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Extended Research Article

Supporting self-management with an internet intervention for low back pain in primary care: a RCT (SupportBack 2)

Adam W A Geraghty,[1*] Taeko Becque,[1] Lisa C Roberts,[2] Jonathan Hill,[3] Nadine E Foster,[4,3] Lucy Yardley,[5] Beth Stuart,[1] David A Turner,[6] Gareth Griffiths,[7] Frances Webley,[7] Lorraine Durcan,[7] Alannah Morgan,[7] Stephanie Hughes,[1] Sarah Bathers,[8] Stephanie Butler-Walley,[8] Simon Wathall,[8] Gemma Mansell,[9] Malcolm White,[10] Firoza Davies[10] and Paul Little[1]

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This article

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Abstract

Background: Low back pain is highly prevalent and a leading cause of disability. Internet-delivered interventions may provide rapid and scalable support for behavioural self-management. There is a need to determine the effectiveness of highly accessible, internet-delivered support for self-management of low back pain.

Objective: To determine the clinical and cost-effectiveness of an accessible internet intervention, with and without physiotherapist telephone support, on low back pain-related disability.

Design: A multicentre, pragmatic, three parallel-arm randomised controlled trial with parallel economic evaluation.

Setting: Participants were recruited from 179 United Kingdom primary care practices.

Participants: Participants had current low back pain without indicators of serious spinal pathology.

Interventions: Participants were block randomised by a computer algorithm (stratified by severity and centre) to one of three trial arms: (1) usual care, (2) usual care + internet intervention and (3) usual care + internet intervention + telephone support. 'SupportBack' was an accessible internet intervention. A physiotherapist telephone support protocol was integrated with the internet programme, creating a combined intervention with three brief calls from a physiotherapist.

Outcomes: The primary outcome was low back pain-related disability over 12 months using the Roland–Morris Disability Questionnaire with measures at 6 weeks, 3, 6 and 12 months. Analyses used repeated measures over 12 months, were by intention to treat and used 97.5% confidence intervals. The economic evaluation estimated costs and effects from the National Health Service perspective. A cost–utility study was conducted using quality-adjusted life-years estimated from the EuroQol-5 Dimensions, five-level version. A cost-effectiveness study estimated cost per point improvement in the Roland–Morris Disability Questionnaire. Costs were estimated using data from general practice patient records. Researchers involved in data collection and statistical analysis were blind to group allocation.

Results: Eight hundred and twenty-five participants were randomised (274 to usual primary care, 275 to usual care + internet intervention and 276 to the physiotherapist-supported arm). Follow-up rates were 83% at 6 weeks, 72% at 3 months, 70% at 6 months and 79% at 12 months. For the primary analysis, 736 participants were analysed (249 usual care, 245 internet intervention, 242 telephone support). There was a small reduction in the Roland–Morris Disability Questionnaire over 12 months compared to usual care following the internet intervention without physiotherapist support (adjusted mean difference of −0.5, 97.5% confidence interval −1.2 to 0.2; $p = 0.085$) and the internet intervention with physiotherapist support (−0.6, 97.5% confidence interval −1.2 to 0.1; $p = 0.048$). These differences were not statistically significant at the level of 0.025. There were no related serious adverse events. Base-case results indicated that both interventions could be considered cost-effective compared to usual care at a value of a quality-adjusted life-year of £20,000; however, the SupportBack group dominated usual care, being both more effective and less costly.

Conclusions: The internet intervention, with or without physiotherapist telephone support, did not significantly reduce low back pain-related disability across 12 months, compared to usual primary care. The interventions were safe and likely to be cost-effective. Balancing clinical effectiveness, cost-effectiveness, accessibility and safety findings will be necessary when considering the use of these interventions in practice.

Trial registration: This trial is registered as ISRCTN14736486.

Funding: This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: 16/111/78) and is published in full in *Health Technology Assessment*; Vol. 29, No. 7. See the NIHR Funding and Awards website for further award information.

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/GDPS2418).

Supplementary material has been provided by the authors to support the report and any files provided at submission would have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer-reviewed.

List of abbreviations

A&E	accident and emergency
CACE	complier-average causal effect
CCA	complete-case analysis
CEAC	cost-effectiveness acceptability curves
CRN	Clinical Research Network
CUA	cost–utility analysis
DHI	digital health interventions
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GP	general practitioner
HCP	healthcare professional
HEAP	health economics analysis plan
ICER	incremental cost-effectiveness ratio
IMD	Index of Multiple Deprivation
LBP	low back pain
MAR	missing at random
MCID	minimally clinically important difference
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NNT	number needed to treat
NSAID	non-steroidal anti-inflammatory drug
PBA	person-based approach
PCS	Pain Catastrophising Scale
PHQ-4	Patient Health Questionnaire-4
PN	practice nurse
PPI	patient and public involvement
PSEQ	Pain Self-Efficacy Questionnaire
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RMDQ	Roland–Morris Disability Questionnaire
SAE	serious adverse event
SAP	statistical analysis plan
SB2	SupportBack 2
STarT Back	Subgroups for Targeted Treatment for Back
TSK	Tampa Scale of Kinesiophobia

Plain language summary

Low back pain is very common; most people will experience it at some point in their lives. For some, it will limit what they do day-to-day and cause a lot of concern. The advice people with low back pain are often given is to keep themselves active and 'self-manage'. This means working those things in their lives that will be helpful for alleviating their pain. However, often self-managing well, can require support.

In this study, we wanted to know whether a website built to help people self-manage was more effective when added to the care people usually receive from their doctor. We also wanted to know whether adding phone calls from a physiotherapist made the website more effective. Finally, we explored whether these options would represent 'good value for money' for the National Health Service.

People with low back pain were randomly split into three groups. Group one had access to normal care from their doctor; group two had access to normal care from their doctor plus access to a self-management website; group three had access to normal care from their doctor, plus access to the website, and three brief calls from a physiotherapist. As per our main focus, they answered questions about their back-pain-related disability at 4 time points, over 12 months.

We found small reductions in disability between both website groups and the group who received normal care from their doctor over 12 months. These differences were not significantly different and were smaller than those we judged to be clinically important. However, the website did not cause harm and was likely to offer value for money.

Overall, although the impact of the website on disability was limited, it was safe and could be accessed by a lot of people. Clinicians will need to balance these findings on impact, with access, safety and costs when deciding to offer the website.

Scientific summary

Background

Low back pain (LBP) is highly prevalent and causes substantial disability. First-line recommendations for those with LBP are to remain active and to self-manage. However, behavioural self-management can be complex. Widely accessible, effective support for self-management is needed to ensure that those with LBP can rapidly access optimal care. Internet interventions, accessible from any device with an internet connection, may provide a means of delivering behavioural self-management support for LBP in UK primary care. Where internet interventions have been delivered previously, remote healthcare professional (HCP) support has been shown to increase the effectiveness. As this HCP element adds costs, it is important to determine if it is necessary in the delivery of internet interventions for LBP.

Objectives

1. To determine the clinical and cost-effectiveness of an internet intervention provided with and without physiotherapist telephone support, on LBP-related disability compared to usual care, in a UK primary care setting.
2. To use a mixed-methods process evaluation to explore issues with the implementation of the interventions, potential mechanisms and contextual factors affecting outcomes.

Methods

The study design was a three parallel-arm, multicentre randomised controlled trial with a nested mixed-methods process evaluation. The study was set in UK primary care. Inclusion criteria were as follows: patients over the age of 18, experiencing current LBP with or without sciatica, with access to the internet and the ability to read or understand English without assistance and provide informed consent. Exclusion criteria: indicators of serious spinal pathology, spinal surgery with the past 6 months and pregnancy. Participants were recruited via list searches, or opportunistically through automated electronic pop-ups triggered in consultations, or where pop-up technology was not implemented, through recruitment packs provided within appropriate consultations.

The three trial arms comprised: (1) Usual care for LBP, which included the option for unrestricted range of care including general practitioner consultations, medication and all referrals or to pain clinics. (2) Usual care for LBP as described, and access to the 'SupportBack' internet intervention. SupportBack was primarily a six-session internet intervention (accessible from any device with an internet connection), designed to provide accessible behavioural support for the self-management of LBP. The focus was on increasing activity, including walking and gentle back exercises. The intervention also included a range of modules on LBP-related topics, such as mood, work, sleep and flare-ups. (3) Usual care for LBP, access to the internet intervention, plus up to three brief telephone calls from a physiotherapist. The calls were designed to address concerns, support use of the interventions and provide motivation to adhere to activity goals.

The primary outcome was LBP-related disability over 12 months as measured by the Roland–Morris Disability Questionnaire (RMDQ). The RMDQ was measured at 6 weeks, 3, 6 and 12 months, and a repeated-measures model was used in the primary analysis. Secondary analyses included RMDQ scores at each time point, proportion of participants reaching ≥ 30% reduction in RMDQ (minimum clinically important difference, MCID) at 12 months, and a number of related measures including pain intensity, days in pain per months, pain self-efficacy, kinesiophobia, catastrophising and physical activity. Health-related quality of life was measured with the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) for the health economic analysis; this was used to generate quality-adjusted life-years (QALYs).

For the power calculation, we used a between-group MCID of 1.5 on the RMDQ, which we proposed as important in the context of low-intensity interventions. For the repeated-measures primary outcome, a difference of 1.5 points

on the RMDQ over the follow-up period of 12 months, assuming a standard deviation of 5 in line with the feasibility trial gave an effect size of 0.30. Alpha was set to 0.025 for the primary analysis to allow both interventions to be independently compared with usual care. Using the four repeated measures, an assumed correlation between repeated measures of 0.7, 90% power and allowing for 20% lost to follow-up resulted in a sample size of 806. Randomisation was fully automated using a concealed computer-generated random allocation sequence. Participants were block randomised to the three arms, stratified by recruitment centre and LBP-related disability (less than four on the RMDQ).

The primary analysis for the RMDQ score over time was conducted using a multilevel mixed-model framework with observations at 6 weeks, 3, 6 and 12 months (level 1) nested within participants (level 2). The analysis was adjusted for baseline RMDQ score, stratification factors, pain duration, Subgroups for Targeted Treatment (STarT) Back risk subgroup. Multilevel models were also used for secondary outcomes. A health economic analysis was undertaken from an NHS perspective. Resource use was measured using general practice patient notes review. EQ-5D-5L scores at baseline, 6 weeks and 12 months were used to estimate QALYs. Results were presented in terms of cost per QALY (a cost–utility study). We also used improvement in the RMDQ between 12 months and baseline to estimate cost-effectiveness in terms of cost-per-point improvement in RMDQ. Incremental costs and effects were estimated using regression-based methods. Because of missing data, multiple imputation was used in the base-case analysis.

A mixed-methods process evaluation was conducted which included a nested qualitative study with participants, a qualitative study with the trial support physiotherapists and a quantitative study examining the use and implementation of the interventions as well as mediation analyses. In both qualitative studies, we used telephone interviews, which were transcribed verbatim and analysed using thematic analyses.

Results

Practices and patients

We recruited 179 primary care practices from 6 regional Clinical Research Networks across the UK. Eleven thousand one hundred and ninety-six potential participants were invited into the study via invitation packs. Of those invited, 2693 (24%) responded. Following screening and sending of a study system link, 825 participants were randomised (7%): 274 to usual primary care, 275 to usual care + internet intervention and 276 to usual care + internet intervention + physiotherapist support. Across the arms, follow-up rates were 83% at 6 weeks, 72% at 3 months, 70% at 6 months and 79% at 12 months. Participant baseline demographic and clinical characteristics were well balanced at baseline across the three arms. Practice notes review data were received for 717 participants (87%) of the trial sample.

Clinical outcomes

There was a small reduction in RMDQ over 12 months compared to usual care following the internet intervention without physiotherapist support [adjusted mean difference of −0.5, 97.5% confidence interval (CI) −1.2 to 0.2; $p = 0.085$] and the internet intervention with physiotherapist support (−0.6, 97.5% CI −1.2 to 0.1; $p = 0.048$). These differences were not statistically significant at the level of 0.025. Overall, there were no significant differences between the interventions and usual care with regard to pain intensity (measured as current pain, least pain in the last 2 weeks and average pain over the last 2 weeks) in a repeated-measures model, over 12 months. Participants in both intervention arms reported a significant reduction of around a day less in pain per month, over 12 months, compared to usual care. At 6 weeks, both interventions significantly improved pain self-efficacy and satisfaction with care for back pain. At 12 months, there were small but significant reductions in kinesiophobia in both intervention arms, compared to usual care. There were no serious adverse events associated with the interventions.

Health economic outcomes

Estimates for the cost of the intervention were £16 and £61 for the internet and internet plus telephone-support groups, respectively. The base-case analysis estimated incremental costs compared to control of −£16 and £96 and incremental QALYs compared to control were 0.011 and 0.013 for the internet and internet plus support groups, respectively. The intervention without support dominated usual care, being both more effective and less costly. Estimates of uncertainty suggested that both interventions were more likely than the usual primary care group to be cost-effective at values of a QALY between £20,000 and £30,000, with the internet group the most likely to be

cost-effective at these values. Results suggest that the interventions may represent efficient use of NHS resources, particularly the internet – only intervention at the National Institute for Health and Care Excellence threshold of 20,000–30,000 per QALY.

Process evaluation

In the nested participant qualitative study, 46 participants were interviewed at a range of time points following randomisation (*n* = 15 after 3 months, *n* = 14 after 6 months, *n* = 17 after 12 months) across all three arms. Participants had diverse LBP histories and were generally positive regarding the online aspects of the intervention. For those who perceived benefit, SupportBack appeared to affect outcomes through specific behavioural support for physical activity, that the participants could choose for themselves. For those who did not report benefit, there were pre-existing barriers, or a lack of perceived benefit when activities were tried. This led to disengagement. Participants in the support arm were positive about calls they received from the physiotherapists; they found them motivating and reassuring. In the physiotherapist qualitative study, five trial physiotherapists were interviewed. Overall, physiotherapists felt well-supported and reported few problems in delivering the telephone support. Some described the perceived limitations of the telephone method and lack of physical contact. Others felt that the telephone contact increased the activation of the participants. Physiotherapists described the benefits of the interactive nature of the internet intervention, and some described the benefit of a 6-week staged delivery of self-management support and behavioural advice.

The quantitative process evaluation study showed that the use of the intervention was higher in the intervention + support arm (86% completing at least session 1 of the internet intervention) than in the intervention without support arm (66% completing at least session 1), where session 1 was the core session introducing rationales and core activities. Physiotherapist telephone support was also delivered at acceptable levels, with 71% in this arm receiving at least two phone calls (the agreed amount for the core of the telephone intervention). Lower or higher usage of the internet intervention was not significantly related to RMDQ outcome in either intervention arm. Usage was also not related to pain self-efficacy at 6 weeks. The conditions to explore whether pain self-efficacy was a mediator of LBP-related disability were satisfied in the intervention without a support arm. Following an instrumental variable approach, pain self-efficacy did not mediate RMDQ outcome at 12 months in the intervention without support arm. Finally, following planned subgroup analyses, there was no evidence that baseline risk of persistent disability, pain duration or deprivation indices impacted the effect of the interventions compared to usual care.

Conclusions

In the SupportBack 2 trial, we showed that an internet intervention, delivered with and without physiotherapist telephone support, had a small and non-significant impact on LBP-related disability across 12 months. The interventions were safe, and generally were delivered and used as intended. Our health economic analysis showed that both interventions were likely to be cost-effective compared to the usual primary care alone group. Additionally, the intervention without support dominated usual primary care, being more effective and less costly. Clinicians will need to balance our findings on clinical effectiveness, cost-effectiveness, and safety with the likely accessibility of the intervention when considering use with patients.

Future research

As these internet interventions were used as intended and safe, future research should focus on increasing effectiveness. In this study, there was little indication of a subgroup identifiable at baseline who benefited more than others. Research to increase effectiveness needs to acknowledge the inherent complexity and heterogeneity of LBP as a condition, that likely compounds with the complexity in mechanistic processes underlying digitally supported self-management. Through our process work, it seemed that those who reported a lack of benefit early in their use of the intervention went on to disengage. Rapidly adaptive interventions that respond to early lack of response may merit consideration in future research.

Trial registration

This trial is registered as ISRCTN14736486.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: 16/111/78) and is published in full in *Health Technology Assessment*; Vol. 29, No. 7. See the NIHR Funding and Awards website for further award information.

Chapter 1 Introduction

Low back pain (LBP) has a lifetime prevalence of up to 84%[1] and is the leading cause of years lived with disability globally.[2] The economic burden of LBP is substantial, with direct costs estimated at £1.6B over a year in the UK.[3]

International guidelines recommend self-management and advice to remain active as first-line interventions for LBP.[4,5] With recommendations for management with medicines restrictive due to risks and limited evidence of effectiveness,[4] behavioural self-management is increasingly important. Although often addressed briefly in guidance,[5] self-management of LBP is a complex, multifaceted process: individuals must draw on self-regulatory resources to affect behavioural, cognitive and emotional changes necessary to improve their musculoskeletal health.[6] General practitioners (GPs) are unlikely to have the time or appropriate training to provide patients with effective behavioural support. While practitioners such as physiotherapists are ideally placed to guide behavioural self-management of LBP, access in primary care is variable and often limited.[7]

To address the need for accessible, scalable behavioural support, the internet and digital resources have been proposed as a potential solution.[8,9] Digital health interventions (DHIs) represent a broad category of interventions delivered via digital technologies and may include smartphone apps and internet interventions.[10] Internet interventions are typically structured behavioural programmes delivered online that provide advice and guidance, often over time.[11] Delivered via websites, internet interventions can be accessed from any device with an internet connection. They can be delivered with accompanying health professional support, or as standalone fully automated interventions.

There is a growing body of research on DHI targeting LBP. Five systematic reviews published on the topic between 2016 and 2022[12–16] report similar conclusions: the trials done in this area were often small and likely underpowered;[14] there is inconsistency in outcomes reported between the trials making comparison difficult; interventions were often not described in full, leading to difficulty in understanding what was delivered.[15] Regarding effectiveness, review authors primarily conclude that the evidence is 'mixed'.[14,15] Where effectiveness for disability or pain was reported, this was primarily in the short term with effects dissipating over time.[13] There was also a noted lack of health economic analyses within the trials.[15] This is a particular issue; the potential often ascribed to DHI stems from their scalability due to their remote and primarily automated delivery. Generally, review authors conclude that large, well-reported trials with health economic analysis are lacking. Such trials are necessary to draw conclusions regarding the effectiveness of DHI for LBP.

The recently published 'selfBACK' trial[17] was designed to determine the effectiveness of a mobile app in supporting self-management of LBP. The mobile app and wristband-based intervention in this trial had a specific focus on tailoring of self-management support. Case-based reasoning methods were used to use knowledge from successful previous participants to suggest the most suitable self-management plan for current participants. The primary outcome in this high-quality trial was LBP-related disability at 3 months. Secondary time points included follow-ups at 6 weeks, 6 and 9 months. At 3 months, the trial team reported small, significant improvements in the mobile app arm, compared with usual care. The changes were sustained at 9 months. The reported change of −0.79 on the Roland–Morris Disability Questionnaire (RMDQ) at 3 months was below their specified minimally clinically important difference (MCID). They concluded that this effect was small and 'of uncertain clinical significance' (p. 1288).[17] While the tailoring used in the app was sophisticated, the necessity to use a mobile app with the activity wristband limits the accessibility of the intervention. Additionally, the trial team restricted inclusion into the trial to only those with score above 6 on the RMDQ. Thus, the effect of the intervention on all those requiring self-management support with RMDQ < 6 remains unknown. Critically, the selfBACK trial did not record health use or include a health economic evaluation.

The aims of the selfBACK and SupportBack projects are similar: to determine the effectiveness of digital health approaches for LBP management. However, our work differs in several important ways. Aligning with guidelines recommending support for self-management be offered to all those with LBP, we took an inclusive approach. This applied to both the content of the intervention, which was designed to be helpful for people with all LBP durations and severities, and to the eligibility criteria of the trial; all those with current LBP could join. We did not exclude based on the RMDQ score. This decision reflected our aim to keep the trial as pragmatic as possible, and mirror potential use in UK primary care practice. Additionally, SupportBack is an internet intervention; it can be accessed via a website from

any device with an internet connection (laptop, tablet, smartphone etc.). This again keeps the programme maximally accessible. Mobile apps exclude all those who do not own or use a smartphone.

In the SupportBack 2 (SB2) trial, we wished to investigate the impact of remote telephone support from physiotherapists, alongside the SupportBack internet intervention. Adding health practitioner support to DHI can make them more effective.[18,19] This may happen through additional accountability impacting adherence to behavioural advice.[18,19] However, the addition of health practitioner support increases complexity in delivery and increases costs. Additionally, trials of digital interventions for other conditions including fibromyalgia,[20] asthma[21] and chronic dizziness[22] have shown effectiveness without health practitioner support. Determining the necessity of practitioner support is critical and led to our three-arm trial design; providing the SupportBack intervention with and without musculoskeletal physiotherapist telephone support, compared to usual care. We have demonstrated the feasibility of our trial design, through a successful randomised controlled feasibility trial[23] and shown qualitatively that patients with LBP found our intervention to be accessible and engaging.[24]

Finally, addressing issues with previous trials, in the SB2 trial we included a full health economic analysis. This allowed us to draw conclusions about the likelihood of cost-effectiveness for both the supported and unsupported internet interventions for LBP in primary care.

Chapter 2 Randomised controlled trial methods

Objectives

Our primary objective in this trial was to determine the effectiveness of the SupportBack internet intervention on LBP-related disability in primary care, delivered with and without telephone physiotherapist support, compared to usual care.

Our secondary objectives were to determine the cost-effectiveness of the SupportBack intervention with and without physiotherapist support, compared to usual care. We also wanted to determine the effect of the SupportBack intervention on a range of secondary outcomes including pain intensity, pain self-efficacy, fear of movement and catastrophising. Finally, we wanted to understand the results of the randomised controlled trial (RCT) by conducting a mixed-methods process evaluation to explore issues relating to implementation and mechanisms of action.

Design

We report on a three parallel-arm (1 : 1 : 1), multicentre RCT conducted to determine the clinical effectiveness and cost-effectiveness of an internet intervention (SupportBack) for patients with LBP in primary care. Participants were followed up at 6 weeks, 3, 6 and 12 months.

