelings of frustration and reduce their psychological burden if they feel that the needs of the person they are supporting are being met.

Participants described multifaceted safeguarding issues, including enabling access to medication supplies and finances, as has been found by others (Kirschbaum, *et al.,* 2020). Therefore, there should be consideration of extending the free provision of access to safe storage devices beyond SMS, and to friends/family who need to keep their own supplies of medication secure. With cost-of-living issues, the financial impact on friends/family, for example in helping to procure access to private healthcare, has also been identified by the charity Adfam (2023b). As some friends/family restricted access to supplies and associated financial means to procure them, health and social care staff must remain vigilant for these issues. This includes the risk of friends/family inadvertently becoming perpetrators of financial abuse, and young people/vulnerable others, being involved in sourcing medicines and other potential safeguarding risks associated with parental OTC/POM misuse. It should also be noted that OTC/POM misuse varied in the impact that it had on different relationships, and did not always affect parenting: however, the 'hidden' behaviours may also make detection of potential issues difficult too.

Future SMS developments may require improved responsiveness and tailoring of the type and frequency of contact and duration of interventions. Encouraging the role of friends/family to improve effective engagement and the success of varied psychosocial approaches, highlights the need for a person-centred approach which is in line with UK government guidance (DHSC, 2017). As friends/family had particular anxieties about the side-effects of OTC/POM misuse, healthcare professionals should consider how friends/family can be more involved in consultations, so they can be kept informed and given reassurance as appropriate. Although there were positive views of prescribed SMS interventions, SMS may need to make additional efforts to ensure that individuals are not rushed through treatment, and proactively include friends/family in robust relapse prevention planning to alleviate their anxieties. This is in keeping with national guidance that clearly outlines the importance of carers being involved in all aspects of care planning (PHE, 2017).

Future research which incorporates additional interviews (especially more friends rather than family members), and more SMS, different treatment providers, and in other areas of the country, may allow for additional perspectives to be obtained and may provide further reassurance that data saturation has been achieved. Additionally, since no characteristics other than the relationship type and gender was captured, there may be value in exploring this further, for example by incorporating ethnicity and age. Involving friends/family with lived experience in undertaking the interviews may also allow for more information to be shared. The nature of the support and education that individuals require and if this differs where their loved ones are using other substances, may also warrant further consideration.

7.5. Conclusion

This study found that OTC/POM misuse was highly variable in how it impacts on friends/family, and was not known to have been previously explored by other researchers, especially in the context of English third sector SMS. Due to the limited number of participants, the findings are tentative; however, they indicate that the consequences associated with OTC/POM misuse are likely overwhelmingly negative, with long-term impact upon health and wellbeing, relationships, and finances. However, positive relationships which facilitate honesty and openness, and improved education and empathy, may enable more support to be provided and improved advocacy. To alleviate anxieties and the impact on the psychological burden of friends and family, improvements are likely required to treatment interventions, including healthcare professionals' approach to withdrawal symptoms, shared decision-making, optimisation of medication supplies and specialist service responsiveness.

Interventions should include friends/family when delivering holistic person-centred care, and as appropriate, consider the use of safe storage facilities for medicines, involvement of SMS, social services, support with housing and finances, school pastoral support, affected peers, personal support networks and other healthcare providers such as GPs and mental health services. Health and care providers should be vigilant for safeguarding issues, and the impact of OTC/POM misuse, especially on children. Future research should include more participants, other SMS providers and geographical areas. More research in this area is required, which also considers the type of support interventions which friends/family may benefit from, how this may differ by their demographic characteristics or what substances, or medicine types are involved.

8. Programme of Research Discussion

The rationale and need for this programme of research, which aimed to explore the misuse of OTC and POM by adults that are accessing SMS, has been outlined in ***Chapter 1 - Introduction***. The systematic review ***(see Chapter 2 – Systematic Review)*** highlighted the paucity of published UK SMS-based evidence, and the need for additional research to be conducted. Therefore, this programme of research has added to the existing evidence base, and especially since the findings from each of the subsequent studies have either been published in international peer reviewed journals (Gittins, *et al.,* 2021; Gittins, *et al.,* 2022a; Gittins, *et al.,* 2022b; Gittins, *et al.,* 2022d; Gittins and Maidment, 2022; Gittins, *et al.,* 2023) or are otherwise currently undergoing review ***(see Appendix 1: Summary of Publications/Contributions)***.

The objectives of the systematic review were to identify the types of medication involved, the pattern of misuse and associated demographic characteristics. Given the limited publications found, this demonstrated the need for further exploration, which led to the study in which adults accessing English community SMS completed a questionnaire ***(see Chapter 4 – Study 1 Questionnaires)***. Indeed, the findings from the systematic review informed the aims, objectives and the methodological approach taken ***(see Chapter 3 - Research Strategy and Design)*** for all of the four subsequent studies ***(see Chapter 4 – Study 1 Questionnaires, Chapter 5 - Study 2: Service User Interviews, Chapter 6 - Study 3: Staff Interviews and Chapter 7 - Study 4: Friend/Family Interviews)***.

The first, questionnaire study ***(see Chapter 4 – Study 1 Questionnaires)***, identified that further research, such as the use of qualitative interviews, was required to explore the issues identified (for example the patterns of misuse in relation to the use of other substances and OST); therefore, confidential semi-structured interviews with people who were currently using SMS were conducted ***(see Chapter 5 - Study 2: Service User Interviews)***. The findings from this second study indicated that OTC/POM misuse had wide ranging socioeconomic and health effects. Furthermore, there was suggestion that SMS interventions impacted upon their patterns of misuse, so to explore this further and to triangulate the findings, semi-structured interviews with SMS staff were conducted ***(see Chapter 6 - Study 3: Staff Interviews)***. Since both the second and third studies identified the involvement of friends/family, such as their role in obtaining supplies and providing individuals with support, it was important to consider their perspectives too. Therefore ethical approval was re-applied for ***(see Appendix 11 – Ethical Approvals)***, to extend this research to explore the experiences of OTC/POM misuse amongst friends/family ***(see Chapter 7 - Study 4: Friend/Family Interviews)***.

Undertaking a similar methodological approach across the three groups has also allowed for triangulation of the findings from each (Noble and Smith, 2015). Therefore, a summary of the key findings from this work, and the strengths and limitations, are outlined in this chapter, which concludes with a discussion of the potential implications for policymakers, clinicians, and recommendations for other researchers.

8.1. Summary of Key Findings

8.1.1. Characteristics of People Who Misuse OTC/POM

Where demographic characteristics were known, the people who misused OTC/POM were broadly typical of those found in national English SMS datasets: middle-aged, White men (OHID, 2023; UNODC, 2023). There was a consistent finding that individuals who misused OTC/POM experienced co-existing health issues (especially mental health/chronic pain) and traumatic life events (including familial histories of problematic substance use), which was in keeping with national data sets and the findings of other researchers (Marsden, *et al.,* 2019; OHID, 2023; PHE, 2020b; UNODC, 2011).

The mention of the concomitant use of other substances, especially cannabis and opioids (usually heroin) arose in all of the studies. In the systematic review, amphetamine was more commonly cited, rather than crack/cocaine which featured more often in the questionnaire and interviews. This was perhaps because this was more typical of current drug trends and the types of illicit substances that are more commonly used by people who access SMS (OHID, 2023), and because these substances have traditionally dominated the British drug market (PHE, 2014). However, the mention of 'monkey dust' only at STARS SMS, highlights how localised drug trends can be.

In some cases, no illicit substance use occurred, though as described by Tetrault, *et al.,* (2008), the concomitant use of other substances such as tobacco and alcohol may also be associated with opioid POM misuse. Indeed, the use of legal substances was commonly reported in the questionnaire, though to a lesser degree in the interviews, which is perhaps to be expected, given that about half of individuals presenting to SMS use alcohol problematically (OHID, 2023). Additionally, there was a suggestion that people who misuse OTC/POM were sometimes distinctly different to people who also used other substances (Rigg and Monnat, 2015): they typically only misused OTC/POM codeine-containing products, and may be more likely to be female, 'working professionals' who present with iatrogenic dependence, so SMS may need to have a different approach to engaging with them (Fingleton, *et al.,* 2019; Tkacz, *et al.,* 2012).

8.1.2. Characteristics of OTC/POM Misuse

Oral administration predominated across the studies, which is in keeping with the findings of other researchers such as Cassidy, *et al.,* (2015) and Dada, *et al.,* (2015). However, there were no OTC/POM identified as being associated with misuse that had not already been reported in the published literature. The frequent citing of benzodiazepines and opioids across all studies is in accordance with current UK national data trends, and the relatively limited mention of OTC/POM stimulants and lack of IPEDs has been similarly found by other researchers (Cassidy, *et al.,* 2015; OHID, 2023; Marsden, *et al.,* 2019; Wang, *et al.,* 2018). Whilst the systematic review identified that antihistamines were mentioned more than gabapentinoids, and this was in contrast to the subsequent studies, this was likely due to the age of some of the publications not being representative of current trends, as gabapentinoids are relatively newer medicines and knowledge about their potential for misuse is more recent (PHE & NHSE, 2014).

Variable patterns of misuse (including long-term, iatrogenic, daily, dependent and high levels), which were impacted by access to the OTC/POM procured from a variety of (legal and illegal) sources, including friends/family, was in keeping with national data sets and with observations for other substances (OHID, 2023; ONS, 2023b; PHE, 2020b). Self-medication for underlying physical and mental health needs was similarly reported across all studies and is well-established (Chiappini, *et al.,* 2020; Fischer, *et al.,* 2006; Lipari, *et al.,* 2017). Each of the studies identified that the pattern of misuse was affected by affordability and relative cost, and availability of OTC/POM and other substances, as has been found by other researchers (Bi-Mohammed, *et al.,* 2017). However, in the friends/family study, polypharmacy was not thought to be as notable and there was less knowledge about how much money was being spent on OTC/POM misuse when compared to the other studies. Perhaps this was due to the lack of openness about the extent of misuse or the use of other substances that affected friends/family were exposed to (Cooper, 2011).

Although this research did not set out to explore the impact of the COVID-19, because it was conducted during the pandemic, there were some associated findings. It was thought that OTC/POM misuse was affected, predominantly due to changes in being able to access supplies, and this was similar to what has been reported for other substances (Crew, 2021). Due to the trauma and other mental health issues associated with the pandemic (such as increased anxiety, loneliness, boredom, and loss of employment), it was perhaps unsurprising that for some their misuse of OTC/POM and use of other substances increased, as has been reported in other UK studies such as LUCID-B (Kesten, *et al.,* 2021).

8.1.3. Negative Experiences of OTC/POM Misuse

Where some service users reported perceived positive effects, over time they were usually outweighed by the negative effects, and especially where polypharmacy occurred (Chiappini, *et al.,* 2020; Jones, *et al.,* 2012). Indeed, all studies outlined overwhelmingly negative, wide-ranging, and sometimes long-term and serious consequences of OTC/POM misuse, including effects on relationships, finances, and personal wellbeing (on people misusing OTC/POM and their affected friends/family), which have also been described in the published literature (Coombes and Cooper, 2019; Cooper, 2011; Kinnaird, *et al.,* 2019). Across all the studies, health related harms were especially associated with combination codeine products, due to the paracetamol-containing contents of co-codamol or the renal and gastro-damaging effects of ibuprofen.

As has been noted by others (Lankenau, *et al.,* 2012; Lyndon, *et al.,* 2017), perhaps of all the negative consequences identified across the studies, withdrawal symptoms were of most particular concern. This was due to their role in initiating, escalating and perpetuating OTC/POM misuse, the impact on relationships, problematic behaviours, anxieties, their association with polypharmacy, including the use of other substances (including unregulated products), or larger amounts of combination codeine products, associated with greater risks and predisposition to adverse effects, such as accidental overdose (Inciardi, *et al.,* 2009; Lankenau, *et al.,* 2012). Researchers such as Clements, *et al.,* (2016) and Canfield, *et al.,* (2010), also suggested that underlying health conditions can predispose to the gateway effect to using illicit substances such as heroin, because of the perceived cost-effectiveness and for the desired effects, when compared to OTC/POM misuse. Withdrawal symptoms were also more pronounced or difficult to manage when the

persons usual supplies (of OTC/POM medication or other substances) were suddenly curtailed (Lessenger and Feinberg, 2008).