The trial was registered as ISRCTN14736486. The trial protocol was published as 'Geraghty *et al.*'.[25]

Setting

The trial was conducted with people with LBP recruited from primary care practices across the UK. Participants could access the digital aspects of the intervention from their own devices with internet access (e.g. a laptop, tablet, smartphone) at a location that suited them (home, work or other environments). Those allocated to receive physiotherapist support over the telephone, again accessed this remote support whenever was convenient for them.

Participants

To enter the trial, people with back pain had to meet the following eligibility criteria.

Inclusion

- Aged 18 and above.
- Current LBP (have experienced pain in the last week) with or without sciatica.
- Access to the internet and an active e-mail address.
- Ability to read/understand English without assistance.
- Ability to provide informed consent.

Exclusion

- 'Red flag' signs and symptoms in a patient with LBP which indicate serious spinal pathology such as infection, malignancy, fracture, inflammatory back pain, progressive neurology and/or cauda equine; or suspected serious pathology.
- Have had spinal surgery in the past 6 months.
- Pregnancy.
- Taken part in the prior SupportBack feasibility study.

Recruitment

Research teams at the University of Southampton and Keele University functioned as recruiting centres, working closely with National Institute for Health and Care Research (NIHR) Clinical Research Networks (CRNs) to recruit primary care practices. At these practices, potentially eligible participants were identified in two ways.

Medical records review

Patients who have consulted with LBP in the preceding 2 months were identified by the GP staff from computerised consultation records. Practice GPs were asked to repeat the searches approximately three times, or until the target number of patients per practice had been reached (eight). The lists of patients that resulted were screened by a practice GP who ruled out patients based on the eligibility criteria.

General practitioner consultation

During a patient consultation and on entering a relevant diagnostic or symptom code into the patient's electronic medical record, GPs were prompted about the trial and patient eligibility by an automated 'pop-up' screen activated by the code. GPs then screened for eligibility (using the listed eligibility criteria) and patient identified as suitable had their medical record electronically tagged. A download of these 'tagged' patients was produced regularly, approximately every 2 weeks. This method was used in practices where the technological infrastructure allowed. Participating GP practices not implementing the pop-up read code method could identify potential patients during the consultation. Having considered eligibility, the practitioner at the practice provided the patient with a trial information pack.

Screening

Patients who were identified by either a medical records review or a GP consultation were mailed a study information pack including an invitation letter from a GP, participant information sheet, reply slip, screening questionnaires and a pre-paid envelope. Interested participants responded by returning the reply slip and screening questions using the pre-paid envelope to the research team. For those who did not wish to take part, the reply slip had some common reasons for non-participation (e.g. lack of time, no longer experiencing LBP) which they could return in the pre-paid envelope if they wished to.

Screening questions consisted of two questions regarding current LBP and access to the internet followed by safety questions listing symptoms which could indicate serious spinal pathology (see *Appendix 1* for the screening questionnaire). If participants answered 'Yes' to the questions regarding internet access and current LBP, and no to the safety questions, they were considered eligible. If they answered yes to any of the screening questions, a clinical physiotherapist attempted to contact them by phone to discuss the symptom and make an appropriate clinical recommendation. Those who failed this stage of the screening or were uncontactable were considered ineligible. All participants who were considered eligible after the full screening process were assigned a unique participant identification number and were sent a link to the study website, to complete the consent form, baseline questionnaires and be randomised.

Interventions

Usual care

Participants randomised to this arm continued to have access to and receive unrestricted usual care for LBP. This included primary care and secondary care referrals. Current UK National Institute for Health and Care Excellence (NICE) guidance for LBP recommends assessment to rule out specific spinal pathology and use of stratification tools [e.g. Subgroups for Targeted Treatment (STarT) Back Screening Tool], alongside guidance and information to support self-management and keep active.[5] Guidance regarding pharmacotherapy restricts recommendations to non-steroidal anti-inflammatory drugs (NSAIDs) at the lowest dose for the shortest period of time.[5] Non-pharmacological care may include referrals to physiotherapy, pain clinics, or psychological interventions such as cognitive–behavioural therapy.

Due to broad eligibility criteria, we expected the usual care that participants received for their LBP to vary greatly; from no further contacts following the GP consultation that resulted in the patient being picked up in our searches, to multiple intensive interventions.

Usual care + internet intervention (SupportBack)

Participants randomised to this intervention arm continued to receive unrestricted usual care as described. In addition, they had access to the SupportBack internet intervention. SupportBack is an interactive, multisession intervention that provides participants with accessible behavioural support, advice and tools to guide the effective self-management of LBP. The SupportBack intervention and its development have been described extensively in a publication by Geraghty *et al.*[24] Briefly, the key components in the SupportBack intervention designed to support self-management comprise graded goal setting, self-monitoring and tailored feedback. These core components, based on self-regulatory and self-efficacy theories,[26,27] are situated within evidence-based information targeting cognitive reassurance and positive expectation about the critical role for physical activity in the management of LBP. SupportBack also contains educational modules on LBP-related topics (including work, sleep, flare-ups).

In terms of interaction with the intervention, participants could access SupportBack from any device with access to the internet, from wherever it was convenient. SupportBack contains six sessions. Participants were encouraged to log in once per week, and the e-mail reminders adhered to this schedule. The first session focused on the importance of physical activity in the management of LBP. It supported participants to set goals to either walk more or engage with a range of gentle back-specific exercises of their choice. Goal options are lightly tailored (e.g. the range of options) based on the extent that participants report their LBP is affecting their day-to-day activities. After this point, the focus in SupportBack is essentially self-tailoring. Participants are encouraged to select activities, goal levels and modules that suit them. Based on self-determination theory, this approach was designed to support autonomous motivation.[28] The sessions that follow (2–6) feature self-monitoring in goal reviews with tailored feedback based on progress, and a resetting of goals for the next week. After the goal-setting section, participants can unlock one LBP-related module (e.g. sleep). These unlocked modules build into a repository, that alongside weekly goals, can be accessed at any time. If engaged with as recommended, the interactive element of the SupportBack website would last around 6 weeks. Once all sessions have been completed, the exercises and back-pain-related modules could be accessed as a static resource for the rest of the trial period.

Usual care + internet intervention (SupportBack) + physiotherapist telephone support

Participants who are allocated to this arm continued to receive usual care, alongside the SupportBack internet intervention. Those in this arm also had access of up to 1 hour of telephone support from a musculoskeletal physiotherapist. The hour was split into three phone calls. The first was up to 30 minutes, and the second and third calls were up to 15 minutes. Although the delivery was designed to be pragmatic to fit in the participant's schedules, the physiotherapists were asked to try to schedule the first call after the first week, the second call between weeks 2 and 3, and the third call after the fourth week. This was to ensure that support was provided over time, to support behavioural initiation, and ideally maintenance.

The aim of the telephone support was to encourage the use of the SupportBack internet intervention, provide reassurance regarding LBP and engaging in activity with LBP, and to encourage adherence to LBP-related goals.[25] The physiotherapists were asked to adhere to a checklist of standardised topics covered for each phone call. The checklist follows the Congratulate, Ask, Reassure, Encourage approach[29] developed specifically to guide 'live' support for digital interventions. While drawing on existing clinical skills, it ensures a generally supportive approach, that requires minimal training (all physiotherapists involved in delivering support as part of the trial attended at 2-hour training session). Physiotherapists could address individual concerns; however, they were asked to avoid additional, individualised participant assessment and recommendations for treatment beyond the suggestions in SupportBack content.

Outcomes

All measures used in the trial and the time points at which they are collected are listed in *Table 1*.

TABLE 1 Outcomes and measures used in the trial

Domain	Measure	Time point
Function (primary outcome)		
LBP-related disability	RMDQ[30]	Baseline, 6 weeks, 3, 6 and 12 months. All arms.
Pain		
Pain intensity	Pain index (numerical rating scales measuring current, average and least pain over the last 2 weeks)[31]	Baseline, 6 weeks, 3, 6 and 12 months. All arms.
Pain duration	Time since last pain free month[32]	Baseline. All arms.
Troublesomeness of pain	Troublesome days in pain over the last month (developed from days in pain measure)[33]	Baseline, 6 weeks, 3, 6 and 12 months. All arms.
Risk of persistent pain-related disability	STarT Back tool[34]	Baseline, 12 months. All arms.
Psychological processes related to pain		
Fear of movement	Tampa Scale of Kinesiophobia (TSK-11)[35]	Baseline, 12 months. All arms.
Catastrophising/negative orientation towards pain	Pain Catastrophising Scale[36]	Baseline, 12 months follow-up. All arms.
Confidence in ability to manage pain	Pain Self-Efficacy Questionnaire[37]	Baseline, 6 weeks, 12 months. All arms.
Self-efficacy for managing LBP	Single item from Musculoskeletal Health Questionnaire (MSK-HQ)[38]	Baseline, 6 weeks, 3, 6 and 12 months. All arms.
Outcome expectation	Expectancy question from Credibility and Expectancy Questionnaire modified for LBP[39]	Baseline, all arms. Following session 1 of SupportBack Internet intervention arms only.
Mental health	Patient Health Questionnaire-4[40] depression and anxiety measure	Baseline, 12 months. All arms.
Physical activity/adherence		
General physical activity	Godin Leisure-time Exercise Questionnaire[41]	Baseline, 12 months. All arms.
SupportBack-related physical activity	Single-item measure developed for the trial	Baseline, 6 weeks, 3, 6 and 12 months. All arms.
Adherence to back-specific activity	Item developed for this trial, based on previous behavioural adherence measures[42]	12 months. All arms.
Difficulties with intervention recommendations	Problematic Experiences of Therapy Scale[43]	12 months. Internet intervention arms only.
Satisfaction and enablement		
Satisfaction with care received for LBP	Single satisfaction item developed for trial	6 weeks. All arms.
Enablement	Patient Enablement Instrument (PEI)[44]	6 weeks, 12 months. All arms.
Health-related quality of life, healthcare resource use and occupational status		
Health-related quality of life	ED-5D-5L[45]	Baseline, 6 weeks, 3, 6 and 12 months. All arms.
Use of over-the-counter (OTC) medication for LBP	Single item measuring self-reported OTC medication usage for LBP	Baseline, 6 and 12 months. All arms.
Participant borne costs	Participant-reported health resource use questionnaire developed for this study	Baseline, 6 and 12 months. All arms.
NHS healthcare resource use (specific to back pain, and general)	General practice medical notes review and participant-reported healthcare resource use questionnaire developed for this trial	Baseline, 6 and 12 months. All arms.

TABLE 1 Outcomes and measures used in the trial (*continued*)

Domain	Measure	Time point
Occupational impact of LBP	Brief occupational questionnaire developed for this trial	12 months. All arms.
Use of internet resources		
Use of internet resources	Single item regarding use of internet resources for LBP over trial period	12 months. All arms.

Primary outcome

The primary outcome in this trial was LBP-related disability over 12 months, as measured by the RMDQ[30] at 6 weeks, 3, 6 and 12 months (a repeated-measures model).

Secondary outcomes

Secondary outcomes included LBP-related physical function measured with the RMDQ at each of the 4 follow-up time points, as well as the number of those reaching a within person MCID on the RMDQ within each arm. The within-person MCID for the RMDQ was defined as a change of 30% between baseline and follow-up at 12 months.[46] Other secondary outcomes included pain intensity,[31] number of troublesome days in pain[33] and risk of pain-related disability.[34] Pain-related psychological variables were measured including kinesiophobia,[35] catastrophising,[36] pain self-efficacy,[37] outcome expectations[39] and symptoms of depression and anxiety.[40] General physical activity was measured with the Godin Leisure-time Exercise Questionnaire.[41] We also measured intervention-specific physical activity with a single item developed for this trial. The Problematic Experiences of Therapy Scale[43] was used to measure issues people had with adhering to the suggested activities.

To support the health economic analysis, health-related quality of life was measured with the EuroQol-5 Dimensions, five-level version (EQ-5D-5L).[45] All resources required to provide the internet interventions and the telephone support were recorded. Details of NHS resource use were recorded in a general practice notes review. This included both primary and secondary care contacts and will cover both general healthcare usage in addition to LBP-specific care in the follow-up period. Additionally, LBP-specific medication use was captured. We also attempted to capture LBP-related services paid for by participants, for example, complementary or alternative medicine. We also asked participants about the time of work related to LBP. These latter questions were asked as part of the self-report follow-up measures at 6 and 12 months. All resources identified were costed using appropriate local and national data, for example, NHS reference costs and Unit Costs of Health and Social Care. Occupational status was measured with a brief questionnaire developed for this trial.

The internet intervention software automatically collects data on the number of logins, page and module views and time spent in each login. These data were used to explore adherence and user engagement to the digital component of the intervention.

Data collection

Data were primarily collected online. The online trial system (LifeGuide) was used to collect consent, baseline data including demographics and follow-up data across the 4 time points (6 weeks, 3, 6 and 12 months). If participants were sent the link to the trial system pre randomisation, but did not log on within a week, they were e-mailed again to check that they received the link and advised to look in their junk mail folder. If there was no response, one call attempt was made by a member of the trial team.

Where there was non-response to the online follow-up questionnaire e-mail triggered at the 4 follow-up time points, two reminder e-mails and text messages were sent. Following non-response, a paper questionnaire pack with a pre-paid envelope was sent 1 week after the last e-mail/text reminder. We deemed the follow-up point at 6 weeks, and the

follow-up point at 12 months to be key chase points. Having these short- and long-term data from participants in the primary repeated-measures model was useful in determining estimates of effect. Consequently, at week 6 and month 12, non-responders to e-mails, texts and postal measures were telephoned by a blinded research assistant to complete the primary outcome measure (RMDQ) and quality-of-life questionnaire (EQ-5D-5L) and pain severity. If the participant was happy to continue, further measures from the questionnaire battery at the respective follow-up point were collected. To encourage continued participation and follow-up measure completion, participants were sent gift vouchers at the 6-month completion point (£5) and the 12-month completion point (£10).

Sample size

The reported MCID between groups for the RMDQ varies. A between-group MCID of 2 or 3 points is often reported. However, a difference of 1.5 between groups may still be important,[33] particularly for low-intensity interventions. SupportBack is a low-intensity intervention with the potential to be rapidly scalable. Consequently, we decided a between-group difference of at least 1.5 to be a meaningful difference in this context.

For our repeated-measures primary outcome, a difference of 1.5 points on the RMDQ over the follow-up period of 12 months, assuming a standard deviation (SD) of 5 in line with the feasibility trial, gave us an effect size of 0.30. Alpha was set to 0.025 to allow both interventions to be independently compared with the usual care-alone arm. Using four repeated measures (6 weeks, 3, 6 and 12 months), and assuming a correlation between repeated measures of 0.7 and 90% power, required 215 participants per arm. Allowing for a 20% loss to follow-up gave a total sample size of 806.

Randomisation

The randomisation process was fully automated. The intervention and data collection software automatically generated the randomisation sequence, and a computer-generated algorithm block randomised participants to the trial arms. Participants were stratified by trial recruiting centre and level of LBP-related function: a score of < 4 on the RMDQ[30] was used to denote a lower level of self-rated physical disability. As the automated software randomises patients, the randomisation sequence was concealed from the trial team. Patients were automatically informed of their group allocation through the internet intervention software.

Blinding

As participants were engaging with a behavioural intervention, they were not blind to allocation. The majority of data were collected online, or by post. Telephone calls were used to collect primary outcome data where there was no response to online and postal follow-up. The callers were blind to group allocation. The statisticians conducting the analysis remained blind to group allocation. The health economist conducted the majority of analysis blinded to group. However, estimates of total cost required the addition of costs specific to the provision of the interventions, so the health economist became un-blinded at this point.

Statistical methods

Clinical effectiveness analysis

Quantitative analysis was followed by cleaning and inspection of the data. Descriptive analysis was conducted to determine outliers and distributions of the data. Where data were not normally distributed, transformations were applied or other appropriate distributions were used. The primary analysis for the RMDQ score was performed using a multilevel mixed-model framework with observations at 6 weeks, 3, 6 and 12 months (level one) nested within participants (level two). Results were reported adjusting for stratification factors (baseline RMDQ and trial centre) and pre-specified confounders (prior pain duration, STarT Back risk group and age). Unadjusted results were also reported for comparison. The primary analysis was reported at a 2.5% significance level. The model used all the observed

data and assumed that missing RMDQ scores were missing at random (MAR) given the observed data. A treatment/time interaction was modelled, but was not included as this was not significant, that is the treatment effect was not significantly varying over time. The assumption of practice level (cluster) effect was tested by comparing a fixed-effect model to a random-effects model, but there were no significant practice level effects. An unstructured covariance matrix was used. The structure and pattern of missing data were examined and a sensitivity analysis based on data imputed using a multiple imputation model was carried out.

Analysis of secondary outcomes was conducted using linear regression for continuous outcomes and logistic regression for dichotomous outcomes, again controlling for baseline outcome, baseline RMDQ, centre, prior pain duration, STarT Back risk group and age. Secondary outcomes were reported at a 5% significance level. All primary and secondary analyses were analysed on an intention-to-treat basis, that is they were analysed as randomised. We also undertook a complier-average causal effect (CACE) analysis,[47] which compared compliant participants in the intervention group, with those in the control group whose characteristics were similar enough to the intervention group compliers to suggest they too would have complied with the intervention, given the opportunity to do so. Compliance for these analyses in the intervention arm was defined as completing at least session 1 of the internet intervention. Session 1 contains the central rationale for the intervention; that physical activity is primary in the management of LBP and provides instructions and advice on goal setting. The latter sessions follow a similar format to the first introductory module. With regard to the physiotherapist telephone support arm, we considered 'per protocol' to be receiving at least two of the three planned phone calls. The telephone element was designed to be pragmatic with the necessary flexibility to fit patients' requirements. However, receiving at least two of three calls indicated that support was delivered over time – an important aspect in the design and integration with the internet intervention. The CACE was estimated using instrumental variables regression of the repeated-measures RMDQ, with compliance as the endogenous variable and randomised group as an instrument. The two-stage least squares approach performs a regression of compliance on randomised group, followed by a regression of the RMDQ outcome on the predicted values from the first regression.

Full details of the analyses are set out in the statistical analysis plan (SAP) which can be found in *Report Supplementary Material 2*.

Summary changes to the project protocol

Table 2 contains brief summaries of minor changes that were made to the protocol over the course of the project.

TABLE 2 List of changes made to the protocol

Protocol date and version	Summary of changes
V1 1 June 2018	First protocol
V2 10 August 2018	1. Secondary outcomes grouped into categories following Research Ethics Committee review. 2. Section 4.4.1 – only GP practice staff will identify potential participants (removal of CRN Research Facilitators who will not identify potential participants).
V3 4 October 2018	Screening Section 4.4.2: clarification of time frame for physiotherapist contact with potential participants who answer 'Yes' to safety screening questions.
V4 20 November 2018	Schedule of Observations, Section 5.3 Baseline and Follow-Up Data Collection, 17 Appendices. Amendment to text around telephone outcome assessment to enable additional collection of 'pain severity'. If the patient is happy to do so, to collect further measures over the phone from the respective time-point questionnaire battery.

continued

TABLE 2 List of changes made to the protocol (*continued*)

Protocol date and version	Summary of changes
V5 18 February 2019	Section 1 Schedule of Observations and Procedures/Section 5.3 Baseline and Follow-Up Data Collection and Section 17 Appendices – Appendix A: texting participants has been added in addition to sending the participant an e-mail reminder, to complete the follow-up questionnaires online. Section 4.4.1 GP consultation, added wording that GP's or nurse practitioners can give an 'Invitation Letter Pack' to potential patients during consultation whom they consider potentially eligible. Section 4.4.2 numbering of safety screening questions updated in accordance with new Screening Questionnaire numbering layout.
V6 2 December 2019	Section 4.4.2 numbering of Safety Screening questions updated in accordance with condensing safety screening questions from 6 to 3 questions and new Screening Questionnaire numbering required.
V7 24 March 2020	Page 11 Schedule of Observations and Section 5.3 revised wording to follow-up data collection method in response to COVID-19 restriction of movement. Wording change to allow telephone follow-up data collection to substitute postal questionnaire collection during COVID-19 phase. Wording enables researchers to adopt most appropriate method at the time of either telephone or postal collection of outcome measures. Page 33 Section 7.6 Process Evaluation, updated numbering of qualitative participant interviews at the 3-, 6- and 12-month follow-up time points.
V8 14 December 2020	P 22, Section 5.3 Baseline and Follow-Up Data Collection updated to reflect increased voucher value from £5 to £10 for participants at the 12-month questionnaire completion time point. P 33, 7.6 Process Evaluation, introduction of £15 voucher for qualitative interviews for participants and £25 for the physiotherapist interviewees. Qualitative interviews conducted with the trial physiotherapists are now worded 'up to 15', reduced from 20 physiotherapists.

Chapter 3 Randomised controlled trial results

Recruitment

We completed recruitment working with 179 practices. One hundred and twenty-nine practices were opened by the Southampton centre, including CRNs in Wessex, West of England, North Thames, Kent Surry and Sussex and North West Coast. Fifty practices were opened by the Keele centre, working with the CRN West Midlands. Recruitment began in November 2018 and closed January 2021. Follow-up completed in January 2022. Overall, 11,196 invite packs were sent out to patients. Of the patients receiving these packs, responses were received from 2693 (24%). Following the screening procedures and removing those who declined to participate, 1258 (11%) were deemed eligible and sent the randomisation link. Following recruitment close, 825 patients used the link and were randomised. See *Figure 1* for a recruitment chart, and *Figure 2* for a Consolidated Standards of Reporting Trials flow diagram of flow through the trial.

Baseline characteristics

Participants in the SupportBack trial had a mean age of 54, with a slightly higher proportion of females (58%) and were mostly white (92%). Most participants were married or living with a partner (70%), a relatively low percentage were in employment (58%) and household income was also relatively low (29% with household income < £20 K), reflecting the age group and the higher proportion of those retired. The socioeconomic status was slightly high [median Index of Multiple Deprivation (IMD) decile 7] compared to the UK population (*Table 3*). The median RMDQ score at baseline was 7 on a scale of 0–24, with an interquartile range (IQR) from 3 to 12, indicating that physical disability due to back pain was mostly in the lower half of the scale (*Table 4*). The average pain intensity over the last 4 weeks was approximately 5 on a scale of 1–10, and participants had on average spent approximately half of the last 4 weeks in pain (median number of days in pain 14 days). More than half of participants reported not having a month without pain for more than 1 year. Approximately half of participants were at low risk of persistent disability on the STarT Back screening tool and 20% were at high risk. Confidence in ability to manage pain was relatively high with a median Pain Self-Efficacy Questionnaire (PSEQ) score of 40 on a scale of 0–60. A mean score of 2.3 on the Self Efficacy for Low Back Pain scale is between 'moderately' and 'very' confident in being able to manage LBP. Fear of movement was

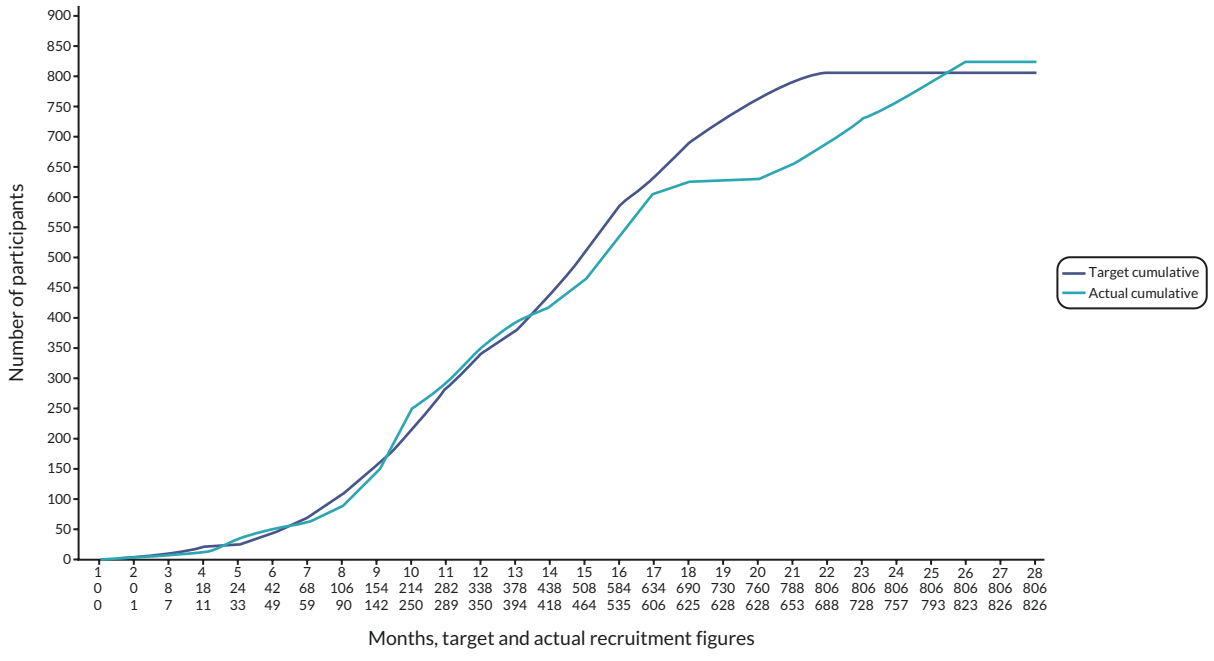

FIGURE 1 Chart of trial recruitment.

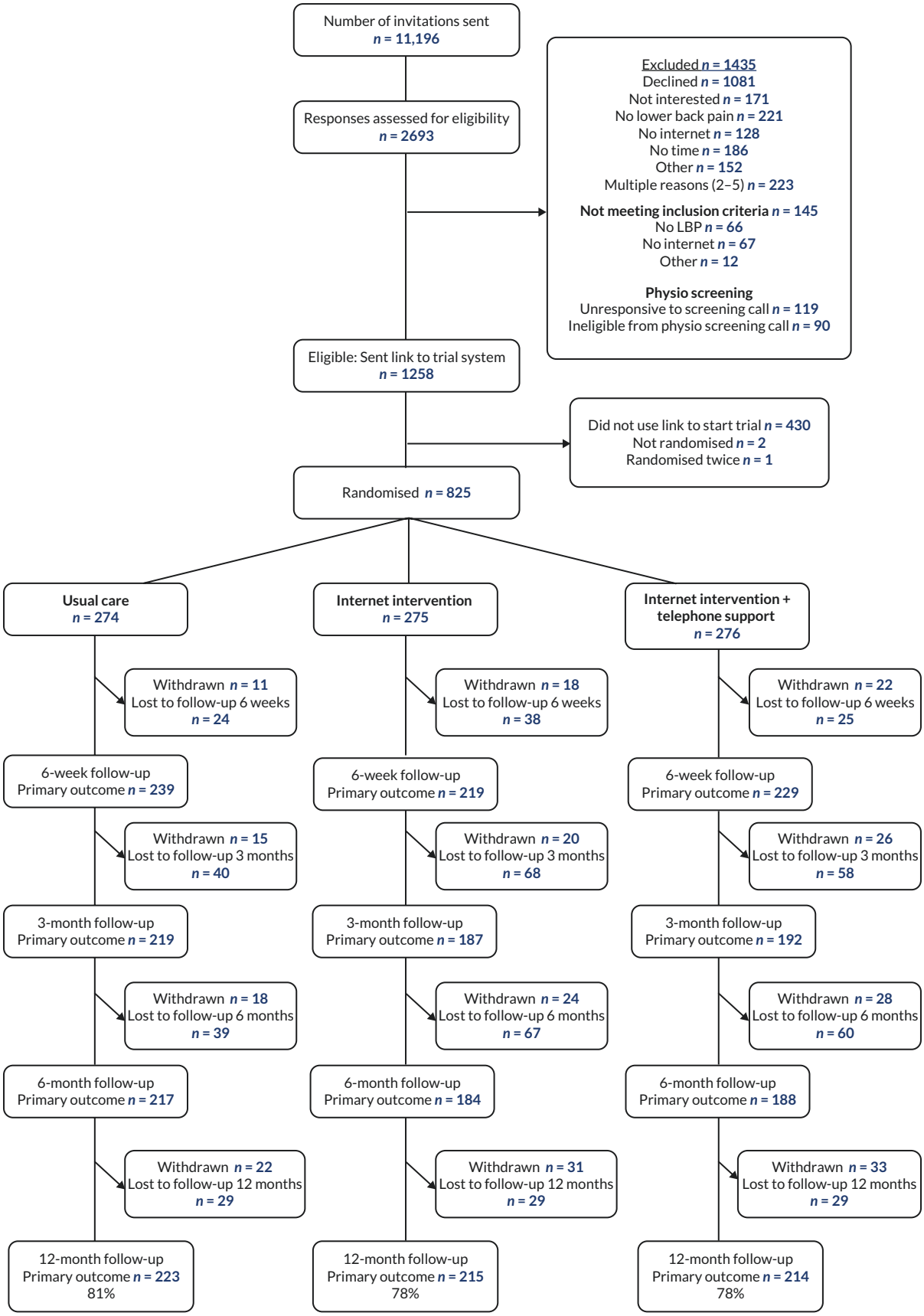

FIGURE 2 Trial flow chart.

TABLE 3 Baseline characteristics

	Usual care alone (*N* = 274)	SupportBack (*N* = 275)	SupportBack + telephone support (*N* = 276)	Overall (*N* = 825)
Gender – female (*n*/*N*, %)	158/273 (57.9)	154/273 (56.4)	167/275 (60.7)	479/821 (58.3)
Gender – male (*n*/*N*, %)	115/273 (42.1)	119/273 (43.6)	108/275 (39.3)	342/821 (41.7)
Age (mean, SD)	54.5 (15.0)	53.5 (16.1)	54.6 (15.2)	54.2 (15.4)
N	271	271	276	818
Ethnicity (n, %)				
White	199 (93.9)	196 (92.0)	196 (90.3)	591 (92.1)
Asian/Asian British	7 (3.3)	4 (1.9)	8 (3.7)	19 (3.0)
Black/African/Caribbean/ Black British	0 (0.0)	5 (2.4)	3 (1.4)	8 (1.3)
Mixed/multiple ethnic groups	4 (1.9)	6 (2.8)	2 (0.9)	12 (1.9)
Other ethnic group	2 (0.9)	2 (0.9)	7 (3.2)	11 (1.7)
N	212	213	216	641
Marital status (n, %)				
Single	51 (18.6)	36 (13.1)	49 (17.8)	136 (16.5)
Married	155 (56.6)	169 (61.5)	165 (59.8)	489 (59.3)
Partner	30 (11.0)	36 (13.1)	26 (9.5)	92 (11.2)
Divorced	22 (8.0)	13 (4.7)	17 (6.2)	52 (6.3)
Separated	5 (1.8)	2 (0.7)	4 (1.5)	11 (1.3)
Widowed	9 (3.3)	14 (5.1)	12 (4.4)	35 (4.2)
Prefer not to answer	2 (0.7)	5 (1.8)	3 (1.1)	10 (1.2)
Age left full-time education (mean, SD)	19.0 (5.0)	18.6 (3.9)	18.8 (4.5)	18.8 (4.5)
N	264	265	266	795
Highest qualification (n, %)				
No formal educational qualifications	26 (9.5)	31 (11.3)	26 (9.4)	83 (10.1)
GCSE/O levels	54 (19.7)	56 (20.4)	69 (25.0)	179 (21.7)
A levels	34 (12.4)	30 (10.9)	39 (14.1)	103 (12.5)
Diploma (non-degree)	40 (14.6)	39 (14.2)	33 (12.0)	112 (13.6)
Degree	55 (20.1)	52 (18.9)	51 (18.5)	158 (19.2)
Higher degree	11 (4.0)	18 (6.6)	13 (4.7)	42 (5.1)
Postgraduate degree	32 (11.7)	26 (9.5)	24 (8.7)	82 (9.9)
Other	20 (7.3)	17 (6.2)	21 (7.6)	58 (7.0)
No response	2 (0.7)	6 (2.2)	0 (0.0)	8 (1.0)

continued

TABLE 3 Baseline characteristics (*continued*)

	Usual care alone (*N* = 274)	SupportBack (*N* = 275)	SupportBack + telephone support (*N* = 276)	Overall (*N* = 825)
Employment status (n, %)				
Full time	98 (35.8)	97 (35.3)	85 (30.8)	280 (33.9)
Part time	41 (15.0)	39 (14.2)	44 (15.9)	124 (15.0)
Self-employed (full time)	10 (3.7)	15 (5.5)	11 (4.0)	36 (4.4)
Self-employed (part time)	9 (3.3)	16 (5.8)	14 (5.1)	39 (4.7)
Homemaker	5 (1.8)	7 (2.6)	6 (2.2)	18 (2.2)
Retired	84 (30.7)	70 (25.5)	86 (31.2)	240 (29.1)
Not in employment due to disability	8 (2.9)	2 (0.7)	12 (4.4)	22 (2.7)
Not in employment due to long-term sickness	5 (1.8)	10 (3.6)	6 (2.2)	21 (2.6)
Unemployed	7 (2.6)	8 (2.9)	9 (3.3)	24 (2.9)
Student	4 (1.5)	7 (2.6)	3 (1.1)	14 (1.7)
No response	3 (1.1)	4 (1.5)	0 (0.0)	7 (0.9)
Household income				
Up to £10,000	33 (12.0)	28 (10.2)	27 (9.8)	88 (10.7)
£10,001–20,000	49 (17.9)	50 (18.2)	55 (19.9)	154 (18.7)
£20,001–40,000	87 (31.8)	85 (30.9)	91 (33.0)	263 (31.9)
£40,001 plus	97 (35.4)	103 (37.5)	93 (33.7)	293 (35.5)
No response	8 (2.9)	9 (3.3)	10 (3.6)	27 (3.3)
IMD decile[a] (median, IQR), N	7 (5–9), 273	6 (4–9), 270	7 (4–9), 270	7 (4–9), 813
RMDQ score[b] (median, IQR)	7 (3–11)	7 (3–12)	7 (3–12)	7 (3–11)
RMDQ Mean (SD)	7.7 (5.2)	8.1 (5.5)	7.9 (5.4)	7.9 (5.4)
Pain intensity[c] (mean, SD)				
Current pain	3.6 (2.1)	3.9 (2.2)	4.1 (2.1)	3.9 (2.1)
Least pain over last 2 weeks	2.9 (2.2)	3.1 (2.4)	3.4 (2.3)	3.1 (2.3)
Average pain over last 2 weeks	4.6 (1.9)	4.9 (2.1)	5.0 (2.0)	4.8 (2.0)
Days in pain over last 4 weeks (median, IQR)	14 (6–28)	12 (6–25)	15 (6.5–27.5)	14 (6–27)
How long since whole month without pain (n, %)				
< 3 months	48 (17.5)	48 (17.5)	47 (17.0)	143 (17.3)
3–6 months	38 (13.9)	24 (8.7)	48 (17.4)	110 (13.3)
7–12 months	43 (15.7)	53 (19.3)	44 (15.9)	140 (17.0)
1–2 years	46 (16.8)	33 (12.0)	36 (13.0)	115 (13.9)

TABLE 3 Baseline characteristics (*continued*)

	Usual care alone (*N* = 274)	SupportBack (*N* = 275)	SupportBack + telephone support (*N* = 276)	Overall (*N* = 825)
3–5 years	41 (15.0)	49 (17.8)	38 (13.8)	128 (15.5)
6–10 years	18 (6.6)	28 (10.2)	24 (8.7)	70 (8.5)
Over 10 years	38 (13.9)	38 (13.8)	37 (13.4)	113 (13.7)
No response	2 (0.7)	2 (0.7)	2 (0.7)	6 (0.7)
STarT Back risk group*[d] *(n/N, %)				
Low risk	125/250 (50.0)	127/256 (49.6)	118/257 (45.9)	370/763 (48.5)
Medium risk	74/250 (29.6)	71/256 (27.7)	94/257 (36.6)	239/763 (31.3)
High risk	51/250 (20.4)	58/256 (22.7)	45/257 (17.5)	154/763 (20.2)
STarT Back score*[d] *(mean, SD)	3.8 (2.3)	3.8 (2.4)	4.0 (2.2)	3.9 (2.3)
PSEQ*[e] *(median, IQR)	42 (29–50)	40 (31–49)	41 (30–49)	41 (30–50)
Self-efficacy for LBP*[f] *(mean, SD)	2.4 (1.0)	2.3 (1.0)	2.3 (1.0)	2.3 (1.0)
N	267	260	264	791
Godin physical activity scale*[g] *(median, IQR)	21 (10–42)	21 (10–41)	22 (11–42)	21 (11–42)
N	249	250	254	753
Insufficiently active (*n*, %)	81 (32.5)	81 (32.4)	74 (29.1)	236 (31.2)
Moderately active (*n*, %)	49 (19.7)	51 (20.4)	56 (22.1)	156 (20.7)
Active (*n*, %)	119 (47.8)	118 (47.2)	124 (48.8)	361 (47.9)
Back-related physical activity*[h] *(n, %)				
0 days	49 (17.9)	53 (19.3)	46 (16.7)	148 (17.9)
1–2 days	71 (25.9)	82 (29.8)	73 (26.5)	226 (27.4)
3–4 days	55 (20.1)	67 (24.4)	78 (28.3)	200 (24.2)
5 + days	99 (36.1)	73 (26.6)	79 (28.6)	251 (30.4)
TSK*[i] *(mean, SD)	24.0 (7.4)	24.0 (7.1)	24.2 (6.9)	24.1 (7.1)
N	253	262	257	772
PCS (median, IQR)	14 (6–24)	13 (5–26)	13 (6–26)	13 (6–25)
N	252	243	252	747
PHQ-4 category*[k] *(n/N, %)				
Normal	152/266 (57.1)	162/266 (60.5)	152/273 (55.7)	465/805 (57.8)
Mild	64/266 (24.1)	60/266 (22.6)	63/273 (23.1)	187/805 (23.2)
Moderate	26/266 (9.8)	27/266 (10.2)	36/273 (13.2)	89/805 (11.1)
Severe	24/266 (9.0)	18/266 (6.8)	22/273 (8.1)	64/805 (7.8)

continued

TABLE 3 Baseline characteristics (*continued*)

	Usual care alone (*N* = 274)	SupportBack (*N* = 275)	SupportBack + telephone support (*N* = 276)	Overall (*N* = 825)
PHQ-4 anxiety (n, %)	56 (20.9)	52 (19.1)	63 (22.9)	171 (21.0)
N	268	272	275	815
PHQ-4 depression (n, %)	52 (19.3)	48 (17.8)	61 (22.3)	161 (19.8)
N	270	269	274	813

GCSE, General Certificate of Secondary Education; TSK, Tampa Scale of Kinesiophobia.
a IMD decile 1 (highest deprivation) to 10 (lowest deprivation.
b RMDQ – on scale 0–24 with higher scores indicating worse physical disability due to LBP.
c Pain intensity on a scale of 0 (none) to 10 (worst).
d STarT Back risk score on a scale 0 (lowest) to 9 (highest) risk of persistent disability due to back pain.
e PSEQ on a scale 0–60, with higher scores indicating greater confidence to manage pain.
f Self-efficacy for LBP on a scale 0 (no confidence) to 4 (extremely confident).
g Godin physical activity scale: < 14 (insufficiently active), 14–23 (moderately active), > 24 (active).
h Back-related physical activity – physical activity over the last week with the aim of helping the back.
i TSK – on a scale of 11–44 with higher scores indicating greater fear of movement.
j PCS – on a scale of 0–52 with higher scores indicating more negative orientation towards pain.
k PHQ-4 screening tool for anxiety and depression.

moderate, with a mean Tampa Scale of Kinesiophobia (TSK) score of 24 on a scale of 11–44. Negative orientation towards pain was relatively low, with a median Pain Catastrophising Scale (PCS) score of 13 on a scale of 0–52. More than two-thirds of participants were active or moderately active on the Godin physical activity scale, and over half had done physical activity to aid their back at least 3–4 days in the past week. Approximately 20% of participants had scores indicating caseness for anxiety and 20% had scores indicating caseness for depression according to the Patient Health Questionnaire-4 (PHQ-4) screening tool. Participant characteristics were balanced across all three randomised groups.

Primary outcome analysis

A repeated-measures analysis of the RMDQ score over 6 weeks, 3, 6 and 12 months showed a small reduction in the RMDQ score in both the internet intervention and internet intervention plus support groups compared to usual care [adjusted mean difference −0.5 with 97.5% confidence interval (CI) −1.2 to 0.2; $p = 0.085$ for internet intervention vs. usual care; −0.6, 97.5% CI −1.2 to 0.1; $p = 0.048$ for internet intervention plus support vs. usual care]. These differences were not significant at a significance level of 0.025 (*Table 4*, *Figure 3*).

Complier-average causal effect primary outcome sensitivity analysis

Adherence was defined as completing at least session 1 for the internet intervention arm (66%) and completing at least session 1 and receiving at least two out of three physiotherapist phone calls in the internet intervention plus support

TABLE 4 Primary outcome – RMDQ (repeated measures)

Outcome	Randomised group	N	Follow-up at 12 months mean (SD)	Unadjusted mean difference (97.5% CI)	Adjusted[a] mean difference (97.5% CI)
RMDQ repeated measures over 12 months	Usual care	249	5.6 (5.6)		
	Intervention	245	4.9 (5.4)	−0.2 (−1.0 to 0.7)	−0.5 (−1.2 to 0.2)
	Intervention + support	242	4.7 (5.1)	−0.6 (−1.5 to 0.3)	−0.6 (−1.2 to 0.1)

a Adjusted for baseline score, recruiting centre, age, pain duration, STarT Back risk group.

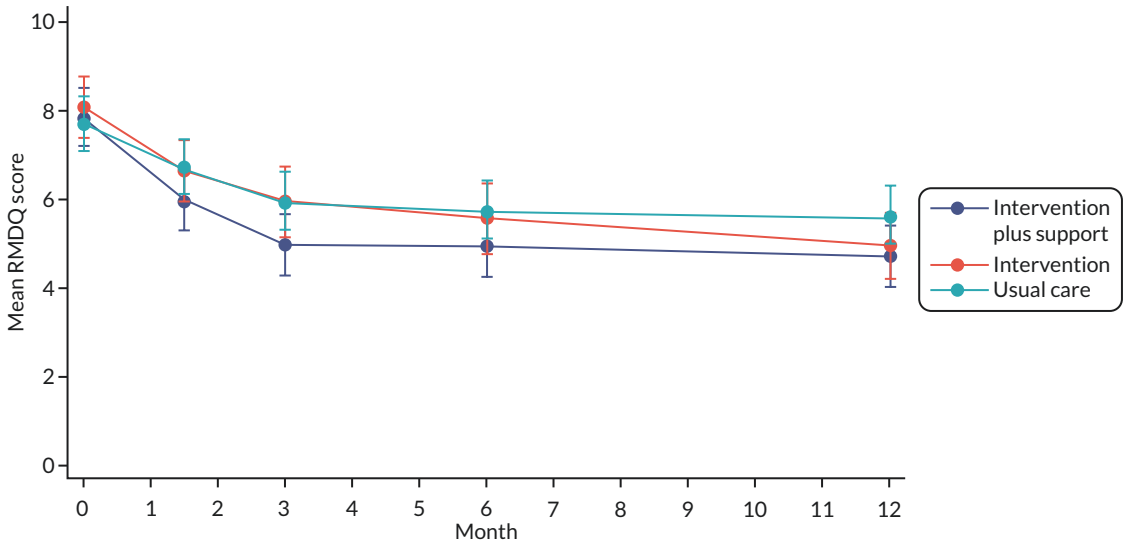

FIGURE 3 Roland–Morris Disability Questionnaire over 12 months.

arm (67%). An adherence-adjusted analysis gave CACE estimates slightly larger than the intention-to-treat estimates but there were still no significant differences between groups at a significance level of 0.025 (internet intervention vs. usual care −0.8, 97.5% CI −1.7 to 0.1; $p = 0.049$; internet intervention + support −0.7, 97.5% CI −1.6 to 0.1; $p = 0.050$) (*Table 5*).