8.2. Summary of Strengths and Limitations

The findings have added to the evidence base, particularly the systematic review, and exploration of the experiences of English SMS third sector staff and affected friends/family, as they were thought to have been particularly unique (Coombes and Cooper, 2019). A notable strength was triangulating the findings from different perspectives to add to their validity (O'Cathain, *et al.,* 2007; Tonkin-Crine, *et al.,* 2016). For example, the questionnaires identified that there was a statistically significant association between changes in OTC/POM misuse and illicit substance use, and the interviews allowed for exploration of the rationale for this. Additionally, the views of friends/family were explored from their own perspectives after service user and staff interviews indicated their role in sourcing OTC/POM supplies and providing support. The strength of using a mixed methods approach has been outlined in the literature (CRD, 2009), and was also highlighted in the service user interviews where there were significant discrepancies identified between OTC/POM misuse reported by the individuals and their HALO/Systm1 entries (PHE, 2020a).

The sampling approach and subsequent inclusion of a broad range of staff roles who had different backgrounds, different friend/family relationships and people who had a variety of different OTC/POM misuse and other substance use histories, meant that a variety of views were likely sought. Participants also represented a geographical range of community English SMS, and in each study, at least five of the potential seven Humankind community SMS were represented. The methodologies were fully described, all publications and participants were accounted for, and the data quality, integrity and completeness were checked prior to analysis. Additionally, checking transcripts against the audio recordings and field notes for accuracy ensured a comprehensive process was applied (Braun and Clarke, 2006). Similar methodological approaches have been found to be effective for exploring similar sensitive substance use issues (Gittins, *et al.,* 2018a; Van Amsterdam, 2015; Van Hout and Bingham, 2012; Van Hout and Brennan, 2011).

Where participant numbers were greater, there was more confidence that data saturation had been achieved, and the number of participants was similar to the publications identified in the systematic review (Buttram, *et al.,* 2019; Coombes and Cooper, 2019; Cooper, 2013a; Ruben and Morrison, 1992). Furthermore, questionnaire/survey response rates can be notoriously poor, especially in SMS, and where they are anonymised which prohibits follow up. Additionally, data saturation has been achieved in other studies and with fewer participant numbers (Gittins, *et al.,* 2018a; Guest, *et al.,* 2006; Van Hout and Bingham, 2012). Where there was less confidence in data saturation being achieved for the qualitative data, or where there was less quantitative data available, the findings were interpreted with more caution, and the associated analysis was more limited (Ritchie, *et al.,* 2013). This was especially the case for demographic characteristics such as gender, ethnicity, and age. Whilst the research findings may not be considered as transferable to other populations (such as secure settings or different countries), they may be broadly applicable to other community UK SMS, since a range of rural, suburban, and inner-city services were included.

As this research occurred during the pandemic, the findings may not be indicative of 'normal' OTC/POM misuse. COVID-19 pandemic restrictions also had a notable impact on the ability to recruit, especially because of increased virtual working, reduced service user/friends/family contact and SMS footfall (EMCDDA, 2021). Recruitment difficulties have been experienced by others conducting research into the use of substances, including during the pandemic, (Draus, *et al.,* 2005; Kesten, *et al.,* 2021; Wang, *et al.,* 2005; Wang, *et al.,* 2007). Due to reliance upon SMS telephone consultations, this reduced opportunities for sharing the online versions of the questionnaires. Organising time for the interviews was challenging, and notably so for friends/family. On occasions interviews could not go ahead at pre-agreed times for a variety of reasons, including:

- For staff, they had clinical/operational priorities, and difficult workloads which was compounded by COVID-19,
- For friends/family, they were busy working or were unable to find space to be able to speak confidentially,
- For service users their telephone number was no longer in use; they had no fixed abode/alternative contact details; the person was intoxicated; they were preoccupied by actively seeking out their dealer to obtain their next supply of substances; they were engaged in unforeseen childcare issues or arguments.

Additionally, as the number of follow up attempts was restricted for the interviews and there was limited persistence when people were asked to complete the questionnaire to avoid potential participants feeling coerced, this may have contributed to low participant numbers. This was perhaps compounded for the interviews, when for security reasons, the Researcher had to make contact from a telephone which did not display the caller identification, which meant some participants declined the call. Given the over-representation of STARS in the questionnaires, and variable representation from different SMS for the interviews, this may be associated with SMS staff engagement at the different SMS with the recruitment processes, suggesting that this should be reviewed if this research is repeated.

The consistent use of the same invitation wording ***(see Appendix 10 – Invitation Wording Guide)*** and semi-structured interview guides ***(see Appendix 7 - Service User Semi-structured Interview Guide, Appendix 8 – Staff Semi-structured Interview Guide and Appendix 9 – Friends/Family Semi-structured Interview Guide)*** standardised the approach to engaging with participants. The use of the same lead Researcher and other, suitably experienced independent reviewers (including an additional person to review disagreements), established tools and checklists (where they existed) and the same data collection form for the systematic review, enabled the data extraction process and the analyses for each study to be standardised, and provided an assurance of rigour (Tong, *et al.,* 2007). Furthermore, as all the documents had PPI and were piloted for use, this helped to ensure their suitability (Brod, *et al.,* 2009).

Reflexivity was demonstrated throughout the studies, and especially during the analysis processes (Morse, *et al.,* 2002): the independent reviewers provided constructive opportunities for critique of the Researchers views which may have otherwise overly impacted on the interpretation of the data (Noble and Smith, 2015). For example, to ensure that (perhaps because of their senior role in SMS), they were not overly critical of

primary care or focused on broader service delivery issues. The Researcher was also mindful to take suitable breaks between undertaking interviews, and the associated analyses, especially following interviews with friends/family which could be particularly emotionally draining.

The use of anonymised questionnaires, and confidential interviews which were completed at a time of the participants choosing, and involved the use of open questions, was thought to have encouraged more comprehensive, relevant, and unique answers from participants. However, it remains possible that views and experiences were not fully disclosed because of the involvement of SMS staff, and the predominant use of virtual rather than face-to-face interviews may have impacted somewhat upon rapport. Involving peers with lived experience, for example in distributing the questionnaires, or undertaking the interviews, may have further optimised response numbers and enabled individuals to have disclosed additional information.

However, given the views which were expressed (including negative SMS experiences), the openness and sensitive details participants disclosed, participants likely felt comfortable sharing their honest opinions. The potential impact was perhaps also somewhat mitigated due to the Researchers extensive prior experience of working in psychiatry/SMS and undertaking research on sensitive topics such as this, their lack of impact on direct care delivery or employment status, and not knowing participants in a personal capacity. Additionally, the use of one-to-one virtual formats and the absence of chaperones, likely increased participants willingness to share their personal experiences despite the 'artificial' environment (Brod, *et al.,* 2009; Van Amsterdam, 2015; Van Hout and Brennan, 2011).

The major limitation remains that the participant numbers were likely too low and as they were all recruited via the same national SMS provider, which may have limited generalisability and confidence in data saturation being achieved. If data had been permitted which captured OTC/POM misuse over a longer period, for example, Kinnaird, *et al.,* (2019), reported on misused codeine in the last 12 months, this may have provided the opportunity for more people to have been involved and incorporating more friend/family relationship types may have enabled a wider variety of views to have been obtained. Additionally, if repeat interviews or more extensive member-checking had been undertaken, this may have provided greater confidence in the findings (Long and Johnson, 2000). However, when limited member-checking was undertaken and the transcripts and associated themes were independently reviewed, no discrepancies were identified, suggesting a degree of validity and reliability.

8.3. Summary of Implications for Clinicians, Policymakers and Researchers

8.3.1. Implications for Commissioners and Policymakers

Whilst a cautious approach was required when interpreting the data due to the limited number of participants, the tentative findings suggest that there are relevant implications for policymakers and commissioners of different services (including SMS). For example, the findings indicate the need for people to be able to promptly access holistic support which considers their co-existing physical/mental health, housing,

employment, and financial support needs. This is in accordance with national directives for the continued embedding of employment and benefit support services into SMS (DHSC, 2022a; OHID, 2024).

When commissioning services, there should be careful consideration of the need for developing joint stakeholder working across all sectors (including GPs, community pharmacies, psychiatry, SMS and hospitals), with a particular focus on improving communication, medicines supply controls, and awareness of OTC/POM misuse (DHSC, 2017; RCGP, 2014a). An example is the likely ongoing need for commissioners and health and social care providers to respond to the reported COVID-related increases in the use of other substances, which have been reflected in national reports, due to the anticipated increased pressures on SMS, hepatology and respiratory services (Fong, *et al.,* 2015; PHE, 2021c; PHE, 2021d). Joint education and training events may also develop collaborative working and clinician confidence in managing OTC/POM misuse (Brown, *et al.,* 2012; Foley, *et al.,* 2016; Jankovic, 2019). Consideration of how best to raise awareness of OTC/POM misuse, how to detect it and actions to be taken, with a focus on harm reduction and adverse effects, should also be extended to people who access SMS, those who are prescribed medicines liable to misuse and their friends/family (Coombes and Cooper, 2019; Fleming, *et al.,* 2004; GPhC, 2024a).

Whilst there should be prompt signposting to SMS where needed, there is a likely need to refine existing treatment pathways, and careful gatekeeping may be required to ensure that SMS are not overwhelmed, especially with primary care referrals. Particular vigilance is required by health and social care professionals for the risk of adverse effects including potential overdose risk, safeguarding issues and knowledge of how to escalate concerns (GMC, 2024; GPhC, 2024b; NMC, 2018), for example in relation to polypharmacy, parenting, sex working, interpersonal violence, accessing medication supplies and finances (Ivandić, *et al.,* 2020; Kirschbaum, *et al.,* 2020). The commissioning of drug checking services may also be considered as a harm reduction intervention for illicitly sourced 'bad batches' (CCENDU, 2021; Guirguis, *et al.,* 2020a). Additionally, the support needs for friends/family require consideration (Manthorpe, *et al.,* 2015), and these issues should be reflected in safeguarding policies.

As there were reports of changes in patterns of OTC/POM misuse/substance use over time, and local geographical trends (Matthews-King, 2018; Staffordshire University, 2023), there should be ongoing pharmacovigilance and monitoring for changes at local, national and international level (Norman, *et al.,* 2016). Whilst restricting access to supplies may assist with reducing misuse, for example by changing legal status of different products, when changes are made, there should be careful consideration of the possible unintended consequences, such as delays in *"timely access to medication, or if the individual resorts to sourcing illicit alternatives or products that put them at risk of other adverse events, such as combination products like co-codamol, which may place individuals at risk of a paracetamol overdose"* (Lipanovic, 2023). Indeed, in 2024, the UK rescheduled codeine linctus to a POM (MHRA, 2024c), which is pertinent given that codeine products were frequently cited as being misused in this research. However, the impact may be transient (Hoffman, *et al.,* 2017), and given the variety of sources reportedly used to obtain OTC/POM, there needs to be consideration that rescheduling products in isolation is unlikely to resolve OTC/POM misuse-

related issues (Caulkins, *et al.,* 2021; Pearce, 2020; Saloner, *et al.,* 2018). There may also be a role for regulators to address poor professional practice, as exemplified by the General Pharmaceutical Council, which has taken action against pharmacies making inappropriate sales of codeine products (GPhC, 2020).