Secondary analyses related to primary outcome

Small mean differences in RMDQ were observed at each of the 4 time points (adjusted mean difference at 6 weeks −0.4, 95% CI −1.0 to 0.3 for internet intervention vs. usual care; −0.7, 95% CI −1.3 to −0.02 for internet intervention plus support vs. usual care) (*Table 6*). The proportion achieving at least a 30% reduction in RMDQ score at 12 months from baseline was significantly higher in both SupportBack and SupportBack with telephone-support arms at 61%, compared to 51% in the usual care alone arm [odds ratio (OR) 1.8, 95% CI 1.2 to 2.7 for SupportBack vs. usual care; OR 1.5, 95% CI 1.0 to 2.3 for SupportBack plus telephone support vs. usual care]. This corresponds to a number needed to treat (NNT) of 10, 95% CI 6 to 82 in the SupportBack group and a NNT of 10, 95% CI 5 to 72 in the SupportBack with telephone-support group.

TABLE 5 Adherence-adjusted (CACE) analysis

Outcome	Randomised group	Unadjusted CACE (97.5% CI)	Adjusted[a] CACE (97.5% CI)
RMDQ repeated measures over 52 weeks	Usual care		
	Intervention	−0.2 (−1.7 to 1.2)	−0.8 (−1.7 to 0.1)
	Intervention + telephone support	−0.8 (−2.1 to 0.5)	−0.7 (−1.6 to 0.1)

a Adjusted for baseline score, recruiting centre, age, pain duration, STarT Back risk group.

Note
Compliance is defined as completing at least session 1 for intervention arm, and in addition receiving at least two out of three phone calls for intervention + support arm.

TABLE 6 Further analysis of RMDQ outcome

Outcome	Randomised group	*N*	Follow-up mean (SD)	Unadjusted mean difference (95% CI)	Adjusted[a] mean difference (95% CI)
RMDQ at 6 weeks					
	Usual care	239	6.7 (5.5)		
	Intervention	219	6.7 (5.5)	0.04 (−0.9 to 1.0)	−0.4 (−1.0 to 0.3)
	Intervention + telephone support	229	6.0 (5.1)	−0.7 (−1.7 to 0.3)	**−0.7 (−1.3 to −0.02)**
RMDQ at 3 months					
	Usual care	219	5.9 (5.4)		
	Intervention	187	5.9 (5.6)	0.04 (−1.0 to 1.1)	−0.3 (−1.1 to 0.5)
	Intervention + telephone support	192	5.0 (4.9)	−0.9 (−2.0 to 0.1)	−0.7 (−1.5 to 0.1)
RMDQ at 6 months					
	Usual care	217	5.7 (5.6)		
	Intervention	184	5.6 (5.6)	−0.1 (−1.2 to 0.9)	−0.5 (−1.3 to 0.3)
	Intervention + telephone support	188	4.9 (4.7)	−0.8 (−1.8 to 0.3)	−0.7 (−1.5 to 0.1)
RMDQ at 12 months					
	Usual care	223	5.6 (5.6)		
	Intervention	215	4.9 (5.4)	−0.6 (−1.7 to 0.4)	**−1.1 (−1.9 to −0.3)**
	Intervention + telephone support	214	4.7 (5.1)	−0.9 (−1.9 to 0.1)	−0.6 (−1.4 to 0.2)

Outcome	Randomised group	Number (%)	Unadjusted OR (95% CI)	Adjusted[a] OR (95% CI)
Proportion achieving at least 30% reduction in RMDQ				
	Usual care	109 (50.5%)		
	Intervention	126 (61.2%)	1.5 (1.1 to 2.3)	**1.8 (1.2 to 2.7)**
	Intervention + telephone support	124 (61.4%)	1.6 (1.1 to 2.3)	**1.5 (1.0 to 2.3)**

a Adjusted for baseline score, recruiting centre, age, pain duration, STarT Back risk group; **bold, significance at $p < 0.05$.**

Subgroup analysis for primary outcome

There were no significant differences in the treatment effects between the three STarT Back risk groups (*Table 7*). For example, the treatment effect for the intervention plus support group was similar in those at high risk of poor outcome compared to those at low risk (mean difference −1.2 vs. −0.6), and this difference was not statistically significant (adjusted interaction −0.6, 95% CI −2.2 to 0.9). Those with chronic LBP for more than 1 year appear to receive slightly greater benefit from the intervention without support than those with acute LBP lasting < 3 months (mean difference −1.0 vs. 0.9 for the intervention without support arm), but the difference between these treatment effects was not statistically significant (adjusted interaction −1.1, 95% CI −2.7 to 0.5). No significant differences in treatment effects by deprivation (IMD quintile) were observed.

TABLE 7 Subgroup analyses for RMDQ

Subgroup	Randomised group	RMDQ – mean difference within subgroup	Unadjusted interaction term (95% CI)	Adjusted[a] interaction term (95% CI)
STarT Back risk group				
Low risk	Usual care	–	–	–
	Intervention	−0.5 (−1.2 to 0.2)	REF1	REF1
	Intervention + telephone support	−0.6 (−1.3 to 0.1)	REF2	REF2
Medium risk	Usual care	–	–	–
	Intervention	−0.2 (−1.9 to 1.4)	0.2 (−1.5 to 1.9)	−0.2 (−1.5 to 1.1)[a]
	Intervention + telephone support	−0.4 (−2.0 to 1.1)	0.1 (−1.6 to 1.8)	0.2 (−1.1 to 1.5)[b]
High risk	Usual care	–	–	–
	Intervention	0.8 (−1.4 to 3.0)	1.3 (−0.6 to 3.2)	0.9 (−0.6 to 2.4)[a]
	Intervention + telephone support	−1.2 (−3.6 to 1.2)	−0.7 (−2.7.1.3)	−0.6 (−2.2 to 0.9)[b]
Pain duration at baseline				
< 3 months	Usual care	–	–	–
	Intervention	0.9 (−1.1 to 2.9)	REF1	REF1
	Intervention + telephone support	0.4 (−1.6 to 2.4)	REF2	REF2
4 months–1 year	Usual care			
	Intervention	0.9 (−0.3 to 2.1)	−0.03 (−2.6 to 2.6)	0.5 (−1.3 to 2.2)[a]
	Intervention + telephone support	−0.5 (−1.7 to 0.7)	−0.8 (−3.4 to 1.7)	−0.02 (−1.8 to 1.7)[b]
> 1 year	Usual care	–	–	–
	Intervention	−1.0 (−2.3 to 0.2)	−1.9 (−4.3 to 0.4)	−1.1 (−2.7 to 0.5)[a]
	Intervention + telephone support	−0.6 (−1.9 to 0.7)	−0.9 (−3.3 to 1.5)	−0.2 (−1.9 to 1.4)[b]
IMD				
2nd to 5th quintiles	Usual care	–	–	–
	Intervention	−0.7 (−1.5 to 0.2)	REF1	REF1
	Intervention + telephone support	−0.02 (−0.9 to 0.9)	REF2	REF2
1st quintile (most deprived)	Usual care	–	–	–
	Intervention	−2.0 (−5.2 to 1.3)	−2.2 (−4.9 to 0.5)	−1.2 (−3.1 to 0.6)
	Intervention + telephone support	−0.8 (−4.2 to 2.7)	−0.3 (−3.1 to 2.5)	−0.2 (−2.1 to 1.7)

a Compared to REF1.
b Compared to REF2.

Secondary outcomes

Reductions in pain intensity (current, least and average over the last 2 weeks) of between 0.2 and 0.3 points on a scale of 0–10 were observed in the intervention without support and intervention plus support groups compared to usual care. A statistically significant reduction in days in pain over the last 4 weeks of just over 1 day was observed in both intervention without support and intervention plus support groups compared to usual care. There was no significant difference in the self-efficacy for LBP score. SupportBack-related physical activity was significantly higher in the intervention plus support group by about 1 day per week compared to usual care (*Table 8*).

TABLE 8 Secondary outcomes (repeated measures over 12 months)

Outcome	Randomised group	*N*	Follow-up at 12 months mean (SD)	Unadjusted mean difference (95% CI)	Adjusted[a] mean difference (95% CI)
Pain intensity[b]					
Current pain					
	Usual care	249	3.0 (2.5)		
	Intervention	245	3.0 (2.4)	−0.06 (−0.42 to 0.31)	−0.26 (−0.52 to 0.01)
	Intervention + telephone support	242	2.7 (2.3)	−0.05 (−0.41 to 0.31)	−0.26 (−0.52 to 0.01)
Least pain over last 2 weeks					
	Usual care	249	2.5 (2.5)		
	Intervention	245	2.3 (2.2)	−0.05 (−0.38 to 0.28)	-0.18 (−0.43 to 0.08)
	Intervention + telephone support	242	2.1 (2.0)	−0.17 (−0.51 to 0.16)	**−0.30 (−0.55 to −0.05)**
Average pain over last 2 weeks					
	Usual care	249	3.6 (2.5)		
	Intervention	245	3.4 (2.5)	−0.04 (−0.38 to 0.30)	−0.20 (−0.46 to 0.07)
	Intervention + telephone support	242	3.1 (2.2)	−0.14 (−0.48 to 0.20)	−0.22 (−0.49 to 0.05)
Days in pain over last 4 weeks					
	Usual care	249	11.0 (10.2)		
	Intervention	245	9.8 (9.8)	−1.5 (−2.9 to −0.04)	**−1.2 (−2.4 to −0.01)**
	Intervention + telephone support	242	9.0 (9.5)	−1.3 (−2.7 to 0.2)	**−1.3 (−2.5 to −0.2)**
Self-efficacy for LBP[c]					
	Usual care	249	2.8 (1.0)		
	Intervention	245	2.8 (1.0)	0.04 (−0.11 to 0.19)	0.06 (−0.06 to 0.19)
	Intervention + telephone support	242	2.9 (1.1)	0.08 (−0.07 to 0.23)	0.06 (−0.06 to 0.19)

TABLE 8 Secondary outcomes (repeated measures over 12 months) (*continued*)

Outcome	Randomised group	*N*	Follow-up at 12 months mean (SD)	Unadjusted mean difference (95% CI)	Adjusted[a] mean difference (95% CI)
Back-related physical activity (days over last week)[d]					
	Usual care	246	3.0 (2.3)		
	Intervention	236	3.5 (2.1)	0.1 (−0.2 to 0.5)	0.3 (−0.1 to 0.6)
	Intervention + telephone support	237	3.4 (2.2)	0.7 (0.3 to 1.1)	**0.8 (0.5 to 1.1)**

a Adjusted for baseline score, recruiting centre, age, pain duration, STarT Back risk group; **bold, significance at $p < 0.05$.**
b Pain intensity on a scale of 0 (none) to 10 (worst).
c Self-efficacy for LBP on a scale 0 (no confidence) to 4 (extremely confident).
d Back-related physical activity – physical activity over the last week with the aim of helping the back.

A statistically significant increase in self-efficacy for pain (PSEQ) at 6 weeks of about 2 points was observed in both intervention without support and intervention plus support groups compared to usual care, but this was not sustained at 12 months. There was a statistically significant improvement of about 1–2 points on the TSK at 12 months in both intervention without support and intervention plus support arms compared to usual care. There was no significant difference in pain catastrophising between groups. There was a statistically significant improvement in enablement of 0.7 points on a scale of 1–7 at 6 weeks in the intervention plus support group compared to usual care. This corresponds to moving from 'neutral' to 'slightly agree' in terms of ability to cope with back pain. There was a statistically significant improvement in satisfaction in both intervention without support and intervention plus support compared to usual care. The improvement in the intervention plus support arm was about 1 point on a scale of 0 (not at all satisfied) to 4 (very satisfied). There were no statistically significant differences between randomised groups in physical activity or anxiety at 12 months, but those in the intervention without support group were more likely to be depressed than those in the usual care group. This is likely to be due to attrition bias rather than a direct negative effect of the intervention, as a relatively high proportion of the intervention arm who were depressed at baseline were missing PHQ-4 at 12 months (60%) compared to usual care (43%) (*Table 9*).

TABLE 9 Other secondary outcomes

Outcome	Randomised group	*N*	Follow-up mean (SD)	Unadjusted mean difference (95% CI)	Adjusted[a] mean difference (95% CI)
PSEQ[b] at 6 weeks					
	Usual care	230	42.0 (14.2)		
	Intervention	206	43.5 (12.8)	1.5 (−1.0 to 4.0)	**1.8 (0.1 to 3.5)**
	Intervention + telephone support	211	43.7 (13.0)	1.7 (−0.8 to 4.2)	**2.4 (0.7 to 4.1)**
PSEQ at 12 months					
	Usual care	206	43.8 (14.4)		
	Intervention	202	45.1 (13.9)	1.3 (−1.3 to 4.1)	1.3 (−0.9 to 3.4)
	Intervention + telephone support	202	46.0 (13.8)	2.3 (−0.4 to 5.0)	1.6 (−0.6 to 3.8)

continued

TABLE 9 Other secondary outcomes (*continued*)

Outcome	Randomised group	*N*	Follow-up mean (SD)	Unadjusted mean difference (95% CI)	Adjusted[a] mean difference (95% CI)
TSK[c] at 12 months					
	Usual care	176	22.5 (8.1)		
	Intervention	162	20.9 (7.2)	−1.6 (−3.1 to 0.03)	**−2.0 (−3.3 to −0.8)**
	Intervention + telephone support	163	20.7 (6.7)	−1.7 (−3.3 to −0.2)	**−1.3 (−2.6 to −0.1)**
PCS[d] at 12 months					
	Usual care	174	11.5 (12.1)		
	Intervention	159	11.0 (11.9)	−0.5 (−3.0 to 2.0)	−0.5 (−2.5 to 1.6)
	Intervention + telephone support	161	10.5 (10.9)	−1.0 (−3.5 to 1.5)	−0.7 (−2.7 to 1.4)
Patient Enablement Index[e] at 6 weeks					
	Usual care	216	4.1 (1.6)		
	Intervention	205	4.3 (1.6)	0.2 (−0.1 to 0.5)	0.1 (−0.2 to 0.4)
	Intervention + telephone support	214	4.8 (1.5)	0.7 (0.4 to 1.0)	**0.7 (0.4 to 1.0)**
Patient Enablement Index at 12 months					
	Usual care	182	4.4 (1.6)		
	Intervention	166	4.4 (1.7)	0.02 (−0.3 to 0.4)	0.05 (−0.3 to 0.4)
	Intervention + telephone support	168	4.5 (1.7)	0.04 (−0.3 to 0.4)	-0.03 (−0.4 to 0.3)
Satisfaction[f] at 6 weeks					
	Usual care	204	2.1 (1.1)		
	Intervention	154	2.4 (1.1)	0.4 (0.2 to 0.6)	**0.3 (0.1 to 0.6)**
	Intervention + telephone support	181	3.1 (0.9)	1.0 (0.8 to 1.3)	**1.0 (0.8 to 1.2)**

Outcome	Randomised group	Follow-up at 12 months (*n*, %)	Unadjusted OR (95% CI)	Adjusted[a] OR (95% CI)
Godin physical activity[g] – moderately active or active at 12 months				
	Usual care	104/140 (74.3)		
	Intervention	87/115 (75.7)	1.1 (0.6 to 1.9)	1.2 (0.6 to 2.4)
	Intervention + telephone support	81/111 (73.0)	0.9 (0.5 to 1.6)	0.8 (0.4 to 1.7)
PHQ-4 anxiety[h] at 12 months				
	Usual care	33/193 (17.1)		
	Intervention	34/171 (19.9)	1.2 (0.7 to 2.0)	1.6 (0.8 to 3.2)
	Intervention + telephone support	28/171 (16.4)	0.9 (0.5 to 1.6)	1.3 (0.7 to 2.6)

TABLE 9 Other secondary outcomes (*continued*)

Outcome	Randomised group	Follow-up at 12 months (*n*, %)	Unadjusted OR (95% CI)	Adjusted[a] OR (95% CI)
PHQ-4 depression[h] at 12 months				
	Usual care	31/190 (16.3)		
	Intervention	33/171 (19.3)	1.2 (0.7 to 2.1)	**2.2 (1.1 to 4.7)**
	Intervention + telephone support	27/174 (15.5)	0.9 (0.5 to 1.7)	1.0 (0.4 to 2.0)

a Adjusted for baseline score, recruiting centre, age, pain duration, STarT Back risk group; **bold, significance at $p < 0.05$.**
b PSEQ on a scale 0–60, with higher scores indicating greater confidence to manage pain.
c TSK – on a scale of 11–44 with higher scores indicating greater fear of movement.
d PCS – on a scale of 0–52 with higher scores indicating more negative orientation towards pain.
e Patient Enablement Index – on a scale of 1–7, where 1 = strongly disagree and 7 = strongly agree with higher scores indicating greater ability to cope with condition.
f Satisfaction with care for back pain – on a scale of 0–4 where 0 = not at all satisfied and 4 = very satisfied.
g Godin physical activity scale: < 14 (insufficiently active), 14–23 (moderately active), > 24 (active).
h PHQ-4 screening tool for anxiety and depression.

A higher percentage of participants were in the low-risk STarT Back group at 12 months compared to baseline, and percentages were broadly similar across groups (*Table 10*).

TABLE 10 Descriptive outcomes

	Usual care	Intervention	Intervention + telephone support
STarT Back[a] risk group at baseline (n, %)			
Low risk	125 (50.0)	127 (49.6)	118 (45.9)
Medium risk	74 (29.6)	71 (27.7)	94 (36.6)
High risk	51 (20.4)	58 (22.7)	45 (17.5)
STarT Back[a] risk group at 12 months N (n, %)	164	168	179
Low risk	119 (66.5)	111 (66.1)	118 (72.0)
Medium risk	39 (21.8)	37 (22.0)	33 (20.1)
High risk	21 (11.7)	20 (11.9)	13 (7.9)
Over-the-counter medication 6 months N (n, %)	214	180	184
Never	74 (34.6)	73 (40.6)	69 (37.5)
Occasionally	44 (20.6)	31 (17.2)	43 (23.4)
Once a week	37 (17.3)	28 (15.6)	36 (19.6)
2–4 per week	14 (6.5)	9 (5.0)	10 (5.4)
Every day	45 (21.0)	39 (21.7)	26 (14.1)
Over-the-counter medication 12 months N (n, %)	194	173	170
Never	74 (38.1)	69 (39.9)	55 (32.4)
Occasionally	33 (17.0)	36 (20.8)	47 (27.7)
Once a week	40 (20.6)	34 (19.7)	39 (22.9)
2–4 per week	15 (7.7)	9 (5.2)	8 (4.7)
Every day	32 (16.5)	25 (14.5)	21 (12.4)

a STarT Back risk group – risk of persistent disability due to back pain.

The number of days taken off work data were highly skewed and were therefore analysed as a dichotomous variable, time taken off work (yes/no). There were no statistically significant differences in time taken off work between randomised groups (*Table 11*). No statistically significant differences were observed in GP, physiotherapist or secondary care consultations, or in LBP-related prescriptions between randomised groups (*Table 12*).

TABLE 11 Time off work

Outcome	Randomised group	Follow-up (*n*, %)	Unadjusted OR (95% CI)	Adjusted[a] OR (95% CI)
Time off work due to back pain at 6 months				
	Usual care	30/131 (22.9)		
	Intervention	25/107 (23.4)	1.0 (0.6 to 1.9)	1.3 (0.6 to 2.8)
	Intervention + telephone support	21/101 (20.8)	0.9 (0.5 to 1.7)	1.0 (0.5 to 2.2)
Time off work due to back pain at 12 months				
	Usual care	12/109 (11.0)		
	Intervention	12/103 (11.7)	1.1 (0.5 to 2.5)	1.1 (0.4 to 3.1)
	Intervention + telephone support	13/100 (13.0)	1.2 (0.5 to 2.8)	1.5 (0.5 to 4.1)

a Adjusted for baseline number, recruiting centre, age, pain duration, STarT Back risk group.

TABLE 12 Primary and secondary consultations at 12 months

Outcome at 12 months	Randomised group	*N*	Follow-up at 12 months	Unadjusted OR (95% CI)	Adjusted[a] OR (95% CI)
GP consultation for back pain (n, %)					
	Usual care		83/228 (36.4)		
	Intervention		87/237 (36.7)	1.0 (0.7 to 1.5)	1.0 (0.7 to 1.5)
	Intervention + telephone support		86/236 (36.4)	1.0 (0.7 to 1.5)	0.9 (0.6 to 1.4)
Physiotherapist consultation (n, %)					
	Usual care		40/223 (17.9)		
	Intervention		42/221 (19.0)	1.1 (0.7 to 1.7)	1.0 (0.6 to 1.7)
	Intervention + telephone support		43/226 (19.0)	1.1 (0.7 to 1.7)	1.0 (0.6 to 1.6)
Secondary care consultation (n, %)					
	Usual care		32/244 (13.1)		
	Intervention		37/249 (14.9)	1.2 (0.7 to 1.9)	1.1 (0.7 to 1.9)
	Intervention + telephone support		36/246 (14.6)	1.1 (0.7 to 1.9)	1.1 (0.7 to 1.9)
Back-pain-related prescriptions (mean, SD)				**Unadjusted IRR (95% CI)**	**Adjusted[a] IRR (95% CI)**
	Usual care	220	1.8 (4.0)		
	Intervention	229	1.9 (3.3)	1.1 (0.7 to 1.6)	0.9 (0.6 to 1.4)
	Intervention + telephone support	230	1.8 (3.7)	1.1 (0.7 to 1.5)	0.8 (0.6 to 1.2)

a IRR, incidence rate ratio, OR, odds ratio, adjusted for baseline number, recruiting centre, age, pain duration, STarT Back risk group.

Additional sensitivity analysis for the primary outcome

A sensitivity analysis using multiple imputation for missing RMDQ data gave similar results to the primary analysis from a linear mixed model. This assumes that the missing data are MAR given the observed data. The additional analyses assuming that the missing RMDQ scores were on average 1.5 points worse or better than the observed RMDQ scores gave broadly similar results to the MAR imputation analysis. These provide lower and upper bounds to the possible treatment effects (*Table 13*).

A descriptive analysis to explore differences in the RMDQ outcome before and during the COVID-19 pandemic was carried out. The pre-COVID-19 period was defined as before 23 March 2020, and 'during' COVID-19 was defined up to 19 July 2021. There was no evidence of clinically meaningful variation between these time periods in the RMDQ outcomes at either baseline or 6 weeks (*Table 14*).

TABLE 13 Sensitivity analyses for missing RMDQ data (repeated measures over 12 months)

Outcome	Randomised group	RMDQ at 12 months mean (SD)	Unadjusted mean difference (97.5% CI)	Adjusted[a] mean difference (97.5% CI)
Multiple imputation				
MAR	Usual care	5.6 (5.8)		
	Intervention	5.0 (5.7)	−0.1 (−1.1 to 0.9)	−0.4 (−1.1 to 0.2)
	Intervention + telephone support	5.1 (5.9)	−0.5 (−1.5 to 0.5)	−0.5 (−1.2 to 0.2)
MNAR missing 1.5 points worse				
	Usual care	6.0 (5.9)		
	Intervention	5.7 (5.8)	0.07 (−0.9 to 1.1)	−0.2 (−0.9 to 0.5)
	Intervention + telephone support	5.7 (6.0)	−0.3 (−1.3 to 0.7)	−0.4 (−1.1 to 0.3)
MNAR missing 1.5 points better				
	Usual care	5.1 (5.8)		
	Intervention	4.4 (5.8)	−0.3 (1.1 to 0.5)	**−0.6 (−1.2 to −0.04)**
	Intervention + telephone support	4.5 (5.6)	−0.6 (−1.2 to 0.2)	**−0.7 (−1.3 to −0.1)**

MNAR, missing not at random. **Bold, significance at $p < 0.05$.**
a Adjusted for baseline score, recruiting centre, age, pain duration, STarT Back risk group.

TABLE 14 Roland–Morris Disability Questionnaire scores during COVID-19 pandemic period

	Pre-COVID			During COVID		
	Usual care	Intervention	Intervention + telephone support	Usual care	Intervention	Intervention + telephone support
RMDQ at baseline (mean, SD)	7.7 (5.1)	8.2 (5.6)	7.8 (5.3)	7.8 (5.7)	7.9 (5.3)	8.0 (5.7)
RMDQ at 6 weeks (mean, SD)	6.4 (5.5)	7.0 (5.5)	5.9 (5.0)	7.0 (5.4)	6.2 (5.4)	6.1 (5.4)

Serious adverse events

There were seven unrelated serious adverse events (SAEs) reported during the trial: three in the usual care group, one in the SupportBack group and three in the SupportBack with telephone-support group. These SAEs included an unrelated death in the SupportBack with telephone-support group (*Table 15*). There were also seven adverse events reported that did not meet seriousness criteria. These included five operations deemed non-serious by a lead clinician at the practice (three in the SupportBack with telephone-support group, two in the SupportBack group), one report of increased back pain following a car accident (SupportBack group) and one report of increased leg-to-ankle pain which the participant stated stopped them taking part in the intervention as they would have liked (SupportBack with telephone support). As part of the notes review, there were 38 hospital stays listed for usual care (34 patients), 44 stays listed (39 patients) for SupportBack and 52 stays (42 patients) listed for SupportBack with telephone support. All were assessed clinically, and none were deemed related to the intervention. See *Appendix 3* for details of the notes review hospitalisations.

TABLE 15 Adverse events reported during the trial

	Usual care alone (*N* = 274)	SupportBack (*N* = 275)	SupportBack + telephone support (*N* = 276)
Unrelated SAEs			
Left inferior pubic rami fracture left clavicle fracture	1	0	0
Prostatectomy	0	0	1
Fracture to right ankle	1	0	0
L3/L4 foraminal compression	1	0	0
Lumbar microdiscectomy for L5–SI disc prolapse and nerve root compression.	0	0	1
COVID pneumonitis	0	1	0
Death	0	0	1
Reported adverse events deemed non-serious			
Non-serious operations	0	2	3
Back pain following car accident	0	1	0
Leg pain	0	0	1

Chapter 4 Qualitative process study – participants

Overview and aims

In this nested qualitative study, we aimed to explore participants' experiences of the interventions and any impact they may have had on their activity and LBP. We wished to understand: (1) how participants used the interventions (implementation); (2) possible mechanisms of change based on their described experience; (3) whether contextual factors, such as previous pain experienced appeared to be related to themes developed from the data. In this nested study, we went beyond our previous qualitative work on SupportBack,[24] exploring the impact of the interventions at varying time points since randomisation. We interviewed participants after 3, 6 and 12 months since they first accessed the intervention. Different participants were interviewed at each time point, enabling exploration of whether prominent impacts or descriptions of utility change the further participants are from the interactive aspect of SupportBack. Interviews beyond 12 months allowed us to explore any longer-term impacts of the intervention.

Methods

Design

This was an in-depth qualitative interview study nested within the SB2 trial. We interviewed different participants after 3, 6 and 12 months post randomisation to the trial arms.

Participants

We purposively sampled SB2 participants across the different arms of the trial. We aimed to ensure diversity in age, gender and symptom severity (physical function, pain duration). We also sampled to recruit participants with high and low usage of the internet intervention, and high and low engagement with the physiotherapist telephone support. Drawing on the concept of information power,[48] as we recruited to each time point, we monitored data to ensure diversity and breadth of responses from a range of participants. We monitored specificity of responses and the strength of the dialogue.

Interviews

Participants who had provided consent for interviews as part of the trial were interviewed by telephone by experienced female qualitative researchers working with the project team (SH pre-doctoral, MS with a PhD). There was no prior relationship with interviewers prior to the interview. Participants knew the interviews wished to find out more about their experience of the study. Interview audio was recorded and transcribed verbatim. Interviewers used a semistructured interview guide comprising of open-ended questions and prompts to be used flexibly (available on request), as well as writing field notes and memos. Questions focused on participant experience of using the internet intervention, receiving telephone support and experiences in usual care. Open-ended questions encouraged participants to share any perceived impact (or lack of impact) on pain and physical activity, along with descriptions of their history of LBP, previous relevant treatment experiences and any concurrent treatments/processes. The interview topic guides were very similar for 3- and 6-month interviews. For the 12-month interviews, several new questions were added regarding long-term implementation of strategies.

Analysis

Interview data were transcribed verbatim. We used a thematic analytic approach drawing on aspects of the approach outlined by Joffe and Yardley[49] and Braun and Clarke.[50] The presented analysis was developed from independent double coding of the 46 interviews by SH and AG [using NVivo software (QSR International, Warrington, UK)], early discussion of initial findings from the coding with the wider team (including LR, LY, PL and our public contributors MW FD), development of a coding manual, followed by ongoing discussion between AG and SH regarding salient patterns. An initial draft was produced by AG. We then engaged in an additional round of discussion of the developed themes with our public contributors and LR, SH and LY. We discussed descriptions and agreed their interpretation. The analytic approach presented integrates qualitative description[51] with initial interpretive analysis, drawing on the latter

particularly when considering mechanisms related to impact, or lack of impact, on back pain-related function or pain. Despite the growing period from the interactive part of the intervention, the participants' responses to the questions in the topic guide remained very similar across the timepoints. Consequently, they were analysed together. Where we focus the analyses on long-term impacts and implementation, the data drawn on are primarily from the 6- to 12-month interviews. Interviews continued until it was agreed that we had sufficient information power to meet the aims of this study. Member checking was not carried out. *Figure 4* provides an overview of the overarching themes that will be covered in turn.

Results

Ninety-two participants were invited to interview in total across three different time points within the study (3, 6 and 12 months). Forty-six participants agreed to interview (3 months *n* = 15, 6 months *n* = 14, 12 months *n* = 17). Interviews ranged in duration from 19 to 59 minutes. See *Table 16* for the baseline characteristics.

Figure 4 provides an overview of the developed themes that will be discussed in turn.

Previous pain and care contexts

In the SB2 trial we wished to explore the effect of the internet-based self-management packages on all those reporting LBP in primary care, without indicators of serious spinal pathology. We did not define a specific duration of LBP for those in the trial, such as acute, subacute or persistent/chronic. This was reflected in the diverse pain experiences participants described before entering the trial.

> *Okay, so I've had issues with my lower back for a long time going back to the early 1980s and I'm now 62. So my first incidence of time off work was in the early 1980s and it's been off and on since.*
>
> *K0504 3m, episode duration 3–5 years*

> *Yes, well, I have arthritis, I have it in my spine and I have it in my hips and I had my first hip problems, probably about 18 years ago and that was also part of – which gave back problems as well.*
>
> *S1206 12m, episode duration 3–5 years*

> *Well I've been experiencing mild to moderate back pain in the lower lumber region for approximately six to nine months and I, well unusually it's worse when I'm at rest.*
>
> *K0875 3m, episode duration 3–5 years (Telephone support)*

The majority participants reported having previous experience of physiotherapy before entering the trial. These participants were mixed about their experience, with some suggesting that exercises provided by physiotherapists had been useful. Others reported negative experiences of previous physiotherapy, describing that they had felt little impact.

> *I've had some physio and just sort of exercises and what have you to do, which, like I say, I am mindful, even though I don't still have the physio, I'm very mindful of the exercises that they gave me to sort of help.*
>
> *K0787 12m, episode duration 10 + years (Web alone)*

> *I: Have you tried any other treatments for your back pain at all? Before the trial?*
> *P: I had some physio at the hospital, which was before they did the MRI scan and then it didn't really do anything.*
>
> *S0650 3m, episode duration < 3 months (Telephone support)*

Due to recruitment through primary care, all participants described the care they had received from GPs before the trial. As with physiotherapy, experiences varied. The majority described negative or somewhat neutral/transactional experiences with their GPs. Participants described a lack of continuity of care, and perception of lack of interest in LBP,

TABLE 16 Baseline characteristics of nested qualitative study participants

Characteristics		
Gender, n (%)		
Male	26	56.5
Female	20	43.5
Age, mean (SD)	56.5	13.7
Education, n (%)		
No response	1	2.2
No formal qualifications	2	4.4
GCSE/O levels or similar	9	19.6
A levels or similar or ONC/OND	5	10.9
HNC/HND degree	8	17.4
Degree	9	20.0
Higher degree	3	6.5
Postgraduate degree	8	17.4
Other	1	2.2
Ethnicity, n (%)		
White	39	92.9
Black	3	7.1
Missing	4	8.7
Baseline RMDQ, mean (SD)	6.5	5.5
Pain duration, n (%)		
Less than 3 months	9	19.6
3–6 months	4	8.7
7–12 months	8	17.4
1–2 years	5	10.9
3–5 years	11	23.9
6–10 years	3	6.5
Over 10 years	6	13.0

GCSE, General Certificate of Secondary Education; HNC, Higher National Certificate; HND, Higher National Diploma; ONC, Ordinary National Certificate; OND, Ordinary National Diploma.

or the perception of a lack of options. The minority who reported positive experiences with GPs and care for their LBP appeared to do so in the context of a strong positive relationship with a particular GP.

> *My particular practice I'm with at the moment, every time I make an appointment I . . . There just seems to be no recognition of a condition. You go to your doctor's surgery and sit in a chair for an hour and then you see a different doctor every time and he just looks at your notes and, I don't know. They don't seem to have any kind of recognition.*
>
> *K720 12m, episode duration > 10 years (Telephone support)*

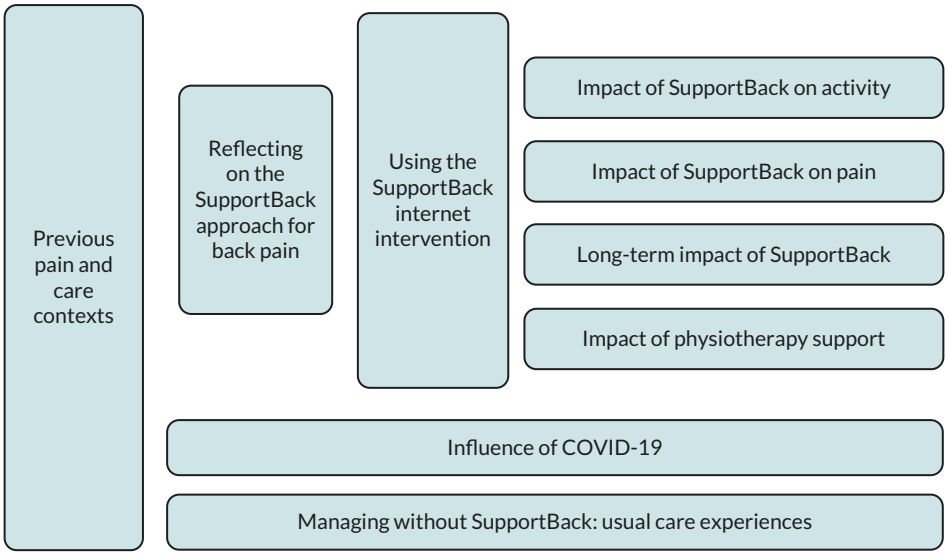

FIGURE 4 Schematic of overarching themes.

> *My GP was brilliant because I had ME as well several years ago and that wasn't a good time. Yes, my GP has been brilliant regarding my back because they know me because I used to work there and they know that I was a genuine person, that I was having issues with my back. I found them very supportive and sadly she's retired now but I've got another one.*
>
> *S1205 12m, episode duration 3–5 years*

Reflecting on the SupportBack approach

When considering the SupportBack approach that was offered generally, there was a full range of responses. Some had found the SupportBack approach to self-management to be beneficial and spoke positively about what was offered.

> *Yes, I think it's helped me tremendously. I've had very little support from anywhere else, other than if I've paid obviously for it – which I had done for physiotherapy and this other stuff – I'd be still there today, paying and not getting any better. The website gave me the initiative to look at these exercises which were available, and to do them, and in fact help me progress and boost my confidence up in myself with the pain.*
>
> *S1116 6m, episode duration 3–5 years (Web alone)*

> *I don't have anything negative to say. It's been, for me, a very overwhelmingly positive experience and I've really enjoyed it, yes. I'll probably stick with the exercises that I've got and keep going with them.*
>
> *S0625 3m, episode duration 6–10 years (Telephone support)*

Many of those who were interviewed offered somewhat of a middle-ground perspective, where they were generally positive, but there was uncertainty regarding any effects the intervention had.

> *There were some interesting points I think from the intro, like the intro at the beginning that I hadn't – it was nice; it was interesting to re-read and kind of, there's bits about [unclear words 0:12:46.6] most back pain can be cured from being more active and doing more exercise. So it's a good thing to hear. It's a good thing to make yourself keep active, but in terms of the particular exercises, I think I've probably been given most of them to do before. I didn't do them all, because I was on the trial, and there were probably exercises that were given there that I had been given before that I'd stopped doing, and then I started doing them again, but, yes, it wasn't – I didn't find . . . Having said that [laughs], I did this, and my back pain is much better now than it was before, so maybe it did help. My honest opinion is that I don't think it did, but there's some evidence there.*
>
> *S0882 3m, episode duration 3–5 years (Web alone)*

Alongside the above, some participants were 'underwhelmed' by what was offered. They reported that expectations were not met and they wanted more than what was offered.

> *Well, better than nothing, I suppose, but to be quite honest, the proof of the pudding is that I'm not sure it's achieved very much. I hesitate to say so because I'm sure SupportBack was done with the very best of intentions, but I think it had very limited – I think SupportBack, as it – with just the occasional telephone call and the ability to select some exercises, which I've done fairly regularly, I don't think it was ever likely to make any vast difference. With other people, it might have made greater difference.*
>
> *S1018 6m, episode duration 7–12 months (Telephone support)*

The importance of explanation and support

Participants commonly reported that they valued the videos of exercises alongside explanation of their likely benefit. The descriptions participants gave about the importance they placed on these aspects suggested that although the idea that activity was good for their LBP was not novel, the specificity and accompanying explanations may have increased confidence to actively engage in these behaviours. Additionally, some participants talked about their appreciation of the breadth of material covered, and how it provided strategies to employ that might be protective in a range of situations.

> *SB S0862: The most useful thing? Well, as I say, I think it was the fact that it actually gave you a video and moving examples of how actually to do the exercises, and there were lots of little explanations as to the actual advantages and benefits of doing particular exercises, so that was quite useful.*
>
> *S0862 3m, episode duration 7–12 months (Web alone)*

> *I watched the videos. I read the blurbs. It was a lot better to actually get that information rather than just, 'Okay, do these exercises,' and you're not finding out why? Sometimes you get a physiotherapist that will be good like that and explain why they're doing things. That is a lot better than just somebody saying, 'Do these stretches and exercises.' You've no idea, for a start.*
>
> *S1111 6m, episode duration 6–10 years (Telephone support)*

> *Oh, the one for gardening, because I like to garden, I found that one very useful, reminding me to warm up before I actually go out and go mad digging and doing anything else. That I've found I now tend to do things indoors and get moving, and gentle exercise, so that I'm warmed up before I go out and do a lot of the gardening.*
>
> *S0979 12m, episode duration < 3 months (Telephone support)*

Usefulness and need for tailoring

Perceptions of the tailoring in SupportBack were mixed. For the most part, SupportBack focused on supporting self-tailoring; providing a range of options and support so people could choose their own activity. Some participants liked this approach and felt it enhanced personalisation.

> *[I]t was useful having a set of exercises presented to you on the website. Yes, so that was good, and the fact that you could choose your own programme from how many times you were going to do things, that sort of thing. That was good, the ability to tailor it to your own feeling of ability.*
>
> *K0504 3m, episode duration 3–5 years (Telephone support)*

Others felt that personalisation or tailoring was lacking. For some of these participants, the choices provided were not useful without more expert guidance. For others, there was frustration that the SupportBack approach did not account for the complexity of their condition. These participants were concerned that there was no detailed history taken, or perceived that they needed to be seen directly in person to account for and give direct guidance based on their individual needs.

> *I don't know how you'd do it, but I feel like it lacks personalisation. I just felt it was the same generic exercise that everyone else was getting, so it didn't seem particularly relevant, because I hadn't given like a full history and full background of – all I did was rated my pain from nought to ten, basically. I can't actually remember, but I don't know whether – I think I*

probably would have taken more interest in it if it felt more personalised and it was more tailored to me and my back pain, because I didn't feel like it was.

S0882 3m, episode duration 3–5 years (Web alone)

For me, I wanted more hands-on like . . . 'This is exactly what's wrong with your back,' no there isn't a cure for it or yes there is a cure for it; it's a quick and simple, which it's unlikely to be, or you need to start doing these exercises in this specific area and that will build up your core strength, I don't know.

S1118 12m, episode duration 3–5 years (Web alone)

Using the SupportBack internet intervention

In this theme we bring together participants' descriptions of the use of the SupportBack website, the digital aspect of the approach.

Quite straightforward and easy to navigate

The majority of participants reported that they found the SupportBack website and interface clear, simple and easy to use. Although positive, participants were usually brief in their feedback suggesting that, for most, the website and design delivered information without too many barriers.

Very easy, very easy to navigate around, no problem logging on and also easy to work through, it wasn't all singing all dancing as you might say website so it was quite easy to go through. Also, the fact that there was, you could see your progress on the bar and you knew when you were coming towards the conclusion of that particular session.

K0875 3m, episode duration 1–2 years (Telephone support)

Intervention limited access to material

The SupportBack internet intervention was delivered via a website and was designed to deliver a session of goal setting and LBP-related module, once a week for 6 weeks. Once participants had worked through their module for that week, they had to wait until the next week to 'unlock' new information (they could still access what they had seen previously over the week). This was designed to ensure the use of the material and engagement in behaviours over time. This weekly format frustrated some participants who suggested they would have liked more control over the online system.

What I kind of didn't like that you couldn't access, you only could access one topic out of, which you wanted to read, out of . . . When I start getting into something I want to read everything, so I didn't like it. Yes, I mean, it was fine.

S1029 6m, episode duration 3–5 years (Web alone)

Using in a way that suits you

Although a structure was suggested for the digital aspect of the programme (using a session a week for 6 weeks), participants often reported developing their own patterns of usage. Some 'dipped in and out', when they felt they needed. Others printed or wrote down activities they wanted to engage with, removing the need to go back to the website to apply in their day-to-day life.

Early on, I went through reading a lot of it. Since then, I've dipped in and out. I think there was one exercise, and I thought, I remember that helps, but when I went to do it, I couldn't finally remember exactly what it said. I went back in and looked at it, so that I knew what I was looking for, if you know what I mean. Having read early on, it's quite clear that there are points in there that you read early on, but it comes back to you later and you think, oh, that would be helpful now, so you go back in and find it.

S0979 12m, episode duration < 3 years (Telephone support)

I just dipped in and out. The first couple of times, I was there and I was there for a couple of hours sometimes, but after I got the idea of it, the hang of it, that was it.

S1197 12m, episode duration 3–6 months (Web alone)

Impact of SupportBack on activity

Within this theme, participants consider and describe the impact SupportBack had on their physical activity.

Increasing confidence and provision of reassurance

Increasing confidence was explicitly mentioned by some participants as an important aspect of the intervention. The processes underlying the confidence increase appeared multifaceted: For some, the confidence stemmed from recommended activities coming from trusted source via the internet. This confidence appeared to increase the likelihood of engaging in the activities. Relatedly, confidence was also described as being built through the videos and details of the exercises. These participants described feeling confident they were doing the exercise 'right', and therefore reducing potential harm. Finally, a more general confidence was described as stemming from the availability of a package providing motivation and guidance for specific activities, as well as how to apply them in different contexts.

> *Without a doubt, the pictures of the exercises, I think. That just reinforced the message that I was doing the right thing. I think that's so important, because it would have been quite easy to have injured myself doing something silly . . . It's given me the confidence to use the exercises as positively as possible.*
>
> *S1019 6m, episode duration 7–12 months (Telephone support)*

> *I think I've felt a bit more confident about it because it seemed to be aimed at keeping me fit and disciplined and motivated. I suddenly thought to myself, oh I'm going to feel a lot more confident about how to manage my back pain because it just had little guidelines of what to do if you had the type of back pain incident. Yes, I did feel it was sort of level of support, albeit at a distance.*
>
> *S0862 3m, episode duration 7–12 months (Web alone)*

In the context of LBP, confidence and reassurance are overlapping concepts. Where participants directly discussed reassurance, it was often related to the role of SupportBack in addressing particular concerns participants may have had.