Widening access to SMS beyond people who use traditional illicit substances remains a long-standing issue which requires continued consideration by SMS providers and commissioners. For example, Huhn, *et al.,* (2017), have suggested that counselling-based services accessed via primary care may be preferred by people who are not currently in treatment for opioid OTC/POM misuse. Furthermore, commissioners should consider consulting with relevant stakeholders to identify if separate services for OTC/POM misuse are truly required (BMA, 2015; Coombes and Cooper, 2019; PHE, 2020b). Given the challenges in obtaining public funding for such services and the risk of inadvertently aggravating existing stigma, perhaps such an approach is best reserved for individuals who otherwise refuse to access usual SMS, where no other substance use features, or if they are known to be particularly vulnerable, such young people (APPG, 2016; Kmietowicz, 2016; NHSE, 2023; PHE, 2020b).

8.3.2. Implications for Clinicians

Although the findings may not be robust enough to base significant changes to clinical practice on, there are some likely considerations for clinicians. For example, perhaps the funding and procurement arrangements relating to the provision of access to safe storage devices should be widened beyond SMS and extended to friends/family who need to safeguard their own medicines supplies. Clinicians should also remove medicines which are known to be liable to misuse from pre-authorised repeat prescription requests and undertake regular and careful reviews prior to providing further supplies, monitoring for excessive or early requests (Kinnaird, *et al.,* 2019; RCGP, 2014a). The findings also indicate that shared decision-making should be encouraged, and where appropriate and with consent, involve friends/family in accordance with national guidance (NICE, 2022). As described by Seddon, *et al.,* (2024), it is likely that providing people with more information about their medication, ensuring continuity of care and providing alternative treatment options will improve current treatment provision. Given the notable mention of the need to ensure appropriate withdrawal symptom management, this is especially critical when medication is being discontinued (NICE, 2022), and there should also be proactive consideration of symptomatic relief provision, gradual reductions and mental health needs.

The findings also indicated that clinicians should be careful not to cause unintended consequences when restricting access to medicines supplies, such as people switching to using illicit substances (Caulkins, *et al.,* 2021; Clements, *et al.,* 2016; Lankenau, *et al.,* 2012), or being less likely to identify diversion and safeguarding issues (Inciardi, *et al.,* 2009). There should also be vigilance for self-detoxification, particularly as a result of iatrogenic dependence, and poorly managed physical/mental health conditions which may predispose to misuse, suggesting the need for medicines adherence and OTC/POM misuse to be routinely asked about, and with an empathetic approach, during healthcare reviews (Claffey, *et al.,* 2017; NICE, 2022; RCGP, 2014b). Clinicians may find the incorporation of validated tools into their consultations may facilitate

screening for potential issues (Gryczynski, *et al.*, 2017), and especially in primary care (McNeely, *et al.*, 2016; Strand, *et al.*, 2019).

8.3.3. Implications for SMS

The findings suggested that to increase engagement and retention in treatment, continuity in staff allocation should be considered and interventions should be tailored to the needs of individuals, for example by offering more frequent reviews, virtual consultations, and greater flexibility and allowances for those with caring responsibilities (Alves, *et al.*, 2021; Bergman, *et al.*, 2018; DHSC, 2022b; Thomas, 2021). Whilst a range of PSI should be available and group work may be particularly valued (DHSC, 2017; NICE, 2022), there may be less need for pharmacological interventions to be provided by SMS, with the possible exception of OST for OTC/POM opioid use, and where OST is indicated, relatively short term, lower doses of buprenorphine may be favoured (Nielsen, *et al.*, 2015a; Van Hout, *et al.*, 2015). Reductions should be undertaken at the speed that suits the individual to avoid unnecessary withdrawal symptoms, and relapse prevention plans should be proactively co-produced as appropriate.

Due to the notable self-reported adherence rate to prescribed interventions found in the questionnaires, and the positive reports about liberalised dispensing regimens received, (that were then echoed across the subsequent interviews), increased SMS liberalisation was perhaps a positive consequence of the pandemic (Brothers, *et al.*, 2021; Kesten, *et al.*, 2021). However, it is important to note the nationally reported increase in drug related deaths involving methadone (Friedman and Akre, 2021; ONS, 2023a; PHE, 2021b), and the questionnaire findings that methadone adherence may be poorer than for other types of OST. Additionally, the national guidance which had supported greater liberalisation has since been rescinded (PHE, 2021a). It is therefore important that monitoring prescribing/dispensing arrangements across SMS and evaluation of the impact remains ongoing. Furthermore, due to the views expressed about the utility of drug tests, SMS should consider routinely stocking point of care tests which incorporate medicines such as pregabalin, and ensure that they are used in a cost-effective, non-punitive way (Kim and Hill, 2003; Wen, *et al.*, 2019).

Whilst a variety of longer-term interventions to mitigate the negative impact of OTC/POM misuse are likely needed, harm reduction interventions may require prioritisation for those most at risk. This may include young people, older people (Chhatre, *et al.*, 2017; Sheridan, *et al.*, 2019), when there are existing health needs, concomitant use of substances/medicines which have additive effects (Jones, *et al.*, 2012; Macleod, *et al.*, 2019; MHRA, 2020) and misuse of codeine combination products (Greene, *et al*, 2005). There should be consideration of how the routine, proactive use of physical health checks, such as liver function tests and paracetamol levels can best be embedded into SMS delivery, perhaps in collaboration with local primary and secondary care providers: other harm reduction interventions may include take home naloxone provision and wider education about cold water extraction (Burton, *et al.*, 2021; DHSC, 2019; Mercer, *et al.*, 2023; Schofield, *et al.*, 2021).

To encourage SMS staff recruitment and retention, and to ensure that they are delivering evidence-based interventions in a confident and competent way, protected time for undertaking continuing professional

development, and the provision of peer support and structured practice/clinical supervision should be enabled (DHSC, 2022a; Murphy, 2022; NHS, 2019; RCPsych, 2020). Due to the finding that clinical records were not necessarily an accurate reflection of current OTC/POM misuse, this suggests that there may be a training need for SMS staff to ensure that they are routinely asking about it, and accurately complete documentation. Additionally, when services are developed, including the views and experiences of people (and SMS staff) in recovery, would enable a co-production approach (O'Connor, 2015; PHE, 2014; Welsh Government, 2014), whilst being sensitive to their want for confidentiality (Akvardar, *et al.,* 2002).

As outlined by advocacy organisations and national public health guidance for commissioners, providing early intervention and ongoing support to address the mental wellbeing needs of friends/family (including children) is important (AFA, 2018; PHE, 2021e). This was highlighted by the finding that friends/family are involved with providing support, facilitating access to treatment, and reducing feelings of loneliness and isolation, which may be especially pertinent to women who may provide more of a 'carer' role (Sharma, *et al.,* 2016). Developments may include SMS providing group PSI, family therapy and facilitating peer support, as recommended in national guidance (NICE, 2022; PHE, 2020b; PHE, 2021e), recent government strategy (DHSC, 2022a), and advocacy charities such as Adfam (2023a). However, collaborative, multiagency working, including school pastoral services, counselling services, housing and financial support and social services should also be considered (Cooper and Nielsen, 2017; Lander, *et al.,* 2013).

8.3.4. Proposed Future Research

As the number of participants lead to limitations in the generalisability of the findings, future research should aim to maximise participation, and perhaps focus on including more friends/family and additional SMS. With funding, future research could incorporate drug testing analyses to verify the accuracy of OTC/POM misuse self-reports (Fendrich, *et al.,* 2004; Garg, *et al.,* 2016). Future work should also explore if the treatment needs of individuals vary by the type of OTC/POM being misused, demographic characteristics such as geographical location (including non-Humankind SMS and beyond England), ethnicity, age and gender (Nielsen, *et al.,* 2015b). There should also be consideration of other types of OTC/POM such as steroids (Hinde, 2019), which were identified in the literature but rarely or ceased to feature in the questionnaire or interviews respectively.

Furthermore, future research should also explore what changes are required to existing treatment pathways, taking into account potentially diverse literacy and cognitive needs (Novotna, *et al.,* 2017), and identify what barriers may exist, so that interventions can be developed to better meet the needs of individuals and their friends/family. This could include if there are any differences between people who only misuse OTC/POM and those who use other substances, and in different SMS settings. Given that there were particular concerns raised regarding opioids, it may be useful to specifically focus on this type of medication and associated treatment needs (Brady, *et al.,* 2016). Additionally, further research which formally captures if SMS staff and friends/family have lived experience of OTC/POM misuse or other problematic substance use, as well as additional demographic characteristics such as their age and ethnicity may also allow for

exploration about how their views and experiences may vary too. As other key stakeholder organisations have also been identified (such as housing, mental health, GPs, community pharmacy and employability services), then the perspectives of the people working in these settings could also be explored.

As drug trends change, it is likely that OTC/POM misuse will continue to evolve, and there will be ongoing changes to OTC/POM availability, for example as a consequence of changes in UK OTC codeine availability (MHRA, 2024c; Pearce, 2020; Robinson, 2023); therefore, future research should explore how this impacts upon OTC/POM misuse and associated experiences over the forthcoming years. Furthermore, as this research was undertaken during COVID-19 and when several changes in pandemic restrictions were experienced in England, repeating this work may allow for long-term trend monitoring, comparisons of changes post-pandemic, and may enable SMS to consider how they continue to adapt post-COVID-19. Additionally, there could be further exploration of why more changes in OTC/POM misuse than the use of other substances may have occurred during the pandemic, and investigation of the correlations between OTC/POM misuse at different pandemic stages. Such work should also consider the perspectives of SMS staff and friends/family, and the findings similarly triangulated (Noble and Smith, 2015). This may consequently inform future approaches to education and prevention strategies too.

9. Programme of Research Conclusion

Due to the growing concerns about OTC/POM misuse because of the associated negative socioeconomic and health implications, more needs to be known about how this affects people who are accessing SMS to improve specialist care provision. Therefore, this programme of research aimed to explore the misuse of OTC and POM by adults that were accessing community SMS. Commencing with a systematic review which highlighted the current paucity of the published evidence base relating to OTC/POM misuse by adults who are accessing SMS in the UK, this informed the consequent mixed methods research design of a questionnaire and semi-structured interviews with SMS staff, service users, and friends/family. Whilst this approach enabled triangulation of the findings, conducting research during the COVID-19 pandemic was challenging, and consequent limited sample size impacted upon the strength of the findings and generalisability.

Oral administration of OTC/POM with sedating profiles (especially opioids) predominated, and they were procured from a variety of both legal and illegal sources. Although long-term, daily dependent use and iatrogenic dependence was reported, patterns of misuse varied significantly. As this was impacted by cost and availability, it should be routinely enquired about, and future research should explore changes in trends over time. Polypharmacy and the concomitant use of other substances was not unusual. However, it is likely that two distinct groups exist: one which uses other substances and one which does not, and further research is required to determine if differing SMS interventions/settings are necessary to optimise engagement.

OTC/POM misuse was associated with a range of socioeconomic, physical, and psychological health effects, and traumatic life events, physical and mental health issues were often co-existing. The need for effective harm reduction strategies was highlighted, and especially for codeine combination products. Adverse consequences were common: withdrawal symptoms were a significant issue and perpetuated misuse. SMS need to be vigilant and mitigate the associated risks, by ensuring appropriate provision of health, overdose prevention and safeguarding interventions. Effective medicines optimisation is also required, and whilst the questionnaire study identified that where people had their OST dispensing regimens liberalised there was reported good adherence, the service user participants were typical of national English SMS datasets (middle-aged White men). Further research should therefore consider if differing SMS approaches are required depending on the persons demographic characteristics or the type of medicines that are being misused. This will also require the inclusion of other SMS providers and different geographical areas.

Data from the semi-structured interviews with service users highlighted that NDTMS data may not accurately capture OTC/POM misuse, and the studies which explored the experiences of English third sector SMS staff and friends/family were particularly unique. They highlighted the need for improved shared decision-making and increased awareness of OTC/POM misuse. To support this, updated national guidance and better resourced care pathways are likely required, which cover all OTC/POM types. Furthermore, SMS should sensitively consider how to incorporate the views of staff with lived experience and optimise the input of friends/family when planning/providing interventions.