> *It's a refresher, sort of thing. It's a great, little – okay, my back's hurting, am I doing something a little wrong? It's a great reassurance. Am I doing this wrong, am I doing that wrong? You go on to the website, you have a good look at it, and it's like, 'No, they're all fine.' I am doing this right.*
>
> *S1111 6m, episode duration 6–10 years (Telephone support)*

Supporting activity increases or maintenance

It was common for participants in the intervention arms to talk about increases in activity over the trial period. Some directly attributed this to the SupportBack intervention, some were not sure but thought it could have been the intervention, others felt their activity had increased generally. Where participants directly related improvements to SupportBack, for some it appeared to be the reassurance that had led to increases in activity. Once people began activity and noted positive changes, this appeared to reinforce and sustain these behaviours.

> *Probably increased a bit more actually, and in some ways, I think that's helped actually . . . I think I'm now less conscious and worried about my back pain whilst I'm doing stuff. I think it's a gradual thing, I think it seems to be more, maybe the little bit, the time when my back recovered doing some simple stretch and I could do more exercise and I think the more I did of that, the better my back got overtime. To the point where I suddenly realised that I wasn't worried about my back anymore.*
>
> *S0914 12m, episode duration 1–2 years (Telephone Support)*

Some participants emphasised that it was instrumental support; for instance, practical specific instructions for certain situations that appeared to support the increases in activity.

> *SB S0979: [It's] increased quite a lot from the first. Well, when I was first contacted, I had trouble getting up and down the stairs. Literally, I was almost crawling up the stairs, because I was in so much pain. The things that helped were how to do*

certain things when you were in pain, if you know what I mean, and I've gradually increased my exercise, a) by gardening and b) by walking.

S0979 12m, episode duration < 3 months (Telephone support)

Familiarity reduced impact

Where participants reported a lack of impact of the interventions on their activity, they often related this to them being active before the trial and sustaining that activity. Other participants suggested they had a lot of experience with physiotherapy-related exercise and already did them. For these participants, there appeared to be a perceived lack of novelty. This familiarity seemed to reduce a sense of 'gain'; thus, the intervention did not impact their behaviour.

I suppose I was going to say I'm more active in the winter because the animals are stabled and things so, therefore, there is more work to do around them, but then in the summer there is just different work to do, so no, my activity levels I don't think really changed, not a huge amount. Like I say, I'm mindful to make sure moving, being the lotion and all that, so yes, I'm mindful to keep moving anyway.

K0787 12m, episode duration > 10 years (Web alone)

I think that because a lot of the stuff that was on there available to me – suggestions, tips, exercises and things like that – because I have a long history of back ache with physios and stuff like that, a lot of it I already know. I already try to implement. Some of the exercises work, some don't, so I use the exercises that do work for me, but yes, I think it's definitely because I have prior knowledge of that and that's why I didn't really gain that much from it.

K0693 6m, episode duration 1–2 years (Telephone support)

Impact of SupportBack on pain

The subthemes that comprise this overarching theme have a focus on how participants in the interventions perceived SupportBack to impact on their LBP. As with impact on activity, impact on LBP varied.

Increasing the association between activity and pain reductions

When participants talked of reductions in pain, in most cases, it was through the use of activity as a management strategy. Through these descriptions it appeared that the SupportBack programme had provided an opportunity to associate or link activity increases with pain reduction over a focused period. Thus, for these individuals, the trial became an opportunity to experientially learn that activity was an effective strategy for them in managing their LBP.

It must be having a good effect. I've noticed before, if I've been suffering really badly with pain, I have at some stages just stopped doing the exercises altogether. Then it's been really hard to get back into it, and you've gone back to square one, you're nowhere near where you were. It's like right, just do it, but obviously don't push yourself too far. I found out, if you do the exercises, it does help.

S0952 6m, episode duration 7–12 months (Web alone)

I think partly because the exercises have reduced the pain and given me flexibility again, and the exercises and everything help all the time. Knowing that there's something there that I can go and look at, can read, it gives you that mental stimulation, if you've got nobody.

S0979 12m, episode duration < 3 months (Telephone support)

I've been more active and I feel – now I can do everything I want in my life and I just have a bit of back pain, and I have to sleep a bit weird, in a [unclear] position to be comfortable, and it's sore in the morning, but if I get up and do my exercises it's all right and it doesn't really affect my life.

S0882 3m, episode duration 3–5 years (Web alone)

No impact, no association between pain and exercises

For the participants who felt that SupportBack intervention had no impact on their LBP, it appeared to be driven by the inverse of the above, a *lack* of association between physical activity and their LBP. This may have been described through direct experience, for example, trying activities/exercises and experiencing no difference in pain. Alternatively,

some participants seemed to hold beliefs that would limit such an association. For instance, a participant may believe the cause of their pain to be a skeletal problem that could not be affected by exercise. This appeared to prohibit engagement with the SupportBack activities.

> *That's the reason why over the last, say, two years it's progressively got worse now to a stage where no matter, even if do the exercise, it doesn't make a blind bit of difference.*
>
> *K704 12m, episode duration < 3 months (Web alone)*

> *I have to say, I was doubtful that it would create much improvement because my GP had told me that my vertebrae had actually been – as I understand it – permanently displaced. I think the vertebrae partly crumble or something, I think, and the disks between the vertebrae, as you probably know, they thin with age. This is always a problem causing pain. Because of the permanent degradation with age, I wasn't really expecting a programme of exercises to make a vast difference.*
>
> *S1018 6m, episode duration 7–12 months (Telephone support)*

Long-term impact of SupportBack

Those who reported experiencing benefits from the SupportBack intervention, often describing continuing with the activities they had found helpful in the longer term. This could have been the back-related exercises, or walking. Some reported the development of a habit with a focus on longer-term maintenance of any gains they had made. Others spoke about using the exercises more reactively when they experienced pain. In both cases, participants appeared to be effectively employing activity as a self-regulatory strategy: in the former, with the aim of longer-term goals around maintaining fitness and improvements and, in the latter, focusing on the short term, for example, lessening immediate pain.

> *I: Do you still do the SupportBack exercises?*
> *P: Yes.*
> *I: What motivates you to keep doing them?*
> *P: The fact that I'm not having the amount of pain that I used to get in my back. Intermittently, I must admit, but it wasn't as bad as the sciatica, but it has strengthened up my back muscles and I aim to keep them as strong as possible, to keep me mobile and out of pain.*
>
> *S0979 12m, episode duration < 3 months (Telephone support)*

> *Well, I did some exercises there; I think I put down the ones that I was very happy with, and I kept them up but as soon as I stopped, it started to come back again. So if I forget and my back starts hurting, I think to myself, oh, I haven't done my exercises! So I spend ten minutes, quarter-of-an-hour doing my exercises.*
>
> *S1197 12m, episode duration 3–6 months (Web alone)*

Where participants reported no longer-term impacts, they often spoke of lack of impacts continuing as time went on. Some reported feeling like their pain had worsened.

> *I: How have you found managing the pain itself as the time has passed?*
> *P: I've found it really difficult. I've been feeling that it took over my life. Especially, I made the decision, because I was for quite a bit of time during lockdown I wasn't working, so I really committed myself to trying to sort it out with exercises. I do feel actually that I probably made myself worse.*
>
> *S1029 6m, episode duration 3–5 years (Web alone)*

Impact of physiotherapist telephone support

Participants allocated to receive telephone physiotherapist support coupled with the SupportBack internet intervention primarily reported positive experiences of that support. This theme brings together salient features of their descriptions, particularly focusing on the physiotherapist's role in motivation and ability to further individualise the information.

Providing encouragement

Many of the participants who received telephone support described how the encouragement they received supported their motivation. This was both motivation to try specific approaches as well as providing a level of accountability; some participants described how the regular calls provided a prompt to engage with the material and associated activities.

> *I thought the conversations with the professional physiotherapists were good actually and they were particularly good at encouraging you to do what you should be doing before you spoke to them. It is mostly isn't it about discipline and doing the right thing for your own benefit? Yes, so anything that can be done through that to encourage people to do the right thing is going to be helpful and make it more effective I would have thought, obviously without being Draconian about it. It often takes that little bit of psychological nudge to say, 'Oh yes, actually I'd better do that because I'd have to report that I haven't done it' sort of thing.*
>
> *K504 3m, episode duration 3–5 years (Telephone support)*

Providing reassurance and guidance

Participants often discussed how they found the physiotherapists reassuring. It was common for them to report feeling reassured about whether particular exercises are right for them. Other participants were also reassured by being listened to, specifically around their own ideas regarding the cause and what was good for their LBP,

> *P: [They] made sure I understood the exercises, and everything was okay. It was just quite nice talking to somebody and they had a little bit more time than at the GP or someone would have, so yes, I think it was just nice to have some sort of human interaction even over the phone just to discuss bits and pieces.*
> *I: Can you tell me what was particularly good about it?*
> *P: I think it was just the reassurance I was doing the right thing and I'd understood the exercises*
>
> *S0914 6m, episode duration 1–2 years (Telephone support)*

Some participants discussed how they thought the guidance from the physiotherapist integrated well with the website.

> *I thought just giving the base in the physio chat on the phone was good, because I could look at the exercises, and I knew what I was thinking about, but she could describe to me what I needed to do. I think, after the first week, I got so enthusiastic with the exercises that I did too much! You would do anything to get better, so unfortunately, yes, I did overdo it and she did say, 'Look, you don't have to do every exercise for the number of repeats every day.' She said, 'Do some on one day, some on another, don't go mad at it,' which I did do, to start with, and she controlled me, in that sense!*
>
> *S0979 12m, episode duration < 3 months (Telephone support)*

The ability of the physiotherapists to further tailor and personalise suggestions from the SupportBack website was also appreciated by some patients in this group. This personalisation appeared to increase confidence in the activities as well as increase expectations for benefit.

> *I think he was just really understanding, and he explained some of the exercises that I would find better for my back, rather than some of the other exercises. He explains which ones would probably be better for my actual backache than other exercises. When I said I found some didn't really do anything and they gave me backache, he explained about the pressure on it and that, so he was quite helpful explaining to me about which exercises would probably be better for me.*
>
> *S0650 3m, episode duration < 3 months (Telephone support)*

Would have liked more

Amongst some participants, there was a perception that the physiotherapist support on offer was limited. These participants described how they would have liked a video link (support was delivered via the telephone in the current trial) so they could be seen and guided in doing the exercises. Alternatively, one participant described how any form of support offered by a physiotherapist without physical contact would be limited.

> *As I've said before, I think although it's all done with the best will in the world, any form of physiotherapy, quite frankly, is going to be very limited if it's not involving physical contact, physical examination and testing, and watching the patient actually carrying out certain activities so you can see what the responses are.*
>
> *S1018 6m, episode duration 7–12 months (Telephone support)*

Influence of COVID-19 pandemic

The COVID-19 pandemic and associated lockdowns occurred when the majority of participants were being followed up in the trial. The effect on participants' activity was not uniform; experiences appeared balanced between having no impact, reducing or leading to increases in activity.

> *Even when it was stricter with the COVID, we could still go out, couldn't we, for an hour, so that's what I do most days. I tend to finish work at half-three and then I'll go out. If I don't do an exercise, I'll go out and have a walk, even if it's only 45 minutes or whatever. No, it hasn't really impacted.*
>
> *K0902 6m, episode duration 7–12 months (Web alone)*

Reduced access to facilities was described by many who reported activity reductions in lockdown periods:

> *I think it has decreased because, as I say, I was going swimming quite regularly and walking quite a lot. I mean I have only just recently started going on walks and down the street to local parks to meet people, but it's nowhere near as much walking as I was before, so that has had an impact.*
>
> *S0862 3m, episode duration 7–12 months (Web alone)*

For those who described increases in activity, this was often due to the greater flexibility working from home enabled. Reductions in sitting commutes were also described as helpful.

> *My activity has been higher because I've had nothing else to do, so I get out more. I don't have a long . . . I used to have to drive for an hour, not every day, but most days of the week, so I don't have that and that, I often felt contributed to my back. I do have a desk job, so even at home I have to sit in a chair in front of a computer, but because I'm not in an office anymore, nobody knows when I'm not and if I don't have the work to do, I don't sit here.*
>
> *S1035 6m, episode duration < 3 months (TAU)*

Some described the positive impact having access to SupportBack during lockdown periods with reduced healthcare provision.

> *The fact that I had access to the website during COVID while lockdown was on and there was no physical way of getting any sort of treatment whatsoever, was a benefit, massively. The fact that that now might be a chance to be out there for good, as well, I think it will be a very good idea, personally. There's people that can't get to physio or are struggling with their cognitive capacity due to the painkillers.*
>
> *S1111 6m, episode duration 6–10 years (Telephone support)*

Managing without access to SupportBack

When interviewing those from the usual care arm of the trial, our primary focus beyond their back pain history was how they managed their LBP over the trial period. We were also interested in any perceived changes to their LBP or function over that time.

'Nothing has really changed'

It was common for these participants to discuss their management of LBP remaining fairly consistent over the period of the trial. It was clear some had quite specific management regimens they had developed themselves, which they

continued to adhere to. Some patients discussed introducing new approaches to management over the trial period, despite generally reporting they were 'doing the same thing'.

> *No, not in the way I manage, no. I know my limitations now. I know what I can do comfortably and safely, so I just adhere to that. I might have pushed the envelope a little bit with the weather being nice and going out in the garden, maybe doing a few little bits. I thought, should I really be doing this, but then just thought, okay, enough is enough really now, but not overall. No, I don't think so.*
>
> *K0898 3m, episode duration 3–6 months (TAU)*

> *I keep on doing the same thing. I guess the only addition that I, which I started working with my physio was about a year ago to start running again. That's like in addition to my other exercises that I now do which was a great milestone to be able to do it.*
>
> *S1096 12m, episode duration 3–5 years (TAU)*

Variance in perceived low back pain outcomes over time

Participants differed in how they discussed their LBP and its impact on their lives post 12 months from randomisation into the trial. For some, based on no changes or worsening over the course of the trial period, there was an expression of reluctant acceptance.

> *It's part of my life. I don't think it'll ever go. I'll always have backache and that's just it. There's nothing that anyone or anything can do about it . . . I think it'll be part of me forever. I don't want to go down the surgery route, as far as I've been told by various doctors, the success rate on back surgery is very, very low.*
>
> *S1121 12m, episode duration > 10 years (TAU)*

Other participants discussed changes in perceptions of pain based on amendments to management, with medical management discussed.

> *Yes, yes, and obviously I think that's got a lot to do with the painkillers that I've been taking and, I don't know, maybe the warmer weather, because obviously we were going into cold weather and I think that just makes you a little bit more tense, doesn't it, so it's hard of your muscles to relax? I think the warm weather that we've had recently has probably been beneficial as well, yes.*
>
> *K0898 12m, episode duration 3–6 months (TAU)*

Summary

This nested qualitative study demonstrated the variety of experiences reported during the SB2 trial. People entered the trial with a wide range of LBP histories, and similarly wide-ranging experiences of care for LBP. Generally, the digital/online aspects of SupportBack were experienced positively by most participants. They found the system easy to navigate and clear. For those who reported beneficial improvement following the use of SupportBack, it appeared to be through the provision of specific behavioural support for engaging in physical activity that they could choose for themselves. Critically, for these participants, when they engaged in activity, they perceived direct benefits, whether through decreased pain or greater mobility. For participants who did not report benefits, this seemed related to talk of seeing and trying the suggested activities previously. Some reported already doing them; thus, additional benefit was not possible. For others, they had tried the exercises before and they did not work, or they tried them as part of the SupportBack programme and did not perceive them to be helpful. These latter reports were often associated with talk of disengagement with the intervention and associated activities.

Physiotherapist telephone support was reported to be helpful by most interviewed who were allocated to the support arm. The reports suggested the telephone support had been beneficial through providing motivation, reassurance and tailoring for specific individual issues. The reported impact of COVID-19 restrictions varied. Some participants reported doing more activity due to working from home. Others reported no impact. Some reported doing less activity particularly due to the closure of gyms and swimming pools.

Those from the usual care arm who we interviewed also reported a variety of experiences over the trial. Some participants reported that their activity and pain levels had not changed over the trial period. Others reported that they had started new activities and were more active than before the trial. There were also descriptions of worsening pain, and declining musculoskeletal health generally.

Reflexivity

Within this project, a combined/integrated approach was taken to the team with regard to process and outcome evaluation. AG is an experienced mixed-methods researcher – designing and leading RCTs of behavioural intervention as well as leading complex qualitative research studies. SH is an experienced qualitative researcher, and within this project, SH conducted all interviews and collaborated closely with AG on the analyses with input from LR and LY alongside others in the team. LR and LY have extensive experience in qualitative methodologies and nested qualitative studies. AG led the development of the intervention alongside a number of the current trial team. The team has remained in equipoise regarding the likely impact of an internet-based approach for the self-management of LBP.

While this approach differs from having an independent process evaluation group within the team, the familiarity of the team with the interventions and the intended behavioural processes allowed for an appreciation of nuance and subtlety in participants' descriptions of what happened when they used the interventions. However, to ensure one person's reading of the data did not dominate, detailed coding manuals were developed for both the participants and the physiotherapists data sets, and were shared amongst the whole trial team. This meant that the broader team had access to extensive data excerpts, with which to refer to when considering the developing themes and interpretations. Our public contributors, MW and FR, were also closely involved with the developing interpretations of the data, seeing both the coding manuals as well as discussing and agreeing early draft analytic work. Additionally, close attention was paid to finding disconfirming cases and negative narratives regarding the intervention processes. Nevertheless, we do acknowledge that having the same team involved with the trial and the process evaluation could have influenced the recruitment of participants; those with negative views may have been less likely to agree to be interviewed.

Chapter 5 Qualitative process study – physiotherapists

Overview and aims

In this process study, our aim was to explore the experience of the physiotherapists who delivered the telephone support. Our focus here was primarily on implementation. We wanted to understand how they had found delivering the support; aspects they felt worked well and where issues and problems may have occurred. The physiotherapists in the trial received a 2-hour training session. They were asked to offer three telephone calls (one up to 30 minutes, and two follow-ups of up to 15 minutes) evenly spaced over the 6-week digital interactive stretch of the intervention. They were asked to follow a checklist for the sessions (see *Report Supplementary Material 1*), and broadly follow a 'CARE' approach (Congratulate progress, Address concerns, Reassure, Encourage[29]).

Methods

Design

This was an in-depth qualitative interview study nested within the SB2 trial.

Participants

We interviewed the physiotherapists who provided telephone support in the SB2 trial. The number of available physiotherapists was too low to purposively sample on background characteristics (12 physiotherapists were involved in providing support over the course of the trial). Physiotherapists were interviewed after all participants had completed the digital, interactive intervention components of SupportBack.

Interviews

Participants were interviewed over telephone by an experienced female qualitative researcher (SH, pre-doctoral) using a semistructured interview guide (this can be provided on request). The interviewer had no relationship with the physiotherapists prior to the interviews. The interviewees knew the interviews would be about their experiences as part of the study/trial. The interview questions were open-ended, the guide contained prompts, and was used flexibly. All interviews were audio-recorded and transcribed verbatim. The interviewer SH took field notes throughout the interview process. The focus of the interviews was on (1) their experience of delivering the support, (2) their perspectives on the approach taken to support-self-management and (3) any barriers or issues they had encountered.

Data analysis

We used a thematic analytic approach drawing on elements of the approaches outlined by Braun and Clarke[50] and Yoffe and Yardley.[49] Data were coded by SH, through a process of descriptive labelling phrases or elements of the interviews that related to the study aims. NVivo software was used to support coding. A codebook was developed and agreed upon by SH and AG. Descriptive themes were developed summarising the salient features in the codes. The initial analysis draft was written by SH and discussed with AG; themes and analyses were agreed with the wider team. The extent of the analyses was limited by the number of physiotherapists we were able to recruit. Nonetheless, due to the specific nature of the interviews, we had reasonable information power with five participants (see below). Member checking was not conducted.

Results

Twelve trial physiotherapists were contacted by e-mail for an interview (all those involved in the trial who delivered support). Of those 12, 4 had changed e-mail addresses and we did not have follow-on details and 3 did not respond; the remaining 5 trial physiotherapists were contactable and agreed to be interviewed (42%). Interview duration ranged from 18 to 41 minutes. *Table 17* provides demographic and professional characteristics.

TABLE 17 Demographic and professional characteristics of interviewed physiotherapists

Characteristics	*N*/Mean	%/SD
Gender		
Male	1	20
Female	4	80
Age	41.2	10
Band		
6	1	20
7	3	60
8a	1	20
Years qualified	19.6	9.61
Mean years working in musculoskeletal	14.4	5.94

Four main themes were developed: 'Reflecting on delivery modality', 'Implementing within the trial', 'Reflecting on the SupportBack approach to self-management' and 'Perceptions of participant experience'. These themes along with related subthemes are described below.

Reflecting on delivery modality

Role differed from normal clinical practice

The role for the physiotherapists in the SB2 trial differed from their usual roles within clinical practice. In usual clinical practice, the physiotherapist would conduct an initial (usually face-to-face) assessment and devise a personal plan for each individual. In SB2 the physiotherapists were required to relinquish control over the programme and instead act as a support, providing guidance through a standardised, pre-set programme, with a script to guide them. Much of the telephone physiotherapy in the SB2 trial was conducted before the COVID-19 pandemic, and conducting sessions by telephone was an unfamiliar territory for most. This mode of delivery became much more common practice with the onset of the pandemic.