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11. Appendices

Appendix 1 - Summary of Publications/Contributions

In addition to the activities outlined below, the Researcher also held professional and expert advisory roles, and was involved in formal research collaborations (including workstreams funded by NIHR and Scottish government), during the time that this research was conducted.

Events where this research has been shared

Date	Event/Title	Format/Location	Organiser
January 2022	An Exploration of the misuse of OTC/POM by people accessing SMS: Preliminary Findings	Webinar (Worldwide - virtual)	CMHP-PRUK
October 2021	An Exploration of the misuse of OTC/POM by people accessing SMS: Preliminary Findings	Conference presentation (Northampton, UK -in person)	CMHP
April 2022	Exploring Over the Counter and Prescription Only Medication misuse amongst adults accessing specialist treatment services: a survey during Covid-19 Misuse of Over the Counter and Prescription Only Medication by people accessing specialist treatment services: a Systematic Review	Conference poster presentation x 2 (Worldwide -virtual)	Health Services Research and Pharmacy Practice
October 2022	Exploring friends and family perspectives on over the counter and prescription only medication misuse during COVID-19	Conference presentation (Valletta, Malta -in person/pre-recorded)	International Society of Addiction Medicine
October 2022	Priorities for tackling overprescribing in the NHS – Overprescribing (and de-prescribing): Psychiatry and Addiction Perspectives	Presentation - Policy conference (UK -virtual)	Westminster Health Forum
November 2022	Exploring OTC and POM misuse in specialist treatment services during COVID-19	Presentation - PhD Symposium (Bristol, UK - in person/pre-recorded)	Society for the Study of Addiction
December 2022	Overdose risks of over the counter and prescription medication use and the role of pharmacies in overdose prevention – Exploring non-medical over the counter and prescription only medication use by people accessing specialist treatment services (during COVID-19)	Webinar (Scotland - virtual)	Drugs Research Network Scotland
January 2023	Over the Counter and Prescription Only Medication Misuse: Current UK Perspective	Presentation (UK and North America -virtual)	Minimum Continuing Legal Education
February 2023	Identifying and managing OTC/POM dependence	Training session (England -virtual)	MORPh
June 2023	Street Drugs Discussions: A Deep Dive into Naloxone	Webinar (Worldwide - virtual)	Drug Science
February	*"It were my best friend":* exploring the experiences	Conference poster (UK –	RCGP and

2024	of adults accessing specialist treatment services who misuse over the counter and prescription only medication	in person)	Addiction Professionals

Publications directly relating to this research

- Gittins R, Maidment I. 2022. Exploring Over the Counter and Prescription Only Medication misuse amongst adults accessing specialist treatment services: A survey during COVID-19. Int J Pharm Pract. 30(s1): i23–4. doi: 10.1093/ijpp/riac019.032
- Gittins R, Missen L, Maidment I. 2021. Misuse of medication in adult substance misuse services: a systematic review protocol. BMJ Open. 11(6): e047283. doi: 10.1136/bmjopen-2020-047283
- Gittins R, Missen L, Maidment I. 2022b. Misuse of over the counter and prescription only medication by people accessing specialist treatment services: a systematic review. Int J Pharm Pract. 30(s1): i45–6. doi: 10.1093/ijpp/riac019.063
- Gittins R, Missen L, Maidment I. 2022a. Misuse of Over the Counter and Prescription Only Medication by Adults Accessing Specialist Treatment Services in the UK: A Narrative Synthesis. Subst Abuse. 16: 11782218221111833. doi: 10.1177/11782218221111833
- Gittins R, Vaziri R, Maidment I. 2023. 'It's a horrible situation for everyone': The impact of over the counter and prescription medication misuse on friends and family. Drug Sci, Policy Law. 9. doi:10.1177/20503245231215407
- Gittins R, Vaziri R, Maidment I. 2022d. Surveying Over the Counter and Prescription Only Medication Misuse in Treatment Services During COVID-19. Subst Abuse. 16: 11782218221135875. doi: 10.1177/11782218221135875
- ***Awaiting publication (currently undergoing peer/editorial review)***
    - *Gittins R, Vaziri R, Maidment I. 202X "It were my best friend": the experiences of people in treatment misusing over the counter and prescription medication*
    - *Gittins R, Vaziri R, Maidment I. 202X "The most high risk people are given the most high risk drugs in the most high risk way": experiences of treating problematic over the counter and prescription only medication use in substance misuse services*

Additional publications relevant to (and undertaken during) this research

- Ferreira PM, Winstock AR, Schlag AK, Brandner B, Henderson G, Miller I, Van Amsterdam J, Phillips LD, Taylor P, Gittins R, Rolles S, Van Den Brink W, Nutt D. 2022. A comparative study of the harms of nitrous oxide and poppers using the MCDA approach. Drug Sci Policy Law. 8. doi: 10.1177/20503245221127301
- Gittins R, Cole S. 2021. Buprenorphine for the management of kratom dependency during covid-19: A case report. Drug Sci Policy Law. 7: 1-7. doi:10.1177/20503245211021193
- Gittins R, Tay Wee Teck J, Madill A. 2022. Examining the gender dimension in the non-medical use of over the counter and prescription only medication. Drug Sci Policy Law. 8. doi: 10.1177/20503245221132548
- Rolles S, Gittins R. 2020. Pharmacists can help put an end to illicit drug deaths by being at the centre of a new non-medical use market. PJ. doi: 10.1211/PJ.2020.20208600

Relevant media commentary provided during this research

- Patient safety spotlight: risks of cyclizine misuse and promoting safe provision for patients https://www.pharmacyregulation.org/about-us/news-and-updates/regulate/patient-safety-spotlight-risks-cyclizine-misuse-and-promoting-safe-provision-patients
- MHRA consults on reclassifying codeine linctus as a prescription-only medicine https://pharmaceutical-journal.com/article/news/mhra-launches-public-consultation-on-reclassifying-codeine-linctus-as-a-prescription-only-medicine
- Drug-related deaths among people treated for opioid dependence more than treble in ten years, study finds https://pharmaceutical-journal.com/article/news/drug-related-deaths-among-people-treated-for-opioid-dependence-in-scotland-more-than-treble-in-ten-years-study-finds
- Woman left paralysed after getting addicted to laughing gas balloons https://www.cosmopolitan.com/uk/body/health/a41002761/nos-laughing-gas-nerve-damage/
- Government advisory body has 150 medicines on watch list for signs of misuse https://pharmaceutical-journal.com/article/news/government-advisory-body-has-150-medicines-on-watch-list-for-signs-of-misuse
- 'Unprecedented' rise in drug overdoses in England linked with synthetic opioid https://pharmaceutical-journal.com/article/news/unprecedented-rise-in-drug-overdoses-in-england-linked-with-synthetic-opioid
- Roz Gittins - CMHP-PRUK Researcher Blog - Pharmacy Research UK http://pharmacyresearchuk.org/roz-gittins-cmhp-pruk-researcher/
- Rise in antihistamine-related deaths prompts call for move to POM status https://pharmaceutical-journal.com/article/news/rise-in-antihistamine-related-deaths-prompts-call-for-move-to-pom-status
- 'Reporting illicit drug reactions' pilot to close following lack of use https://pharmaceutical-journal.com/news-and-analysis/news/reporting-illicit-drug-reactions-pilot-to-close-following-lack-of-use/20207594.article?firstPass=false
- Drug-related deaths in England and Wales at highest ever level https://www.chemistanddruggist.co.uk/news/drug-related-death-england-and-wales-highest-level-ons-says
- Nitrous oxide users unaware of health risks, nurses warn https://www.theguardian.com/society/2019/may/21/nitrous-oxide-users-unaware-of-health-risks-nurses-warn
- The difficulty with speaking to patients about codeine addiction https://www.chemistanddruggist.co.uk/CD005138/The-difficulty-with-speaking-to-patients-about-codeine-addiction
- Prescription pills under review after surge in drug deaths https://www.thetimes.co.uk/article/prescription-pills-under-review-after-huge-rise-in-drug-deaths-j6k2wjkvz
- Why Are Young Men Risking Dangerous Steroid Side Effects To Bulk Up? https://www.huffingtonpost.co.uk/entry/anabolic-steroids-why-are-young-men-risking-dangerous-side-effects-in-the-pursuit-for-muscle_uk_5cfe5ca0e4b0aab91c09256d

- Love Island star says pressure to look good makes him take steroids https://www.walesonline.co.uk/news/wales-news/love-island-tom-powell-steroids-15838831
- Crime gangs sell tanning drugs to Tinder generation https://www.thetimes.co.uk/article/crime-gangs-sell-tanning-drugs-to-tinder-generation-bjqgkwd7z
- Hugely addictive cough medicine 'cocktail' Sweeping UK - warning to students and parents https://www.express.co.uk/news/uk/1020506/cough-medicine-lean-drug-uk-students
- Lethal cough syrup drug blamed for Ariana Grande's ex-boyfriend rapper Mac Miller's death is sweeping the UK https://www.thesun.co.uk/news/7300774/mac-miller-death-ariana-grande-syrup-purple-drank/
- "Laughing gas" canister find on beach sparks health warning https://www.thecourier.co.uk/fp/news/angus-mearns/699917/laughing-gas-canister-find-on-beach-sparks-health-warning/
- How Britain became hooked on Adderall, the illegal 'study drug' which will make you feel smarter and faster... at a cost https://www.thesun.co.uk/news/5755264/adderall-britain-study-smart-drug/
- Grandad died after consuming fatal dose of prescribed medication and alcohol https://www.kentlive.news/news/kent-news/grandfather-canterbury-died-after-consuming-1394416
- The disturbing rise of ‘study drugs’ https://www.thetimes.co.uk/article/the-disturbing-rise-of-study-drugs-2sd73tf3b
- Clinic opens to help teens hooked on illegal pills bought online https://www.theguardian.com/society/2018/jan/27/addiction-clinic-teenagers-hooked-illegal-medicines

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- ***Awaiting publication (currently undergoing peer/editorial review)***
    - *Brocklehurst's Textbook of Geriatric Medicine and Gerontology: Chapter 55 - Mental Health in Older Adults*
    - *Magic mushrooms: a virtual pharmacokinetics clinical trial*
    - *Interventions to improve opioid agonist therapy in acute hospitals: a systematic review and narrative synthesis*
    - *Improving hospital care for people who use drugs: deliberative process development of a clinical guideline for opioid withdrawal management*
    - *Improving hospital-based opioid substitution therapy (iHOST): protocol for a mixed-methods evaluation*
    - *Individual factors associated with initiation of Extended-Release Buprenorphine (XR-BUP) in Opioid Dependence and comparison of outcomes with oral Medication for Opioid Use Disorder (MOUD)*
    - *Are treatment services ready for the use of big data analytics and artificial intelligence in managing opioid use disorder?*
    - *RCGP Guide to the management of drug misuse in primary care:*
        - *Chapter 7 - Exploring the role of pharmacy*
        - *Chapter 9 - Practical aspects of methadone treatment*
        - *Chapter 15 - Injecting drug use – reducing the harm*

Additional achievements relevant to (and achieved during) this research

- British Association of Psychopharmacology – Clinical Certificate Part 2: 2022

- Health Services Research and Pharmacy Practice Conference - Day Lewis Scholarship for ‘Top 20’ best abstracts: 2022
- CMHP - re-credentialing accreditation: 2021
- Bristol University - Questionnaire design, application and data interpretation course: 2021
- Bristol University - Introduction to qualitative research methods course: 2021
- RCGP – Management of Substance Misuse Certificate Part 1 Recertification and Plus and accredited senior trainer: 2019