> *Obviously most, well pretty much all the data I captured, was pre-COVID. So it was still the only thing I was doing like that. I think, what you'd find now is obviously pretty much every therapist around has now got more telephone experience. So it would be a much more natural process for them post-COVID, as opposed to before. I think it was sort of taking that step back, following a script or a line of questioning, should I say, as opposed to, delving off into other areas. So trying to provide that over the phone and stay on track with that script, certainly was a new thing in the beginning, for sure.*
>
> *P08*

Desire for some face-to-face contact

Generally, the physiotherapists were positive about their role in the trial, and felt they could deliver effective support by telephone. However, they would have preferred at least some face-to-face contact:

> *I think providing support through telephone was quite nice, but I think as a clinician obviously we're quite tactile people. It wouldn't be something that I'd want to do all the time, even during COVID-19, we'd still get people in and look at them if we really needed to. I think the beauty of touch and assessing that way is still something that I hold quite close. It wouldn't be something that I'd want to do all the time.*
>
> *P03*

Benefits of telephone support

One physiotherapist felt that support at a distance was beneficial to patient engagement, giving them less opportunity to be passive in their recovery:

> *I think when they're seeing someone face-to-face it's very much the patient's got far more of an opportunity to be passive. Whereas I think, what the programme does is definitely puts that onus on the patient more, which I think in the long run, is the way we should be going with things.*
>
> *P08*

Another physiotherapist explained that the move from face-to-face to remote spurred on by the pandemic has increased physiotherapist confidence in the patient's ability to self-motivate:

> *[I]t wasn't a routine thing for me to be telephoning patients and discussing things over the phone in so much detail. At the time, I would want to provide paper copies of things, and give them information and point out the bits I'd really want them to focus on. Obviously, now it's different. We give people a little more credit for actually reading things and being able to see what we can see, even if it is over the phone.*
>
> *P09*

This physiotherapist felt the benefits of being able to help people regardless of where they were, and valued the opportunity to help people in places where they may struggle to get access to physiotherapy through the normal routes:

> *I was thinking, actually, we're giving advice to people really well, that they may not have had access to locally, because of either timescales or waiting lists or whatever. They wouldn't have got that advice, they wouldn't be able to ask the questions.*
>
> *P09*

Implementing within the trial

No major barriers to delivering physiotherapy support by telephone in the trial were reported. Some minor barriers included, occasionally struggling to contact participants to make appointments, occasionally participants forgetting about their telephone sessions, some participants wanting out of hours calls that did not suit the physiotherapist, and the odd participant did not want to engage with the programme.

> *Getting hold of people who weren't really that keen, or persuading people to comply when they weren't really that keen. I have one example where a patient said, 'I don't know what you're going to be able to do for me because . . . I said, 'Well, you're on the trial, so why have you signed up for the trial if you didn't think I was going to help?' Actually, it turned out, well, the GP told me to, and so, yes, you're going to get that mentality of people who don't actually want to be there, but they feel they have to be because the GP suggested it.*
>
> *P09*

This physiotherapist stated that this issue is not isolated to SB2, and the same issue is present with general GP referrals.

The physiotherapists felt well-equipped to deliver the programme due to the training provided, and felt supported by the wider study team.

> *I felt if I needed to contact – which I did, probably, on three or four occasions, have to contact the team about something – because a couple of them had to be withdrawn because of medical things – I felt as though there was always somebody to ask.*
>
> *P04*

Misunderstanding of the physiotherapist's role

Some physiotherapists felt that the participants misunderstood the role of the physiotherapist in this context, and had unrealistic expectations about the support they could give. For example, some were expecting the physiotherapist to know their medical history, some were expecting more clinical guidance and some wanted technical support for the website.

> *Some people were maybe under the impression that I was providing actual physio for them. That was the only negative, that sometimes people were asking me clinical questions about stretches of a certain limb, when we were really working on the online aspect and how you're getting on with that. I think their expectations sometimes were a little bit, oh, now I've got hold of a physio, now I can ask all these questions!*
>
> *P03*

One physiotherapist addressed this by establishing ground rules right at the start, making their role clear and building the participant's trust:

> *Then I think, establishing over the phone that it was a trusted relationship, based on the fact that I was a professional and I knew what I was talking about, then allowed them to take on board what I was saying, so I think it was important to establish some ground rules a little. To go, yes, I'm here for the trial and I'm here to talk about your back. I'm not here to talk about your nephew's ankle sprain or something.*
>
> *P09*

Reflecting on the SupportBack approach to self-management

Benefit of staged information delivery

For one physiotherapist, SB2 led to reflection on the delivery of information. They described valuable lessons that could be learnt from SB2 to improve practice. In standard practice, this physiotherapist described that they tend to give patients everything they need to know in one go, making it difficult for patients to remember everything. They saw value in the way the SupportBack intervention gave chunks of information and then unlocked the next section as time went on to help them digest each bit of information slowly.

> *Whereas, if you go, no, this is where I want them to start, and I want you to read and I want you to work through, and then you unlock the next bit, and then you unlock the next bit as you go along, and seeing that journey as I ring the patient back to see how they're managing, actually, was quite an interesting way of looking at rehab for back pain and giving it to them in chunks that they can digest and understand, and then move on when they felt ready was really interesting.*

Benefits of interactive nature of the website

The same physiotherapist also reflected on how they currently deliver information using leaflets, which, compared to the SB2 website, was missing the interactive aspect:

> *I guess, prior to taking part in the trial, I was looking at information that I would give to patients that would be a guide, but it wasn't interactive . . . from a technology point of view, seeing how patients reacted, and understanding and being able to hear first-hand their thoughts on the interactive bit was interesting. Thinking about that a little bit more, going forward, and especially now, if we had more interactive websites where patients could use information and go back to it.*
>
> *P09*

The website as a focal point

The physiotherapists felt that having the website as a focus point was beneficial for several reasons. First, they reported it was helpful because the website demonstrated exercises to the patient, acting as a point of reference; something for them to both look at and for the patient to learn from. Second, they described how the website inspired patient self-initiative and encouraged self-management:

> *It helped direct a little bit of the conversation back to them. How did you find this bit of the website? What did you pick off this bit? Rather than them asking me questions and me imparting my knowledge, as it were, which – it's breaking down that relationship perception that I am there as the font of all knowledge, and you're there to ask me questions and gain knowledge from me. It's trying to establish it the other way round. Get them to take onus of their progress and their progression across the weeks. They could then tell me what they've been doing. They could use the website as a way of saying, 'I've done this and I've achieved that, and I've chosen this as my goal, and this is how far I've got.'*
>
> *P08*

Finally, some physiotherapists suggested the website seemed to deflect focus away from patient pain, and direct it instead to proactive, helpful activities:

> *but then also keep I think, the patient focused on what they're doing, rather than say, some of the symptoms, you know, some of the more clinical things that we would check. Things like just, focusing on aspects they can't do, or this and that. The website had, as I said, that positive focus, looking at well, what can they do, how long are they doing it for, etc. So I think helpful yes, to almost deflect away from some of the negative aspects of back pain potentially. Given that the real focus is actually on activity and enabling function, as opposed to, what the problem is, if that makes sense.*
>
> *P08*

Perceptions of participant experience

Appreciation for the calls

The physiotherapists felt participants responded positively to the physiotherapy calls and showed appreciation:

> *Generally, the conversations I was having with patients were making a difference and, actually, they were quite appreciative of the fact that they were getting some advice, even if it was over the phone, which, actually, wasn't routine at that point.*
>
> *P09*

Contributing to motivation

Physiotherapist calls seemed motivating for the participants, and physiotherapists felt that participants engaged and worked towards their goals harder than they might have done without the phone calls:

> *Most people said they appreciated the call – I think, like I said before, because they knew someone was going to ring up, it had made them do stuff where they didn't feel like they would have done stuff if they hadn't had the call; that was the overwhelming thing, really.*
>
> *P04*

Provision of reassurance

The physiotherapists viewed reassurance as a large part of their role, and participants valued the reassurance coming from back pain experts:

> *It was just that you were able to reassure people, I think. A lot of it was just general reassurance, that what they were experiencing was normal.*
>
> *P04*

Summary

Overall, physiotherapists felt supported by the trial team, felt that the training for the delivery of the intervention telephone support was sufficient, and did not report any major barriers to delivering the support. There were some minor issues with contacting participants, and participants' motivation for the process differed. The trial physiotherapists suggested that there was a need to adjust to the differing requirements of the trial support. Some

described how they find face-to-face contact central to their role, making telehealth support more difficult. One physiotherapist suggested that the distanced nature of the calls had the benefit of supporting participants to be more active and less passive in their care. Some participants appeared to misunderstand the physiotherapists' role within the trial, expecting the same level of support they might have been offered in standard physiotherapy consultations.

When considering the general approach to self-management of LBP contained with the SupportBack material and intervention process, physiotherapists were positive: one felt that the staged offering of material over time was useful, perhaps supporting greater integration of material than when delivered in standard practice. Others felt that the interactivity was beneficial, and the website provided a focus for sessions away from pain. Regarding their perceptions of participants' experiences, generally, the trial physiotherapists felt that participants appreciated the calls, finding them motivating and reassuring. A limitation of this study was the number of physiotherapists recruited. Although rich data were provided by the five trial physiotherapists we interviewed, further data from additional physiotherapists in the trial would have strengthened the analysis.

Chapter 6 Quantitative process study

Overview and aims

In this chapter, we describe the process analysis with a focus on the relevant quantitative data collected. Specifically, we focus here on quantitative aspects of implementation and delivery of the interventions, along with possible mechanistic processes. The third aspect of a process evaluation listed in the Medical Research Council guidance[52] are contextual factors or potential moderators. This has been addressed in our pre-specified subgroup analysis in the main effectiveness evaluation (focusing on risk of persistent disability, pain duration and social deprivation at baseline), and will not be presented here.

Usage is an important variable to explore in the context of digital, or internet intervention trials.[53] Usage refers to metrics, such as number of logins, time spent on site, or completion of modules. It is one aspect of engagement with an internet intervention, where engagement is described as a multidimensional concept that also includes subjective experience, such as attention, affect and interest.[53] Determining usage patterns and their relationship to outcome, in this case, LBP-related disability, may help to guide implementation beyond trials. For instance, linear relationships between usage and beneficial outcomes may indicate additional support for adherence when rolled out. Determining how usage relates to outcome may also as support the development specific programme theory regarding how the intervention leads to beneficial change. We also wished to explore other aspects of implementation, including numbers of calls delivered by the physiotherapists.

In addition to exploring usage and other factors related to implementation, we planned to determine if certain relevant variables mediated any beneficial outcomes that were seen in LBP-related disability. The planned mediation models were based on the logic model for the SupportBack intervention. This logic model detailed our initial proposed theory of change. The model included several hypothesised routes of action for the SupportBack intervention (see *Appendix 3*). To keep participant burden in terms of completing extra measures low in the trial, we centred on two key variables as primary mediators of the effect of the interventions on LBP-related disability: (1) self-efficacy and (2) physical activity related to the intervention. This focus was detailed in our published protocol.[23]

Self-efficacy

Self-efficacy has consistently been found to be an important construct in pain intervention research,[54] often associated with outcome.[55] Self-efficacy to manage pain was a key target of our SupportBack intervention, in which participants were supported to become experts in managing their LBP. Many of the intervention components directly targeted self-efficacy (e.g. modelling, providing opportunities for mastery experience). In the trial, self-efficacy was quantitatively measured in two ways: (1) Using the PSEQ at baseline, 6-week follow-up and 12 months. The PSEQ measures people's confidence that they can continue with activities despite pain. Relating to the intervention, if pain can be successfully managed, people may be more confident that they can continue with day-to-day activities. (2) Using a single-item self-efficacy question from the Musculoskeletal Health Questionnaire, measured at baseline, 6-week, 3-, 6- and 12-month follow-up. This single item is more direct in specifically asking about confidence to manage LBP. All self-efficacy questions were asked across all three trial arms.

Physical activity related to the intervention

Physical activity is a key part of guidelines for the management of LBP,[4] with systematic reviews showing evidence that exercise interventions can reduce LBP-related disability.[56] The question of how physical activity interventions reduce LBP-related disability is complex, with aspects of physical interventions likely targeting multiple physical, psychological and social mechanisms. However, the extent to which participants engage with proposed physical

activity may be a primary mediator for the impact of physical activity guidance on LBP-related disability. In the trial we included a single-item measure of self-reported engagement in physical activity: participants were asked, in the last week, how often they have been physically active with the aim of helping their back. Responses range from 0 to 3, with 0 indicating '0 days' and 3 indicating '5 + days'. This question was asked across all trial arms at baseline, 6 weeks, 3, 6 and 12 months. A brief, single-item approach to measuring physical activity as a mediator was chosen to limit the potential of the measure to inadvertently act as a prompt/intervention for physical activity, as it was asked across all arms.

SupportBack 2 was a complex trial with two primary quantitative mediators measured, three arms and four follow-up points. Consequently, our approach to mediation needed to be flexible and the final approach was determined on the basis of the preceding effectiveness analysis.

Determining approach based on effectiveness analysis: usage related to outcome

The changes between groups in our primary outcome, LBP-related disability over time, were not significant and did not meet our MCID for either of the interventions compared to usual care. However, those in both intervention groups were significantly more likely to achieve a 30% reduction in LBP-related disability at 12 months as measured with the RMDQ, than those in usual care. Therefore, we decided to explore whether the usage was related to this within-person MCID. We also explored whether usage of the digital interventions was related to increases in pain self-efficacy at 6 weeks.

Determining approach based on effectiveness analysis: mediation

The analyses conducted to determine our mediation strategy were guided by the basic logic of mediation as outlined in *Figure 5*.

As our primary outcome was not significantly different between trial arms, we kept our mediation analysis exploratory, brief and related to secondary outcomes where the model in *Figure 5* could be plausible. Based on the effectiveness analysis, the effect of the internet intervention on LBP-related disability (measured with the RMDQ) at 12 months compared to usual care satisfied requirements for path 'c'. The internet intervention also significantly improved pain self-efficacy at the 6-week time point compared to usual care, satisfying requirements for path 'a'. Therefore, we conducted a mediation analysis to determine path 'b', and whether improvements in pain self-efficacy at 6 weeks mediated improvements in LBP disability at 12 months in the intervention-alone group. We did not conduct mediation analyses on physical activity, as there were no instances/paths where either of the interventions had an effect on data related to physical activity compared to usual care, and also affected LBP-related disability.

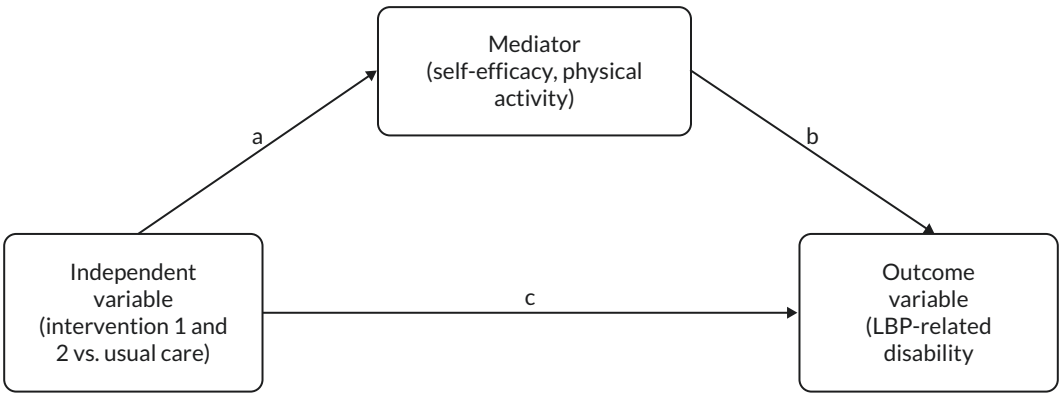

FIGURE 5 Logic of mediation containing SB2 variables.

Methods

Participants

Participants provided data as part of the SB2 trial; eligibility and characteristics can be found on page 3 of this report.

Measures

Usage and implementation

Usage for this analysis was primarily defined as the completion of specific sessions in the SupportBack programme. Session complete points were set in the programming of the digital intervention. Most sessions in the SupportBack intervention featured a core section supporting the use of activity to manage LBP through goal setting, monitoring and personalised feedback based on goal progress. Following this core section, participants could select a LBP-related module to explore (e.g. sleep, mood, flare-ups). These modules were not interactive in the same way as the goal section. Session complete tags were recorded in the data if a participant had at least completed the full goal setting section of the session they were engaged with. We regarded this as the core 'active' part of each session. When a participant had completed all six sessions, if they returned to the SupportBack intervention, they had access to a static repository of physical activity material and all the LBP-related modules. For this analysis, accessing of the static material was determined by whether they had visited the 'home page' for this static section (from which further static material could be accessed).

The number of calls successfully made to the participants in the telephone physiotherapist support arm was recorded by the trial team over the intervention period. Physiotherapists were asked to offer up to three calls, up to an hour in total (up to 30 minutes for the first call, 15 up to minutes for the second call, up to 15 minutes for the third call).

Low back pain-related disability

As reported in the RCT chapter, LBP-related disability was measured with the RMDQ. In this quantitative process analysis, the RMDQ was used in two ways: when exploring how usage was related to outcome, a within-person MCID of a 30% reduction in RMDQ from baseline to 12 months was used. As described above, in the mediation analysis, the RMDQ at 12 months was used.

Pain self-efficacy

For this quantitative process analysis, we used pain self-efficacy as measured by the PSEQ at the 6-week follow-up point in this trial.

Analysis

The usage analysis was primarily descriptive, reporting numbers and percentages completing aspects of the intervention in each intervention arm, as well as numbers of phone calls received for the internet intervention with the support group. Regression models were used to determine if usage level was related to outcome. To allow enough data for the models to converge, usage patterns were split by (1) low usage: completing at least one to three modules, and (2) high usage: completing four to six modules. Our pre-specified within-group MCID (30% change from baseline at 12 months) from our effectiveness SAP was used as an outcome. These models were repeated focusing on pain self-efficacy at 6 weeks.

For the mediation analysis, we used an instrumental variable approach, which aims to account for potential confounding between the mediator and the outcome by adjusting for instrumental variables. This involved: (1) a linear regression of RMDQ at 12 months on PSEQ at 6 weeks and randomised group, adjusting for baseline RMDQ, centre, age, prior duration of pain and STarT Back risk group; and (2) a linear regression of PSEQ at 6 weeks on randomised group and the instrumental variables, which were the two-way interactions of each covariate with randomised group.

Results

Intervention usage

Intervention use was higher in the internet intervention plus support arm than in the internet intervention arm. A similar percentage started session 1 in both groups, but fewer completed at least session 1 in the internet intervention arm (86% in internet intervention plus support vs. 66% in internet intervention arm complete at least session 1). The most popular modules were sleep, relieving pain and flare-ups (*Table 18*). Use of the static information following the six-session interactive period was low.

Effect of intervention usage on outcomes

Among participants in the internet intervention arm, there was no evidence of a difference in the proportion achieving the MCID according to intervention usage (67% in the higher usage group vs. 66% in the lower usage group, adjusted OR 0.9, 95% CI 0.4 to 2.1), see *Table 19*. Among participants in the internet intervention plus support arm, there was no evidence of a difference in the proportion achieving the MCID according to intervention usage (63% in the higher usage group vs. 57% in the lower usage group, adjusted OR 1.7, 95% CI 0.8 to 3.6).

Among participants in the internet intervention arm, there was no evidence of a difference in PSEQ at 6 weeks by intervention usage [median 46.5 in the higher usage group compared to 46 in the lower usage group, adjusted incidence rate ratio (IRR) 1.01, 95% CI 0.96 to 1.07]. Similarly, among the internet intervention plus support arm, there was no evidence of a difference in PSEQ at 6 weeks by intervention usage (median 45 in the higher usage group vs. 50.5 in the lower usage group, adjusted IRR 0.97, 95% CI 0.92 to 1.01).

TABLE 18 Intervention usage

	Internet intervention	Internet intervention + telephone support
Sessions started (mean, SD)	2.8 (2.2)	3.7 (2.0)
Sessions completed (mean, SD)	2.4 (2.4)	3.4 (2.2)
Session 1 started (*n*, %)	265 (96.4)	271 (98.6)
At least session 1 completed (*n*, %)	182 (66.2)	236 (85.8)
At least two out of three physiotherapist telephone calls (*n*, %)	–	196 (71.0)
At least session 1 completed and at least two out of three physiotherapist telephone calls (*n*, %)	–	186 (67.4)
Modules accessed (n, %)		
Mood	47 (17%)	77 (28%)
Relieving pain	67 (24%)	109 (40%)
Sleep	75 (27%)	124 (45%)
Work	54 (20%)	84 (31%)
Daily living	52 (19%)	86 (31%)
Flare-ups	64 (23%)	105 (38%)
Accessed static information (*n*, %)	12 (4.4)	24 (8.7)
Number of times static information accessed (median, IQR)	1 (1–2)	1 (1–2)

TABLE 19 Outcomes by intervention usage (sessions completed)

	Internet intervention		Internet intervention + telephone support	
Reached MCID[a]	Number (%)	Adjusted[b] OR (95% CI)	Number (%)	Adjusted[b] OR (95% CI)
Completed sessions				
1–3	41 (66.1)	Ref	35 (56.5)	Ref
4–6	58 (66.7)	0.9 (0.4 to 2.1)	77 (63.1)	1.7 (0.8 to 3.6)
PSEQ at 6 weeks	**Median (IQR)**	**Adjusted[b] IRR (95% CI)**	**Median (IQR)**	**Adjusted[b] IRR (95% CI)**
Completed sessions				
1–3	46 (31.5–54.5)	Ref	50.5 (38–56)	Ref
4–6	46.5 (34–53)	1.01 (0.96 to 1.07)	45 (32–54)	0.97 (0.92 to 1.01)

a Reached 30% reduction in RMDQ at 12 months compared to baseline.
b Adjusted for baseline RMDQ, centre, STarT Back risk group, previous duration of pain and age.

Mediation analysis

In the mediation analysis, we wished to determine whether PSEQ at 6 weeks was a mediator for LBP-related disability (RMDQ) at 12 months, comparing the internet intervention arm to usual care. The instrumental variable approach to mediation produced an indirect effect of −0.2, 95% CI −0.7 to 0.3, indicating no evidence of a mediating effect of PSEQ at 6 weeks on RMDQ at 12 months for the internet intervention arm (*Table 20*).

Summary

In this quantitative process analysis, we explored the usage of the internet intervention and whether this was related to outcomes. We also explored whether there was any evidence of mediation of LBP-related disability outcomes by our pre-specified variable self-efficacy.

The addition of telephone support increased the use of internet intervention. This was true of both the sessions and the LBP-related modules. Use of the static information following the interactive sessions was low in both arms. The focus of the intervention was on the six interactive sessions, use after the sixth session was not emphasised.

Lower or higher use of the internet intervention both with and without support was not significantly related to the likelihood of a ≥ 30 reduction in LBP-related disability at 12 months. Low or high use of the internet intervention both with and without support was not significantly related to increased pain self-efficacy at the 6-week time point. Pain self-efficacy at 6 weeks did not mediate reductions in LBP-related disability at 12 months in the internet intervention alone arm, compared with usual care. As there were no instances where the interventions impacted physical activity and were related to reductions in LBP-related disability, it was clear that our measures of physical activity were not reflecting an important process related to intervention outcome.