Appointments relevant to (and held during) this research

- 2024 to Present: Chief Pharmacy Officer and Deputy Registrar - GPhC (paid)
- 2023 to 2024: Director of Care Standards and Practice Improvement – Via (paid)
- 2022 to Present: Visiting Research Fellow – Aston University (voluntary)
- 2022 to 2024: Programme Guardian - Addiction, misuse and dependency: A focus on over-the-counter and prescribed medicines e-learning and e-assessment - Centre for Pharmacy Postgraduate Education (paid)
- 2022 to 2024: Programme Guardian - Improving the quality of over-the-counter consultations for simple analgesics e-assessment - Centre for Pharmacy Postgraduate Education (paid)
- 2022 to 2023: Project Group Member - Patient Decision Aid Stopping benzodiazepines or z-drugs – NICE (voluntary)
- 2022 to 2023: Expert Reviewer - Misuse of OTC opioids e-learning programme – Health Education and Improvement Wales (paid)
- 2021 to Present: Immediate Past President (Vice-President/Registrar 2019 to 2021; President 2021-2023) – CMHP (voluntary)
- 2019 to 2023: Director of Pharmacy – Humankind (paid)
- 2019 to 2024: Expert Advisor – BBC (paid)
- 2019 to 2024: Medicines, Ethics and Practice Advisory Panel Member – Royal Pharmaceutical Society (voluntary)

Appendix 2 - Systematic Review Search Strategy

Undertaken 10th May 2021

Cochrane

Cochrane Reviews, Cochrane Protocols, Trials, Clinical Answers, Editorials and Special Collections

Search Number	Search Term	Number of Results
#1	"POM" OR "prescription medic*" OR "over the counter" OR "OTC" OR "pharmacy medic*" OR "pharmacy only medic*" (Word variations)	3892
#2	MeSH descriptor: [Prescription Drugs] explode all trees	108
#3	MeSH descriptor: [Nonprescription Drugs] explode all trees	188
#4	#1 OR #2 OR #3	2426
#5	(misus* OR abus*)	17706
#6	(treat* OR service*)	917259
#7	#4 AND #5 AND #6	105

Ovid Medline

Ovid MEDLINE® and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions® 1946 to 7/5/2021

Search Number	Search Term	Number of Results
#1	("POM" OR "prescription medic*" OR "over the counter" OR "OTC" OR "pharmacy medic*" OR "pharmacy only medic*").tw	20491
#2	Prescription Drugs/	6290
#3	exp Nonprescription Drugs/	6269
#4	1 or 2 or 3	28905
#5	(misus* or abus*).tw.	158368
#6	(treat* or service*).tw.	6220478
#7	4 and 5 and 6	672

Pubmed

Search Number	Search Term	Number of Results
#1	"POM" OR "prescription medic*" OR "over the counter" OR "OTC" OR "pharmacy medic*" (Text Word)	20,188
#2	“Prescription Drugs” OR “Nonprescription Drugs” (MeSH Terms)	16,048
#3	#1 OR #2	32,091
#4	misus* OR abus* (Text Word)	213,469
#5	treat* OR service* (Text Word)	7,122,263
#6	#3 AND #4 AND #5	1,184

((("POM"[Text Word] OR "prescription medic"[Text Word] OR "over the counter"[Text Word] OR "OTC"[Text Word] OR "pharmacy medic*"[Text Word]) OR ("Prescription Drugs" OR "Nonprescription Drugs"[MeSH Terms])) AND (misus*[Text Word] OR abus*[Text Word])) AND (treat*[Text Word] OR service*[Text Word])*

Scopus

Search Number	Search Term	Number of Results
#1	"POM" OR "prescription medic*" OR "over the counter" OR "OTC" OR "pharmacy medic*" OR "pharmacy only medic*" (All Fields)	132,459
#2	misus* OR abus* (All Fields)	1,148,726
#3	treat* OR service* (All Fields)	24,476,019
#4	#1 AND #2 AND #3	10,410
#5	#4, Restrict to Article Title/Abstract/Keywords	9,776
#6	#5, Restrict to Title/Abstract/Keywords	859

TITLE-ABS-KEY ((treat OR service*) AND (misus* OR abus*) AND ("POM" OR "prescription medic*" OR "over the counter" OR "OTC" OR "pharmacy medic*" OR "pharmacy only medic*"))*

Web of Science

Search Number	Search Term	Number of Results
#1	ALL FIELDS: "POM" OR "prescription medic*" OR "over the counter" OR "OTC" OR "pharmacy medic*" OR "pharmacy only medic*" (Core Collection)	33,240
#2	ALL FIELDS: misus* OR abus* (Core Collection)	400,269
#3	ALL FIELDS: treat* OR service* (Core Collection)	10,310,975
#4	#1 AND #2 AND #3	864

((misus OR abus*) AND (treat* OR service*) AND ("POM" OR "prescription medic*" OR "over the counter" OR "OTC" OR "pharmacy medic*" OR "pharmacy only medic*"))*

Appendix 3 – Questionnaire

Aston University

humankind

Misuse of Over the Counter (OTC) and Prescription Only Medication (POM) whilst accessing UK substance misuse treatment services

Please provide your:

Age: *(years)*	**Gender:**	**Substance misuse treatment service name**:

Ethnicity:

Asian or Asian British – Bangladeshi	Asian or Asian British – Indian	Asian or Asian British – Other	Asian or Asian British – Pakistani	Black or Black British - African	Black or Black British - Caribbean
Black or Black British - Other	Chinese or Other - Chinese	Chinese or Other - Other	Gypsy Roma	Mixed - Other	Mixed – White and Asian
Mixed – White and Black African	Mixed – White and Black Caribbean	Traveller of Irish Heritage	White - British	White - Irish	White - Other

Are you currently prescribed any medication to help with your use of substances? YES/NO

If **YES**, please provide details:

Medication Name(s) *(e.g. methadone/Physeptone®)*	**Formulation** *(e.g. liquid)*	**Amount** *(e.g. 60ml)*	**How often** (e.g. once a day)	**Supervised consumption?** YES/NO
Do you use this medication differently to how it has been prescribed to you? *(e.g. once a week taking less so extra can be sold to others or saved for when heroin unavailable)*	YES/NO	If **YES**, please provide details:		
If this has changed during Covid-19 please provide details of how/why: **If your prescription has changed during Covid-19 (e.g. no longer supervised, larger amounts taken away) what do you think about these changes?**				

In the last month **have you used:**

	YES/NO	**If YES:**	**How often do you usually use it?** (e.g. 3 times a day, every day, once a week)	**How much do you usually use each time?**	**If your use has changed during Covid-19 please provide details of how/why:**
Alcohol (e.g. wine, beer, spirits)					
Tobacco					
Vape/e-cigarette					

PLEASE TURN OVER- QUESTIONNAIRE CONTINUES ON THE NEXT PAGE

In the last month **have you used any substances that are NOT available over the counter/on prescription in the UK:**

Substance name	**YES/NO**	**If YES:**				
		How often? (e.g. 3 times a day, every day, once a week)	**How much each time?**	**How?** (e.g. snort, swallow, groin inject)	**Formulation?** (e.g. pill, powder, liquid, herb)	**If your use has changed during Covid-19 please provide details of how/why:**
Aerosols/solvents						
Amphetamine						
Ecstasy						
Cannabis						
Crack/cocaine						
Heroin						
GHB/GBL						
Khat						
LSD						
Magic mushrooms						
Mephedrone						
Methamphetamine						
Nitrous oxide						
Poppers						
Synthetic cannabis (e.g. Spice)						
Any others? *If so, please provide details:*						

In the last month **have you misused any medicines that ARE available over the counter/on prescription in the UK:**

Medication name	**YES/NO**	**If YES:**					**Do you buy supplies over the counter/are they prescribed for you?** (YES/NO/Sometimes)
		How often? (e.g. 3 times a day, every day, once a week)	**How much each time?**	**How?** (e.g. snort, swallow, groin inject)	**Formulation?** (e.g. tablet, patch, powder, liquid)	**If your use has changed during Covid-19 please provide details of how/why:**	
Amitriptyline							
Anabolic steroids (e.g. testosterone)							
Antihistamine (e.g. promethazine/Phenergan®, chlorpheniramine/Piriton®, diphenhydramine/Nytol®)							
Antiretrovirals (e.g. ritonavir, efavirenz)							
Baclofen							
Benzodiazepines (e.g. nitrazepam, diazepam/Valium®, alprazolam/Xanax®)							
Buprenorphine (e.g. Subutex®, Suboxone®, Espranor®)							
Codeine (non-combination product)							

Codeine combination product (e.g. co-codamol, Nurofen Plus®)							
Dexamfetamine							
Dextromethorphan (e.g. Robitussin®)							

PLEASE TURN OVER- QUESTIONNAIRE CONTINUES ON THE NEXT PAGE

In the last month **have you misused any medicines that ARE available over the counter/on prescription in the UK** *(CONTINUED)*:

Medication name	**YES/NO**	**If YES:**					**Do you buy supplies over the counter/are they prescribed for you?** (YES/NO/Sometimes)
		How often? (e.g. 3 times a day, every day, once a week)	**How much each time?**	**How?** (e.g. snort, swallow, groin inject)	**Formulation?** (e.g. tablet, patch, powder, liquid)	**If your use has changed during Covid-19 please provide details of how/why:**	
Diet/weight loss medication (e.g. Adios®, Alli®, XLS-Medical®, Xenical®)							
Diuretics (e.g. furosemide)							
Fentanyl							
Gabapentin							
Hyoscine (e.g. Buscopan®)							
Ketamine							
Laxatives (e.g. senna, bisacodyl, Movicol®)							
Loperamide (e.g. Immodium®)							
Methadone (e.g. Physeptone®)							
Methylphenidate (e.g. Ritalin®, Concerta®)							
Mirtazapine							
Modafinil							
Morphine (e.g. Sevredol®, MST®, Zomorph®, MXL®, Oromorph®)							
Olanzapine							
Oxycodone (e.g. Oxycontin®, Oxycodone®)							
Pregabalin							
Quetiapine							
Sildenafil (Viagra®)							
Tramadol							
Trazadone							
Zaleplon							
Zolpidem							
Zopiclone							
Any others? *If so, please provide details:*							

Please add anything else that you would like to share about the use of Over The Counter (OTC) or Prescription Only Medication (POM):

Is there anything that you think our service could do differently to help with the misuse of Over The Counter (OTC) or Prescription Only Medication (POM)?

Please return this completed form to Reception or place in the stamped addressed envelope provided. Thank you for your time.

Interviews are also being conducted to gain a more detailed understanding of OTC/POM misuse. If you would like to share more about your experiences with the researcher, please ask a member of staff so that this can be arranged.

Appendix 4 – Service User Participant Information Sheet

Aston University

Misuse of Over the Counter (OTC) and Prescription Only Medication (POM) whilst accessing UK substance misuse treatment services

SERVICE USER Participant Information Sheet

Invitation

You are being invited to take part in a research study. Before you decide if you would like to participate, please take time to read this information sheet carefully and, if you wish, discuss it with others such as your friends or family or a member of staff. If there is anything that is not clear or if you would like more information before you make your decision, please ask the researcher, whose contact details can be found at the end of this information sheet. **Your participation is NOT mandatory, and your CARE will NOT be affected if you decide to take part or not.**

What is the purpose of the study?

The purpose of this study is to explore the use of Over The Counter (OTC) and Prescription Only Medication (POM) by individuals in treatment for substance misuse and to explore the views of treatment service staff that support these individuals. This will include type and pattern of OTC/POM use, details of any positive and negative experiences associated with their use, views about the support that people receive, and how this may have changed during Covid-19. The study has been designed in collaboration with people who have lived experience of POM/OTC misuse.

Why is this study important?

Relatively little is known about the use of OTC and POM by people who have problems with substance misuse. This information will be useful to help organisations who support people who misuse substances and could potentially inform national policy in this area. If more information is known, then healthcare professionals can provide a service which is more able to support the needs of those requiring treatment.

Why have I been chosen?

You have been asked to participate because you are currently in contact with a community Humankind substance misuse service for adults, for support with your substance misuse (and people are being asked to participate to find out more about their experiences regardless of their stage of recovery).

What will happen to me if I take part?

If you choose to participate in the study, you will be asked to complete an anonymised questionnaire which should take no longer than 10 minutes to complete. You are also invited to participate in an interview with the researcher. You may complete either the questionnaire or the interview, or both if you wish to. Interviews should last no longer than 30 minutes. This study is taking place over about three months and your interview will be scheduled during this time. It will be organised at your convenience on the phone. You will be asked some questions relating to your experience of OTC/POM misuse, and with your consent, the conversation will be audio-recorded. If you participate in an interview, your electronic records which the service holds will also be accessed to obtain demographic information about you such as your age, gender, housing and employment status; however, they will not be accessed until you provide verbal consent for this after the interview.

How will the conversation during the interview be recorded and the information I provide managed?

With your permission the interview will be audio recorded and notes may also be taken. 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. Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy. Anything you disclose that is included in the reporting of the study will be anonymous. You of course 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.

Your participation in this study is entirely voluntary. Your care will not be affected in any way whether or not you choose to participate. You can refuse to answer any questions as you wish. If you change your mind about participation in the study during the interview you may leave the conversation or can stop completing the questionnaire at any time and without giving a reason.

Will my taking part in this study be kept confidential?

Yes. The questionnaire is fully anonymised: no personal/identifying details will be recorded, so you cannot be identified; however, this also means that once you have submitted your response, it cannot be withdrawn as it will not be possible to identify which response was yours. If you participate in the interviews, 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 researcher needs to contact you to arrange or undertake the

interview. Analysis of your data will be undertaken using coded data. Your identity will not be shared. The information collected from this study will be kept confidential and only used for the intended purpose. Any information about you, including any direct quotes, will be anonymised by assigning a number instead of your name. The data collected will be stored in a secure document store (paper records) or electronically on an encrypted and password protected computer server/cloud storage. To ensure the quality of the research, Aston University may need to access your data to check that the data has been recorded accurately. If this is required, your personal data will be treated as confidential by the individuals accessing your data.

What happens if I tell you something that concerns you about my health or welfare or that of the person I care for?
In the unlikely event of this happening, we will discuss with you how this should be addressed. If necessary, to protect you and the person you care for, we will report your concern to the appropriate person or bodies.

What are the potential benefits of taking part?
While there are no direct benefits to you of taking part in this study, the data gained will improve understanding about OTC/POM misuse, which may benefit people who require treatment for substance misuse in the future.

What are the potential risks and burdens of taking part?
Substance misuse can be an emotive subject and it is possible that you may find recalling details about substance misuse distressing. Equally, you may benefit from talking about your experiences. If you find the subject distressing please let the researcher/staff know, so they can provide appropriate support. Your involvement and the responses you provide will not be documented in your service records. Interviews will be undertaken at a time that is convenient for you. You may complete the questionnaire at a time that suits you. You may return the questionnaire using the stamped addressed envelope that will be available for you to use in your own time if you would prefer this.

What will happen to the results of the study?
The results of this study may be published in scientific journals and/or published at conferences. 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. If you would like a copy, then please let the researcher know. The anonymised results may be shared with the organisations providing funding for this study. The results will also be used in Roz Gittins' PharmD thesis.

Expenses and payments
You will not be given any money or gifts for participation.

Who is funding the study?
The study us being funded by a Research Grant Award from Pharmacy Research UK (PRUK) and the College of Mental Health Pharmacy (CMHP). This research is part of a Doctorate in Pharmacy Practice at the School of Life and Health Sciences, 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. Aston University takes its obligations under data and privacy law seriously and complies with the General Data Protection Regulation ("GDPR") and the Data Protection Act 2018 ("DPA"). We will process your personal data in order to register you as a participant and to manage your participation in the study. Your personal data will only be accessed and used on the grounds that it is necessary for the performance of a task carried out in the public interest (GDPR Article 6(1)(e). Aston University may process special categories of data about you which includes details about your health. Aston University will process this data on the grounds that it is necessary for statistical or research purposes (GDPR Article 9(2)(j)). Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information at www.aston.ac.uk/dataprotection or by contacting the Data Protection Officer at dp_officer@aston.ac.uk.

Who has reviewed the study?
This study was given a favorable ethical opinion by the Life and Health Sciences Aston University Research Ethics Committee (REC ID 1655).

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 researcher and they will do their best to answer your questions. Contact details can be found at the end of this information sheet. If the researcher is 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 3000. If you wish to raise a complaint on how we have handled your personal data, you can contact Aston University's Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Who can I contact about this study?
If there is anything that is not clear, or you would like further information about this study at any time, please contact the researcher: Roz Gittins, Director of Pharmacy, Humankind Clinical Department, Leeds Regional Office, Units 10 and 20, Armley Park Court, Stanningley Road, LS12 2AE (0113 5122140). The researchers' university supervisor can also be contacted: Dr Ian Maidment, Reader in Clinical Pharmacy, Postgraduate Psychiatric Pharmacy Programme, Room 442f, School of Life and Health Sciences, Aston University (0121 2043002)

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

Appendix 5 – Staff Participant Information Sheet

Misuse of Over the Counter (OTC) and Prescription Only Medication (POM) whilst accessing UK substance misuse treatment services

STAFF Participant Information Sheet

Invitation

You are being invited to take part in a research study. Before you decide if you would like to participate, please take time to read this information sheet carefully and, if you wish, discuss it with others such as your friends or family or a Humankind colleague. If there is anything that is not clear or if you would like more information before you make your decision, please ask the researcher, whose contact details can be found at the end of this information sheet. **Your participation is NOT mandatory, and your employment will NOT be affected if you decide to take part or not.**

What is the purpose of the study?

The purpose of this study is to explore the use of Over The Counter (OTC) and Prescription Only Medication (POM) by individuals in treatment for substance misuse and to explore the views of treatment service staff that support these individuals. This will include type and pattern of OTC/POM use, details of any positive and negative experiences associated with their use, views about the support that people receive, and how this may have changed during Covid-19. The study has been designed in collaboration with people who have lived experience of POM/OTC misuse.

Why is this study important?

Relatively little is known about the use of OTC and POM by people who have problems with substance misuse. This information will be useful to help organisations who support people who misuse substances and could potentially inform national policy in this area. If more information is known, then healthcare professionals can provide a service which is more able to support the needs of those requiring treatment.

Why have I been chosen?

You have been asked to participate because you are currently working in a frontline role in a Humankind substance misuse service, supporting people who have substance misuse issues (as frontline staff are being asked to participate to find out more about their experiences regardless of their job role and level of seniority).

What will happen to me if I take part?

If you choose to participate in the study, you are invited to participate in an interview with the researcher. Interviews should last no longer than 30 minutes. This study is taking place over about three months and your interview will be scheduled during this time. It will be organised at your convenience on the phone. You will be asked some questions relating to your experience of supporting people in treatment, and with your consent, the conversation will be audio-recorded.

How will the conversation during the interview be recorded and the information I provide managed?

With your permission the interview will be audio recorded and notes may also be taken. 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. Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy. Anything you disclose that is included in the reporting of the study will be anonymous. You of course 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.
Your participation in this study is entirely voluntary. Your employment will not be affected in any way whether or not you choose to participate. You can refuse to answer any questions as you wish. If you change your mind about participation in the study during the interview you may leave the conversation at any time and 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 researcher needs to contact you to arrange or undertake the interview. Analysis of your data will be undertaken using coded data. Your identity will not be shared. The information collected from this study will be kept confidential and only used for the intended purpose. Any information about you, including any direct quotes, will be anonymised by assigning a number instead of your name. The data collected will be stored in a secure document store (paper records) or electronically on an encrypted and password protected computer server/cloud storage. To ensure the quality of the research, Aston University may need to access your data to check that the data has been recorded accurately. If this is required, your personal data will be treated as confidential by the individuals accessing your data.

What happens if I tell you something that concerns you about my health or welfare or that of the person I care for?

In the unlikely event of this happening, we will discuss with you how this should be addressed. If necessary, to protect you and the person you care for, we will report your concern to the appropriate person or bodies.

What are the potential benefits of taking part?

While there are no direct benefits to you of taking part in this study, the data gained will improve understanding about OTC/POM misuse, which may benefit people who require treatment for substance misuse in the future.

What are the potential risks and burdens of taking part?
Substance misuse can be an emotive subject and it is possible that you may find recalling details about substance misuse distressing. Equally, you may benefit from talking about your experiences. If you find the subject distressing please let the researcher/colleagues know, so they can provide appropriate support. Your involvement and the responses you provide will not be documented in your employment or supervision records. Interviews will be undertaken at a time that is convenient for you.

What will happen to the results of the study?
The results of this study may be published in scientific journals and/or published at conferences. 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. If you would like a copy, then please let the researcher know. The anonymised results may be shared with the organisations providing funding for this study. The results will also be used in Roz Gittins' PharmD thesis.

Expenses and payments
You will not be given any money or gifts for participation.

Who is funding the study?
The study us being funded by a Research Grant Award from Pharmacy Research UK (PRUK) and the College of Mental Health Pharmacy (CMHP). This research is part of a Doctorate in Pharmacy Practice at the School of Life and Health Sciences, 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. Aston University takes its obligations under data and privacy law seriously and complies with the General Data Protection Regulation ("GDPR") and the Data Protection Act 2018 ("DPA"). We will process your personal data in order to register you as a participant and to manage your participation in the study. Your personal data will only be accessed and used on the grounds that it is necessary for the performance of a task carried out in the public interest (GDPR Article 6(1)(e). Aston University may process special categories of data about you which includes details about your health. Aston University will process this data on the grounds that it is necessary for statistical or research purposes (GDPR Article 9(2)(j)). Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information at www.aston.ac.uk/dataprotection or by contacting the Data Protection Officer at dp_officer@aston.ac.uk.

Who has reviewed the study?
This study was given a favorable ethical opinion by the Life and Health Sciences Aston University Research Ethics Committee (REC ID 1655).

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 researcher and they will do their best to answer your questions. Contact details can be found at the end of this information sheet. If the researcher is 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 3000. If you wish to raise a complaint on how we have handled your personal data, you can contact Aston University's Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Who can I contact about this study?
If there is anything that is not clear, or you would like further information about this study at any time, please contact the researcher: Roz Gittins, Director of Pharmacy, Humankind Clinical Department, Leeds Regional Office, Units 10 and 20, Armley Park Court, Stanningley Road, LS12 2AE (0113 5122140)
The researchers' university supervisor can also be contacted: Dr Ian Maidment, Reader in Clinical Pharmacy, Postgraduate Psychiatric Pharmacy Programme, Room 442f, School of Life and Health Sciences, Aston University (0121 2043002)

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

Appendix 6 – Friends/Family Participant Information Sheet

Misuse of Over the Counter (OTC) and Prescription Only Medication (POM) whilst accessing UK substance misuse treatment services

FRIEND/FAMILY Participant Information Sheet

Invitation
You are being invited to take part in a research study. Before you decide if you would like to participate, please take time to read this information sheet carefully and, if you wish, discuss it with others such as your friends or family or a member of staff. If there is anything that is not clear or if you would like more information before you make your decision, please ask the researcher, whose contact details can be found at the end of this information sheet. **Your participation is NOT mandatory, and the SUPPORT you receive and/or the CARE that the person you provide support for will NOT be affected if you decide to take part or not.**

What is the purpose of the study?
The purpose of this study is to explore the use of Over The Counter (OTC) and Prescription Only Medication (POM) by individuals in treatment for substance misuse and to explore the views of treatment service staff and friends/family members that support these individuals. This will include type and pattern of OTC/POM use, details of any positive and negative experiences associated with their use, views about the support that people receive, and how this may have changed during Covid-19. The study has been designed in collaboration with people who have lived experience of POM/OTC misuse.

Why is this study important?
Relatively little is known about the use of OTC and POM by people who have problems with substance misuse. This information will be useful to help organisations who support people who misuse substances and could potentially inform national policy in this area. If more information is known, then healthcare professionals can provide a service which is more able to support the needs of those requiring treatment/support.

Why have I been chosen?
You have been asked to participate because you are currently supporting someone (a friend/family member) who is in contact with a community Humankind substance misuse service for adults. The individual that you are providing support for has problems with substance misuse (and may be at any stage of their recovery).

What will happen to me if I take part?
If you choose to participate in the study, you will be invited to participate in an interview with the researcher. Interviews should last no longer than 30 minutes. This study is taking place over about three months and your interview will be scheduled during this time. It will be organised at your convenience on the phone. You will be asked some questions relating to your experience of supporting people who misuse OTC/POMs, and with your consent, the conversation will be audio-recorded.

How will the conversation during the interview be recorded and the information I provide managed?
With your permission the interview will be audio recorded and notes may also be taken. 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. Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy. Anything you disclose that is included in the reporting of the study will be anonymous. You of course 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.
Your participation in this study is entirely voluntary. The support that you receive and the care that the person that you are supporting receives, will not be affected in any way whether or not you choose to participate. You can refuse to answer any questions as you wish. If you change your mind about participation in the study during the interview you may leave the conversation at any time and without giving a reason.

Will my taking part in this study be kept confidential?
Yes. If you participate in the interviews, 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 researcher needs to contact you to arrange or undertake the interview. Analysis of your data will be undertaken using coded data. Your identity will not be shared. The information collected from this study will be kept confidential and only used for the intended purpose. Any information about you, including any direct quotes, will be anonymised by assigning a number instead of your name. The data collected will be stored in a secure document store (paper records) or electronically on an encrypted and password protected computer server/cloud storage. To ensure the quality of the research, Aston University may need to access your data to check that the data has been recorded accurately. If this is required, your personal data will be treated as confidential by the individuals accessing your data.

What happens if I tell you something that concerns you about my health or welfare or that of the person I care for?
In the unlikely event of this happening, we will discuss with you how this should be addressed. If necessary, to protect you and the person you care for, we will report your concern to the appropriate person or bodies. We will ensure that you receive the right level of support via a support worker based in your local substance misuse service.

What are the potential benefits of taking part?
While there are no direct benefits to you of taking part in this study, the data gained will improve understanding about OTC/POM misuse, which may benefit people who require treatment/support in the future.

What are the potential risks and burdens of taking part?
Substance misuse can be an emotive subject and it is possible that you may find recalling details about substance misuse distressing. Equally, you may benefit from talking about your experiences. If you find the subject distressing please let the researcher/staff know, so they can provide appropriate support. Your involvement and the responses you provide will not be documented in any service records. Interviews will be undertaken at a time that is convenient for you.

What will happen to the results of the study?
The results of this study may be published in scientific journals and/or published at conferences. 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. If you would like a copy, then please let the researcher know. The anonymised results may be shared with the organisations providing funding for this study. The results will also be used in Roz Gittins' PharmD thesis.

Expenses and payments
You will not be given any money or gifts for participation.

Who is funding the study?
The study us being funded by a Research Grant Award from Pharmacy Research UK (PRUK) and the College of Mental Health Pharmacy (CMHP). This research is part of a Doctorate in Pharmacy Practice at the School of Life and Health Sciences, 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. Aston University takes its obligations under data and privacy law seriously and complies with the General Data Protection Regulation ("GDPR") and the Data Protection Act 2018 ("DPA"). We will process your personal data in order to register you as a participant and to manage your participation in the study. Your personal data will only be accessed and used on the grounds that it is necessary for the performance of a task carried out in the public interest (GDPR Article 6(1)(e). Aston University may process special categories of data about you which includes details about your health. Aston University will process this data on the grounds that it is necessary for statistical or research purposes (GDPR Article 9(2)(j)). Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information at www.aston.ac.uk/dataprotection or by contacting the Data Protection Officer at dp_officer@aston.ac.uk.

Who has reviewed the study?
This study was given a favorable ethical opinion by the Life and Health Sciences Aston University Research Ethics Committee (REC ID 1655).

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 researcher and they will do their best to answer your questions. Contact details can be found at the end of this information sheet. If the researcher is 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 3000. If you wish to raise a complaint on how we have handled your personal data, you can contact Aston University's Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Who can I contact about this study?
If there is anything that is not clear, or you would like further information about this study at any time, please contact the researcher: Roz Gittins, Director of Pharmacy, Humankind Clinical Department, Leeds Regional Office, Units 10 and 20, Armley Park Court, Stanningley Road, LS12 2AE (0113 5122140)
The researchers' university supervisor can also be contacted: Dr Ian Maidment, Reader in Clinical Pharmacy, Postgraduate Psychiatric Pharmacy Programme, Room 442f, School of Life and Health Sciences, Aston University (0121 2043002)

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

Appendix 7 – Service User Semi-structured Interview Guide

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SERVICE USER Semi-structured Interview Guide

Participant ID: # **Date:**

Opening statement:
"Thank you for agreeing to take part in this interview. Before we start, I need to make sure you're aware that everything that we discuss is confidential. I will be recording our conversation and may need to make some notes, but this will be kept secure and separate from any information that could identify you. If I use any quotes from our discussion, they will not identify you directly."

Confirm informed consent, to include:
- The Participant Information Sheet has been read and understood
- Has had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- Understand that participation is voluntary
- Understand that the interview may be ended, and questions can be left unanswered without giving any reasons and at any time if desired
- Agree to having personal data from this interview collected and processed as described in the Participant Information Sheet.
- Agree to having client management system accessed to collate demographic information (e.g. housing and employment status) and processed as described in the Participant Information Sheet
- Understand that if during the interview any information is disclosed that raises concerns that someone may be likely to suffer harm, this may need to be looked into further confidentiality may need to be broken in order to protect them
- Agree to the interview being audio recorded and to anonymise any direct quotes so they cannot be identified in any resulting publications.
- Confirm agreement to participate in the study

Researcher signature to confirm verbal informed consent obtained:
"Before we start do you have any questions or concerns?"
"So we'll make a start: if you have any questions or change your mind about speaking to me as we go along then please let me know."

Questions:
"I would like to find out more about the use of over the counter and prescription only medication amongst the people who are currently using our service so will be asking you some questions around this theme."

Explore history of substance misuse (5mins):
- "What substances (e.g. heroin, cannabis, alcohol) do you have experience of using and how/when do you use them?
- Have you used medication that can be bought over the counter or prescribed for someone else or in a way that it is not intended for use before?"
- Any alcohol, smoking, other meds?

Explore type and pattern of use of OTC/POM that have been taken before (10mins):
- "What types of medicines have you used? (e.g. codeine, methadone)
- How did you take them? (e.g. smoke them, swallow pills, skin-popping)
- How did they fit in with your other substance misuse?
- Where did you get them from? (e.g. online, friend, relative, dealer)
- How often did you use them? (e.g. every day, a couple of times a week)
- When you used them, how much do you usually spend? (e.g. on an 'average' week)
- Has your use of OTC/POM misuse changed during Covid-19? (the amount or types of medication involved, impact of dispensing liberalisation)?If so please describe how"

Explore positive/negative experiences of OTC/POM use (10mins):
- "What did you like about them?
- Is there anything you didn't like about them?
- How did they affect your mental health?
- Have they affected your physical health?"
- Anything good that helped/didn't help? Any service changes needed?

Closing statement:
"Is there anything that you would like to add or talk about that we haven't covered?"
"Do you have any questions?"
"Thank you for your time."

Appendix 8 – Staff Semi-structured Interview Guide

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STAFF Semi-structured Interview Guide

Participant ID: # **Date:**

Opening statement:
"Thank you for agreeing to take part in this interview. Before we start, I need to make sure you're aware that everything that we discuss is confidential. I will be recording our conversation and may need to make some notes, but this will be kept secure and separate from any information that could identify you. If I use any quotes from our discussion, they will not identify you directly."

Confirm informed consent, to include:
- The Participant Information Sheet has been read and understood
- Has had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- Understand that participation is voluntary
- Understand that the interview may be ended, and questions can be left unanswered without giving any reasons and at any time if desired
- Agree to having personal data from this interview collected and processed as described in the Participant Information Sheet.
- Understand that if during the interview any information is disclosed that raises concerns that someone may be likely to suffer harm, this may need to be looked into further confidentiality may need to be broken in order to protect them
- Agree to the interview being audio recorded and to anonymise any direct quotes so they cannot be identified in any resulting publications.
- Confirm agreement to participate in the study

Researcher signature to confirm verbal informed consent obtained:
"Before we start do you have any questions or concerns?"
"So we'll make a start: if you have any questions or change your mind about speaking to me as we go along then please let me know."

Questions:
"I would like to find out more about the experiences of staff who work in substance misuse services, that support individuals who misuse Over The Counter and Prescription Only Medication, so will be asking you some questions around this theme."

Explore experience of working in services (5mins):
- "What is your current job title?
- Please give a brief summary of your experience of working in substance misuse treatment services (e.g. how long in current role, any roles in services before this one)"

Explore experience of supporting people who have misused OTC/POMs (10mins):
- "What types of medicines have the service users you've supported been misusing?
- How did they take them? (e.g. smoke them, swallow pills, skin-popping)
- How did they fit in with their other substance misuse?
- Can you provide any other details about the medicines used e.g. where did they get them from? (e.g. online, friend, relative, dealer) or how often did they use them? (e.g. every day, a couple of times a week)
- Was there anything about their use that concerned you? (e.g. mental/physical health, safeguarding)
- Do you think that their use of OTC/POMs benefitted them in any way?
- Have you seen OTC/POM misuse changing during Covid-19? (the numbers or types of people seeking support or types of medication involved, impact of dispensing liberalisation)?If so please describe how"

Explore potential changes to current service provision (10mins):
- What interventions have people who misuse OTC/POMs been provided with to support them? (e.g. prescribed/psychological intervention, signposting to other services)
- "Do you feel confident and competent in supporting people with OTC/POM misuse and if not, what do you think you could need to improve this?
- What would you like to see the service being able to do differently to improve the current treatment offer for OTC/POM misuse?"

Closing statement:
"Is there anything that you would like to add or talk about that we haven't covered?"
"Do you have any questions?"
"Thank you for your time."

Appendix 9 – Friends/Family Semi-structured Interview Guide

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FRIEND & FAMILY Semi-structured Interview Guide

Participant ID: # **Date:**

Opening statement:
"Thank you for agreeing to take part in this interview. Before we start, I need to make sure you're aware that everything that we discuss is confidential. I will be recording our conversation and may need to make some notes, but this will be kept secure and separate from any information that could identify you. If I use any quotes from our discussion, they will not identify you directly."

Confirm informed consent, to include:
- The Participant Information Sheet has been read and understood
- Has had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- Understand that participation is voluntary
- Understand that the interview may be ended, and questions can be left unanswered without giving any reasons and at any time if desired
- Agree to having personal data from this interview collected and processed as described in the Participant Information Sheet.
- Understand that if during the interview any information is disclosed that raises concerns that someone may be likely to suffer harm, this may need to be looked into further confidentiality may need to be broken in order to protect them
- Agree to the interview being audio recorded and to anonymise any direct quotes so they cannot be identified in any resulting publications.
- Confirm agreement to participate in the study

Researcher signature to confirm verbal informed consent obtained:
"Before we start do you have any questions or concerns?"
"So we'll make a start: if you have any questions or change your mind about speaking to me as we go along then please let me know."

Questions:
"I would like to find out more about the experiences of friends and family members who are supporting individuals who misuse Over The Counter and Prescription Only Medication, so will be asking you some questions around this theme."

Explore experience of accessing services (5mins):
- "Please give a brief summary of your experience of accessing support from substance misuse treatment services (e.g. how long, any support from services before this one)
- Are you accessing any other support services?"

Explore experience of supporting people who have misused OTC/POMs (10mins):
- "What is your relationship to the person/people you are currently supporting?
- What types of medicines has the person you're supporting been misusing?
- How did they take them? (e.g. smoke them, swallow pills, skin-popping)
- How did they fit in with their other substance misuse?
- Can you provide any other details about the medicines used e.g. where did they get them from? (e.g. online, friend, relative, dealer) or how often did they use them? (e.g. every day, a couple of times a week)
- Is there anything about their use that concerned you? (e.g. mental/physical health, safeguarding)
- Do you think that their use of OTC/POMs has had any benefits?
- Have you seen OTC/POM misuse/associated support change during Covid-19? (access to support or types of medication involved, impact of dispensing liberalisation)?If so please describe how"
- [Defining moment?]

Explore potential changes to current service provision (10mins):
- "What interventions have been useful to support the person? (e.g. prescribed/psychological intervention, signposting to other services)
- What would you like to see the service being able to do differently to improve the current treatment offer for OTC/POM misuse?"
- What interventions have been useful to support you?"

Closing statement:
"Is there anything that you would like to add or talk about that we haven't covered?"
"Do you have any questions?"
"Thank you for your time."

Appendix 10 - Invitation Wording Guide

Following on from discussion at the recent Team meeting, here is the phrasing that should be used when offering people the opportunity to participate in the OTC/POM research:

Opening statement:

“There is a research study currently being conducted in Humankind services by our Director of Pharmacy (Roz Gittins) to help gain a better understanding about how our service users may be misusing Over the Counter or Prescription Only Medication.”

For service users: “Anyone using our service may take part and it does not affect the care that you receive from us if you do or do not participate.”
For friends/family members: “Anyone getting support from our service may take part and it does not affect the support that you receive from us or the care of the person that you are supporting, if you do or do not participate.”
For staff: “Any of our frontline staff in this service may take part and it does not affect your employment if you do or do not participate.”

“Would you like to know more about it?”
- *If no:* “that’s ok”
- *If yes:* provide Participant Information Sheet and signpost in case of any questions

Questionnaire (for all service users):
“Would you like to complete the questionnaire?”
- *If no:* “that’s ok”
- *If yes (face to face):* “here’s a copy. Would you like a stamped addressed envelope so you can return it in your own time?”
- *If yes (virtual):* “would you like me to send you a link to the online questionnaire or shall I send you a paper copy with a stamped addressed envelope so you can return it in your own time?”

Interview (service users/friends or family members/frontline staff):
“Would you like to take part in an interview?”
- *If no:* “that’s ok”
- *If yes:* “what contact details can I give to the researcher (Roz) so she can contact you to schedule a convenient interview time?”

Key points to remember:
- Participation is voluntary
- Care/support/employment is not affected if the person chooses to participate or not
- The person may stop answering questions/leave interview at any time
- Confirm informed consent prior to passing on contact details for arranging the interview
- Do not follow up to confirm if they completed the questionnaire/participated in the interview or not
- Do not repeatedly ask the person/try to convince them to participate if they have already refused
- **Signpost to Roz Gittins in case of any problems/queries**

Appendix 11 - Ethical Approvals

- ***Aston University - Original:***

Aston University Ethics Committee
Published on *Aston University Ethics Committee* (https://www.ethics.aston.ac.uk)

Home > PhD Student Ethics Application 1655 > PhD Student Ethics Application 1655

PhD Student Ethics Application 1655

Current state: **Approved**

Workflow History

Date	Old State	New State	By	Comment
Thu, 2020-12-03 18:38	Reviewed	**Approved**	Matt Richards	Favourable opinion issued 12/08/2020 by UREC
Thu, 2020-12-03 18:38	Under Review	Reviewed	Matt Richards	
Wed, 2020-07-08 10:13	Final	Under Review	Matt Richards	UREC Provisional Opinion back to Committee 02/07/2020
Tue, 2020-06-23 08:37	Final to supervisor	Final	Ian Maidment	
Mon, 2020-06-22 23:04	Pending	Final to supervisor	gittinre	Ready for submission. Thank you.
Wed, 2020-05-27 08:13	Final to supervisor	Pending	Ian Maidment	
Wed, 2020-05-27 01:31	Pending	Final to supervisor	gittinre	DRAFT FIRST VERSION FOR COMMENT THANKS
Tue, 2020-05-26 00:01	(creation)	Pending	gittinre	

Source URL: https://www.ethics.aston.ac.uk/node/1655/workflow

- ***Aston University - Revised:***

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4 February 2020

Rosalind Gittens
Supervisor: Dr Ian Maidment
College of Health and Life Sciences

Study title:	Misuse of Over the Counter (OTC) and Prescription Only Medication (POM) whilst accessing UK substance misuse treatment services.
REC REF:	#1655

Confirmation of Ethical Opinion

On behalf of the Committee, I am pleased to confirm a favourable opinion for the amendment to this research as described in the Amendment Request Form dated 2 February 2021 (appendix a)

Documents approved

Document	*Version*	*Date*
Risk Assessment Form	6	02/02/21
Carer&Family Interview Guide and Consent Checklist	1	03/12/20
Invitation Wording	2	03/12/20
Carer&Family Participant Information Sheet	3	03/02/21
Revised Ethics Application 1655	2	02/02/21

With the Committee's best wishes for the success of this project.

Yours sincerely

Professor James Wolffsohn,
Acting Chair, University Research Ethics Committee

- ***Humankind:***

Dear Roz
Thank you for your research proposal. It was considered by the Humankind Trustee Board's Innovation Sub-committee at their meeting on 4th February 2020 and I'm pleased to tell you that they have approved the proposal.

We have a copy of your full proposal to Pharmacy Research UK. We will have to consider the ethical responsibilities of the organisation of your research. I see that you intend to apply to Aston University Research Ethics Committee for approval. We do not need you to go through another research ethics process if you can share your submission to the university Research Ethics Committee that will assure us of the areas of ethical responsibility you have considered and if there are any gaps from our point of view we can pick them up with you directly.

If you can confirm the timescale for the research (i.e. put dates to the Gantt chart in your Pharmacy Research UK paperwork) that will help me keep track for updates to the committee.

If you have any queries or problems do not hesitate to get in touch with me.

Kind regards
Mark Crowe

Mark Crowe
WY-FI Research & Evaluation Co-Ordinator

Appendix 12 - Risk Assessment

SCHOOL/DEPARTMENT:	Life Sciences (Pharmacy)	REFERENCE No.:	Version 6 #1655
MAIN RISK AREA/TOPIC:	People disclosing their experience of substance misuse via written questionnaire/audiotaped telephone interview	ASSESSOR(S)	Roz Gittins
ASSESSMENT DATE:	02/02/21	NEXT REVIEW DATE:	

What are the hazards?	Who might be harmed and how?	What are you doing already?	What further action is necessary?	Action by whom?	Action by when?
The participant may have additional needs e.g. English may not be their first language, they may have impaired sight or have a learning disability so may struggle to understand/provide consent	The person may be unable to provide informed consent if they are unable to understand the information/consent form or the questions being asked.	The Researcher is experienced in working with people who have communication difficulties. The person will be excluded if they cannot speak English, they lack capacity or if their additional needs cannot be met.	Before issuing the questionnaire, the staff member will check for any additional needs so that these can hopefully be met e.g. written in larger font. The Researcher will check for any additional needs prior to interview so that these can hopefully be met e.g. provision of written information that has been written in larger font, easy read style or presence of an interpreter. Immediately prior to interview the Researcher will assess if the person has capacity to consent in accordance with the mental capacity act.	Service staff/Researcher	At time questionnaire is issued/interview takes place.
Disclosure of inappropriate behaviour/concerns	During the interviews participants may disclose inappropriate behaviour/issues which raise concerns regarding themselves/others.	The Researcher has undertaken safeguarding, and clinical supervision training and has access to the organisation's policies, which will be followed at all times.	If inappropriate behaviour or concerning issues are disclosed, the Researcher will take immediate action to ensure safety and seek guidance from colleagues/academic supervisors.	Researcher	At time interview takes place.
The participant may be physically/verbally aggressive	Staff/others/Researcher may be harmed if the person presents with behaviours which may be physically or verbally aggressive.	All service staff have undergone relevant mandatory personal safety training and are experienced in working with people who can be aggressive. The interviews will take place over the phone and the caller ID will not be displayed (so the person cannot use the number for malicious purposes). The questionnaires should not involve any notable interaction between staff/service users except for handing them out/returning them. All activities will take place during the working day so senior management colleagues will be	Service staff (who know service users well) will not issue the questionnaire to the person if they are thought likely to become aggressive, or if they have not agreed to receive it. The person may stop completing the questionnaire/withdraw their involvement at any time and the recovery co-ordinator/support worker will be contacted. If additional support is required, then this will be provided by additional staff/police as appropriate. If	Service staff/Researcher	At time questionnaire is issued/interview takes place.

		available for support if needed. The person will be excluded from the research if they are, or are thought to be, at high risk of presenting with aggressive behaviours. Personal security is a priority and the policy of the organisation will be followed at all times.	necessary and available, the venues panic button will be activated.		
The participant/Researcher may become distressed/have acute mental health needs	Recalling substance misuse issues may be an emotive and potentially distressing subject for participants. If participants become distressed this could cause distress for the Researcher in addition to the participants. The person may have their mental health worsened by their involvement or may be unable to provide informed consent if they become mentally unwell.	Via the participant information sheet, Researcher/service staff, all potential participants will be made aware of the general content of the interview/questionnaire prior to their involvement. The person will not be issued with the questionnaire or be invited to interview if service staff/support worker (who know them well) believe that this may worsen their mental health. The participant will be informed that if they no longer want to participate they may withdraw at any time/immediately cease to complete the questionnaire at any time of their choosing. The Researcher/service staff are experienced in working with people who have substance misuse/mental health problems. All activities will take place during the working day so senior management colleagues will be available for support if needed. Additionally, the person's recovery co-ordinator/support worker/line manager who is familiar to the individual will be immediately accessible.	Immediately prior to interview the Researcher will check with the participant to identify any issues/problems and assess if their mental health is likely to be worsened by the interview and to check that the person has capacity to consent. If the participant's mental health deteriorates, the interview will be stopped and the Researcher will provide immediate support and seek additional input from the persons recovery co-ordinator/line manager/support worker if indicated. Any distress experienced by the Researcher will be discussed with the appropriate clinical or academic supervisor, without compromising the identity and confidentiality of the participant.	Service staff/Researcher	At time questionnaire is issued/interview takes place.
Access by unauthorised individuals to data	Confidentiality of the participants may be breached.	All staff including the Researcher have undertaken mandatory information governance training. The information obtained via the questionnaire will not identify the person in any way (e.g. no name/contact details collected). Anonymised paper questionnaires will only be accessible to authorised staff and electronic responses will only be accessible to the Researcher. All information about the interview participants will be anonymised by assigning a number to each person instead of their name. Data will be kept separate from any information that could otherwise identify the participants directly. All paper documents and audio recordings will be kept in a locked filing cabinet in a secure workspace and will be destroyed as soon as they have been typed up and checked	If there is a breach in confidentiality, the Researcher will take immediate action and will seek guidance, from senior healthcare professionals/academic supervisors.	Service staff/Researcher	At time questionnaire is issued/interview takes place and at the time that any data is moved/processed/stored or any incident arises.

		for accuracy, which is expected to take place within a week of the data being collected. All electronic data will be stored on a password protected computer. National legislation such as the Data Protection Act 1998 and organisational policies in relation to confidentiality will be followed.			

	YES	NO
Does this risk assessment require the development of a Safe Operating Procedure?		X
	The service user participants will already be receiving treatment for their substance misuse and carers/family members will already be receiving support so will already be routinely disclosing details about substance use/their experiences. The staff participants are familiar with discussing their case management during their managerial/clinical supervision sessions. The Researcher has experience in talking to people who have acute mental health/substance misuse problems and in providing line management/clinical supervision where case management is discussed. An SOP is therefore not required because it is not outside the 'normal' scope of the Researcher's/organisation's work.	

AUTHORISATION AND SIGN-OFF

For students, this form should be co-signed by a member of university staff.

I am satisfied that this risk assessment is suitable and sufficient.

ADDITIONAL COMMENTS:							
Person conducting the assessment:							
NAME:	Roz Gittins	POSITION:	PharmD student	SIGNATURE:	[redacted]	DATE:	02/02/21
Member of Staff approving the assessment:							
NAME:	Ian Maidment	POSITION:	Reader in Clinical Pharmacy	SIGNATURE:	[redacted]	DATE:	7/12/20