TABLE 20 Mediation analysis of PSEQ at 6 weeks on RMDQ at 12 months

Mediator	Indirect (mediating) effect (95% CI)	Direct effect (95% CI)
PSEQ at 6 weeks	−0.17 (−0.67 to 0.32)	−0.81 (−1.92 to 0.29)

Chapter 7 Health economic evaluation

Introduction

Background

Low back pain is one of the most common and costly problems seen in GP surgeries. Internet interventions may provide a new and efficient way of supporting and encouraging patients to become more active in self-management of LBP. They would be expected to be relatively low cost and widely accessible. Internet interventions may therefore be a practical way of providing effective care with low additional resource requirements. As such they may represent an efficient use of scarce NHS resources. However, for this to be true these interventions need to be shown to be both effective and to represent 'value for money'. This would mean they would represent a good use of NHS resources compared to using those resources on alternative NHS care. For this reason, the SB2 study was designed with a clinical component to assess effectiveness, but it was also designed to have a parallel health economics component to assess these wider issues of value for money. This health economics component would generate additional information designed to inform the potential decision as to whether to provide any of the tested interventions. The methods employed in this economic evaluation and the results obtained are presented in this chapter.

Study rationale

The rationale of the health economics component reported in this chapter was, therefore, to perform an economic analysis alongside the RCT to collect data on resource use and effectiveness to inform future decision-making about the potential adoption of the interventions evaluated in the clinical trial.

Objective(s) of economic evaluation

- To estimate the costs associated with each of the three interventions and to estimate incremental cost differences between each intervention.
- To estimate quality-adjusted life-years (QALYs) generated over the 12 months follow-up in each of the interventions and to estimate incremental differences between interventions.
- To estimate cost–utility in terms of cost per additional QALY and to estimate cost-effectiveness in terms of cost per improvement in RMDQ between baseline and the 12-month follow-up.

Methods

Design of the health economics component

The economic analysis reported here is a 'within trial' analysis. The term 'within-trial' means that analysis was conducted using data obtained from SB2 participants within the time frame of follow-up in the trial (1 year). The economic analysis was performed using individual patient-level data from SB2. Two types of economic evaluations were carried out. Firstly, a cost–utility study was conducted using the outcome of QALYs. This was the primary or base-case analysis. Secondly, a cost-effectiveness study was conducted using the outcome of improvement in RMDQ over the follow-up period of the study. This is presented as a secondary analysis as part of the sensitivity analysis, see the results section for further details.

As SB2 was conducted in the UK and all participants were treated within the UK NHS, the analysis presented here applies to the UK, but conclusions are likely to be relevant to other jurisdictions, if appropriate caveats are made. The perspective for the economic analysis was that of the NHS. As the duration of the study was 1 year, neither costs nor benefits were discounted. All costs reported in the analysis were in Great British pounds and were for the cost year 2020–1. Where costs were obtained from different cost years, they were adjusted to 2020–1 prices using an appropriate inflator/deflator. Before analysis commenced, the health economics lead (David Turner) compiled a health economics analysis plan (HEAP). This was circulated to the study CI, statistician and team members on the 13 of August 2022 for comment (see *Report Supplementary Material 3*).

Estimation of costs

Costs of the intervention

We estimated two costs associated with the interventions. Costs associated with providing the internet intervention, and costs associated with providing the telephone support. For the internet intervention, the resources included in this analysis were 10% full-time equivalent for a researcher to provide user support, a fee of £800 for hosting the site, and a fee of £2800 for site maintenance. For the telephone support, a log was kept of contacts by the physiotherapists for each participant who received telephone support. This also recorded the number of sessions received by participants. We also had access to data on a sample of 50 participants which gave the duration in minutes for sessions 1, 2 and 3. This sample was used to estimate the duration of each of these sessions and was used to cost the telephone support received. The average duration was for 25, 14 and 13 minutes for sessions 1–3, respectively. Contact time was costed using data from a published source.[57] We assumed an agenda for change grade 6 physiotherapist. To allow for time spent related to the call but not directly calling, we used a multiplier of 1.3. This was taken from Personal Social Services Research Unit (PSSRU) unit costs and was an estimate of the time spent on a call related to other activity for somebody engaging in telephone triage.[57]

National Health Service resource use

For NHS resource use in the follow-up, two alternative sources were available: a review of general practice patient records conducted at the end of follow-up, and a patient-completed questionnaire at 6 and 12 months. We specified in the HEAP that the base-case analysis would use LBP-specific costs obtained from general practice patient records, and these results are presented here.

General practice patient records review

A form was designed for practice staff to enter data. This was based on a modified version of a data collection form used successfully in SupportBack 1, the prior feasibility and randomised trial.[23] This collected data in two time periods: the 3 months prior to recruitment (for primary care-based costs only) and for the 12 months of follow-up. In the follow-up period, data were collected on the following: general practice-based contacts, other primary care contacts; pain-related medicines; LBP-related physiotherapy; hospital admissions, accident and emergency (A&E) contacts; and outpatient visits. For physiotherapy, the completer was asked to divide contacts into primary care (First Contact Practitioner), community musculoskeletal physiotherapy clinic; and musculoskeletal interface/Integrated Clinical Assessment and Treatment Service clinic. For primary and secondary care contacts, the completer was asked to record all contacts as well as how many were specific to LBP. This enabled the estimation of LBP-specific costs as well as an estimate of general costs.

Valuation of identified resources

Healthcare resource use identified by the general practice patient records review was valued using three main sources. For primary care, estimates of unit costs published by the University of Kent were used.[57] For secondary care contacts, a cost was obtained from NHS reference costs.[58] Drugs costs were obtained from the online *British National Formulary*.[59] The main unit costs used are given in *Table 21*.

For primary care costs, there were specific categories covering GP and practice nurse (PN), and there was also an option to record the numbers of telephone contacts with GPs. Other primary care contacts were also requested, common examples included: healthcare assistants (£10.06); pharmacists (£27); phlebotomy (£4.75) and district nurses (£40.52).

For physiotherapy contacts, the total number of contacts was recorded in the general practice patient record review. Also given were numbers of contacts for primary care (first contact practitioner); community musculoskeletal physiotherapy clinic; and musculoskeletal interface/ICATS clinic. However, this detail was incomplete. For only 62% of the estimate of total physiotherapy contacts were details of type of physiotherapy provided. For this reason, we used the data available on the numbers of physiotherapy contacts by type to provide a weighted average estimate for physiotherapy contacts (£93.82). This weighted average was then applied to the total number of physiotherapy contacts recorded to estimate the cost of physiotherapy.

TABLE 21 Examples of common unit costs used

Resource use	Unit cost (£)	Assumptions
GP surgery visit	£34.20[57]	Based on a surgery consultation of 9.22 minutes.
GP telephone contact	£15.32[57]	Assumed same cost as GP telephone triage from PSSRU unit costs
PN surgery contact	£13.41[57]	Cost per hour based on PSSRU 2021, duration of contact taken from earlier edition[60]
Physiotherapy – first contact practitioner clinic	£43.42[57]	Assumes grade 6 and duration of 30 minutes. Costs per hour from PSSRU 2021, duration and multiplier based on PSSRU 2010.[60]
Community musculoskeletal physiotherapy clinic	£104[58]	NHS reference costs
Physiotherapy outpatient	£119[58]	Weighted average of outpatient costs for physiotherapy
Elective	£6,889[58]	Weighted average of all electives
Non-elective	£4,842[58]	Weighted average of all non-electives
Non-elective short stay	£959[58]	Weighted average of all non-elective short stay
Day case	£1,192[58]	Weighted average of all day case
A&E	£114[58]	Weighted average of all non-admitted A&E
Outpatients	£182[58]	Weighted average of all non-admitted A&E

For A&E contacts a single cost was used, a weighted average of all non-admitted A&E contacts. For outpatient contacts, unit costs from NHS reference costs were divided by outpatient speciality. The data from patient records recorded, in the majority of cases, the outpatient department (e.g. orthopaedics) and a procedure or reason. This generally allowed an appropriate outpatient cost to be selected. Only in a few cases was a weighted average outpatient cost used (as given in *Table 21*). However, this gives an approximation of the average unit cost used overall.

Measuring outcomes

Two outcome measures were used for the economic evaluation. Firstly, we estimated QALYs by means of the EQ-5D-5L.[61] To obtain QALYs from the EQ-5D-5L, a UK-based valuation system is required to convert the item scores into a utility-based score. This has the anchor points of 1 (full health) and 0 (dead), but negative scores are also possible with the EQ-5D-5L. Currently, there are three main options for obtaining UK utility values for the EQ-5D-5L. These include: the algorithm published by Devlin and colleagues;[62] values mapped using a 'cross-walk' method from the EQ-5D-3L value set;[63] and a scoring algorithm proposed by Hernández Alava *et al.*[64] Until recently, guidance from the NICE[65] recommended valuation using the 'cross-walk' value set, this was the analysis pre-specified in the HEAP and this value set has been used in this analysis. However, NICE have subsequently updated their guidance to recommend the scoring method proposed by Hernández Alava *et al.*[64]

EuroQol-5 Dimension, five-level version scores were estimated for each of the 5 time points at which the EQ-5D-5L was completed. The original intention, as specified in the HEAP, was to calculate QALY's using these 5 time points. However, analysis of actual data indicated that response rates were lowest at the 3-month and 6-month time points. The 3- and 6-month follow-up points were not accompanied by dedicated telephone follow-up of non-responders, as was the case at the other time points. For that reason, QALYs were also calculated using only the baseline, 6-week and 12-month EQ-5D-5L scores. These were compared with QALY values derived from all 5 time points and found to be similar (mean values within 1%). Subsequently, in consultation with the study CI, the 3-time point QALY scores were used in the analysis. QALY scores were estimated by means of 'area under the curve' assuming a linear relationship between time points. This analysis constitutes a cost–utility analysis (CUA). In addition to the CUA, we also estimated a cost-effectiveness analysis using improvement in RMDQ from baseline to 12-month follow-up.

Analysis

Missing data can be a particular issue in health economic data as both cost and outcomes tend to be aggregates of other variables. For example, in SB2, a QALY can only be calculated if an individual has values for EQ-5D-5L scores at 3 time points.

This tends to have a cumulative effect. When combined with missingness in the estimates of costs as well as the potential for there to be missing data in some of the baseline characteristics used in the analysis, there was the potential for missing data to affect the results. With high levels of missing data, there would be concerns about bias in the estimates if a complete-case analysis (CCA) was used as the base case. For this reason, the base-case analysis used the method of multiple imputation. Imputation was carried out using the 'mi impute chained' command in Stata 17 (StataCorp LP, College Station, TX, USA). The MI model included the following variables: study group; EQ-5D-5L scores at all time points; RMDQ baseline score; RMDQ improvement from baseline to 12 months; costs in 3 months prior to recruitment; costs in study period; age; STarT Back risk group; pain duration; and stratification factors. Multiple imputation was used to create 40 data sets, which were then pooled using Rubin's rules.[66] Forty sets were chosen as advice suggests using one imputation set per percentage point of missing data.[67] We present the CCA as a sensitivity analysis. Guidelines on handling missing data in economic evaluations were followed.[67]

The estimate of cost–utility and cost-effectiveness was evaluated using regression-based methods to allow for the effect of baseline characteristics. Seemingly unrelated regression (sureg) in Stata version 17 was used to estimate costs and benefits allowing for any correlation between them. For QALYs, results were adjusted for baseline EQ-5D-5L score, stratification factors, pain duration, STarT Back risk group and age. For costs, results were adjusted for costs in the 3 months prior to recruitment, stratification factors, pain duration, STarT Back risk group and age. The same baseline characteristics were also used to estimate improvement in RMDQ score, except that baseline RMDQ was added. In all cases, the intervention group was included in the regression equations, with the usual care group specified as the comparator. Coefficients for the intervention group and the intervention plus telephone-support group are both comparisons to the usual care group. Cost and QALY data were combined to calculate an incremental cost-effectiveness ratio (ICER). A similar approach was taken to estimate of cost-effectiveness based on the improvement in RMDQ. It should be noted that the use of sureg necessitated a different approach to the study primary outcome measure in the clinical study as a repeated-measures design was used. Differences in results produced will be compared with the primary outcome measure and this will be considered in the interpretation of results. See *Report Supplementary Material 3* for the full HEAP.

Results

Costs

Of the 825 participants in the study, a cost from GP patient records could be obtained in 699 cases (85%). There were 226, 235 and 238 in the usual care group, intervention group and intervention plus telephone-support groups, respectively. Analysis of primary care-based costs in the 3 months prior to randomisation suggested costs were similar between groups and there was no evidence that any one group was a higher user of LBP-related resources (*Table 22*). Also shown are cost for all reasons, *Table 23*. In the 3 months prior to recruitment, slightly more than half of all primary care resource use was related to LBP.

Low back pain-related costs and costs for all reasons are given in *Tables 24* and *25*, for the 12 months follow-up. As well as primary care these cover secondary care, medicines for back pain, back-pain-related physiotherapy and the cost of the interventions. Back-pain-related costs again appear to be similar between groups though are slightly higher for the intervention plus telephone support intervention. The cost of the internet intervention was estimated as £16 per person and the cost of telephone support was £45 per person. For costs for all reasons there appears to be higher costs associated with the internet-only group, driven by higher costs for hospitalisations. This appears to be due to small numbers of high-cost stays which are not evenly distributed over the groups and were felt to be unlikely to be influenced by the study group (e.g. hip replacement operations). For this reason, we focused on back pain-only costs in our base-case analysis.

TABLE 22 Primary care costs in the 3 months prior to randomisation – back-pain-related costs only

Resource use	Statistics	Usual care	Intervention	Intervention + telephone support
GP surgery visits number	Mean (CI)	0.79 (0.68 to 0.9)	0.82 (0.69 to 0.95)	0.8 (0.67 to 0.93)
GP surgery visits cost	Mean (CI)	26.94 (23.11 to 30.76)	28.09 (23.58 to 32.6)	27.3 (22.94 to 31.66)
PN surgery visits number	Mean (CI)	0.04 (0.01 to 0.06)	0.03 (0.01 to 0.06)	0.05 (0.02 to 0.08)
PN surgery visits cost	Mean (CI)	0.47 (0.15 to 0.8)	0.46 (0.14 to 0.77)	0.68 (0.24 to 1.11)
GP telephone contacts number	Mean (CI)	0.32 (0.22 to 0.43)	0.44 (0.33 to 0.56)	0.31 (0.22 to 0.4)
GP telephone contacts cost	Mean (CI)	4.7 (3.33 to 6.07)	6.78 (4.99 to 8.57)	4.95 (3.38 to 6.52)
Other visits number	Mean (CI)	0.13 (0.02 to 0.24)	0.13 (0.07 to 0.2)	0.12 (0.05 to 0.2)
Other visits costs	Mean (CI)	5.82 (0.84 to 10.81)	5.48 (1.63 to 9.34)	5.56 (1.61 to 9.5)
Total cost	**Mean (CI)**	**38.18 (31.49 to 44.88)**	**40.81 (34.48 to 47.13)**	**38.23 (32.25 to 44.22)**

TABLE 23 Primary care costs in the 3 months prior to randomisation – costs for any reason

Resource use	Statistics	Usual care	Intervention	Intervention + telephone support
GP surgery visits, number	Mean (CI)	1.27 (1.11 to 1.42)	1.37 (1.19 to 1.55)	1.34 (1.15 to 1.52)
GP surgery visits, cost	Mean (CI)	43.3 (37.8 to 48.7)	46.9 (40.6 to 53.1)	45.4 (39.1 to 51.7)
PN surgery visits, number	Mean (CI)	0.3 (0.22 to 0.38)	0.34 (0.25 to 0.43)	0.37 (0.25 to 0.48)
PN surgery visits, cost	Mean (CI)	3.98 (2.87 to 5.08)	4.57 (3.34 to 5.79)	4.9 (3.33 to 6.47)
GP telephone contacts, number	Mean (CI)	0.67 (0.49 to 0.85)	0.71 (0.55 to 0.86)	0.67 (0.5 to 0.83)
GP telephone contacts, cost	Mean (CI)	10.17 (7.41 to 12.93)	10.69 (8.32 to 13.06)	10.17 (10.17 to 10.17)
Other visits, number	Mean (CI)	0.4 (0.18 to 0.62)	0.37 (0.24 to 0.51)	0.37 (0.2 to 0.53)
Other visits, costs	Mean (CI)	11.38 (2.69 to)	13.51 (2.29 to 24.72)	11.8 (5.4 to 18.2)
Total cost	**Mean (CI)**	**68.81 (58.11 to 79.5)**	**75.62 (62.35 to 88.9)**	**72.28 (62.83 to 81.74)**

TABLE 24 Back-pain-related costs in the follow-up period

Resource use	Statistics	Usual care	Intervention	Intervention + telephone support
GP surgery visits number	Mean (CI)	0.44 (0.31 to 0.56)	0.44 (0.31 to 0.57)	0.43 (0.31 to 0.54)
GP surgery visits cost	Mean (CI)	14.98 (10.7 to 19.27)	15.14 (10.67 to 19.6)	14.66 (10.7 to 18.61)
PN surgery visits number	Mean (CI)	0.03 (0.01 to 0.05)	0.03 (0.01 to 0.06)	0.05 (0 to 0.1)
PN surgery visits cost	Mean (CI)	0.36 (0.07 to 0.64)	0.46 (0.11 to 0.81)	0.68 (0 to 1.36)
GP telephone contacts number	Mean (CI)	0.4 (0.26 to 0.54)	0.56 (0.37 to 0.75)	0.57 (0.4 to 0.74)
GP telephone contacts cost	Mean (CI)	8.75 (6.16 to 11.35)	8.54 (5.64 to 11.44)	6.1 (3.97 to 8.24)

continued

TABLE 24 Back-pain-related costs in the follow-up period (*continued*)

Resource use	Statistics	Usual care	Intervention	Intervention + telephone support
Other visits number	Mean (CI)	0.95 (0.72 to 1.17)	0.96 (0.74 to 1.19)	0.92 (0.67 to 1.18)
Other visits costs	Mean (CI)	3.49 (0.57 to 6.41)	2.1 (0.42 to 3.77)	4.59 (−0.01 to 9.2)
Total general practice cost	**Mean (CI)**	**24.93 (18.35 to 31.5)**	**26.23 (19.99 to 32.47)**	**28.68 (21.48 to 35.88)**
Prescriptions for pain – number	Mean (CI)	3.17 (2.22 to 4.13)	4.03 (2.87 to 5.2)	3.45 (2.54 to 4.37)
Prescriptions for pain – cost	Mean (CI)	14.31 (6.29 to 22.34)	15.29 (9.7 to 20.88)	10.52 (7.08 to 13.95)
Physiotherapy, number	Mean (CI)	0.41 (0.28 to 0.54)	0.37 (0.27 to 0.47)	0.53 (0.37 to 0.68)
Physiotherapy, cost	Mean (CI)	40.25 (27.32 to 53.18)	33.97 (24.63 to 43.31)	47.51 (33.75 to 61.28)
Hospitalisations – number	Mean (CI)	0.04 (−0.01 to 0.08)	0.05 (0 to 0.1)	0.13 (0.05 to 0.2)
Hospitalisations – cost	Mean (CI)	55.22 (−16.61 to 127.05)	33.63 (−0.34 to 67.6)	99.81 (29.64 to 169.97)
A&E – number	Mean (CI)	0.03 (−0.01 to 0.08)	0 (0 to 0)	0.02 (0 to 0.04)
A&E – costs	Mean (CI)	3.52 (−1.62 to 8.65)	0 (0 to 0)	2.39 (−0.09 to 4.86)
Outpatient – number	Mean (CI)	0.4 (0.21 to 0.6)	0.43 (0.29 to 0.57)	0.36 (0.24 to 0.49)
Outpatient – costs	Mean (CI)	76.98 (36.1 to 117.85)	85.15 (55.86 to 114.45)	65.49 (41.22 to 89.76)
Cost of internet support		–	16	16
Cost of physiotherapy telephone support		–	–	45 (43 to 48)
Total cost of intervention		–	16	61 (59 to 63)
Total costs for all NHS categories	Mean (CI)	215 (122 to 309)	211 (153 to 268)	316 (232 to 400)

TABLE 25 Costs for any reason in the follow-up period

Resource use	Statistics	Usual care	Intervention	Intervention + telephone support
GP surgery visits number	Mean (CI)	2.24 (1.87 to 2.6)	2.27 (1.92 to 2.62)	2.21 (1.85 to 2.56)
GP surgery visits cost	Mean (CI)	76.6 (64.1 to 89.1)	77.6 (65.7 to 89.5)	75.4 (63.2 to 87.7)
PN surgery visits number	Mean (CI)	1.75 (1.06 to 2.44)	1.2 (0.99 to 1.41)	1.18 (0.87 to 1.5)
PN surgery visits cost	Mean (CI)	23.44 (14.17 to 32.71)	16.15 (13.33 to 18.96)	15.89 (11.72 to 20.06)
GP telephone contacts number	Mean (CI)	2.82 (2.28 to 3.36)	2.98 (2.46 to 3.5)	2.84 (2.25 to 3.43)
GP telephone contacts cost	Mean (CI)	43.25 (34.96 to 51.54)	45.7 (37.72 to 53.68)	43.51 (43.51 to 43.51)
Other visits number	Mean (CI)	0.95 (0.72 to 1.17)	0.96 (0.74 to 1.19)	0.92 (0.67 to 1.18)
Other visits costs	Mean (CI)	20.67 (9.63 to 31.7)	22.15 (12.91 to 31.39)	22.17 (13.95 to 30.38)
Total practice costs	**Mean (CI)**	**164 (140 to 188)**	**162 (142 to 181)**	**157 (137 to 177)**
Prescriptions, number	Mean (CI)	3.17 (2.22 to 4.13)	4.03 (2.87 to 5.2)	3.45 (2.54 to 4.37)

TABLE 25 Costs for any reason in the follow-up period (*continued*)

Resource use	Statistics	Usual care	Intervention	Intervention + telephone support
Prescriptions, cost	Mean (CI)	14.31 (6.29 to 22.34)	15.29 (9.7 to 20.88)	10.52 (7.08 to 13.95)
Physiotherapy – number	Mean (CI)	0.41 (0.28 to 0.54)	0.37 (0.27 to 0.47)	0.53 (0.37 to 0.68)
Physiotherapy – costs	Mean (CI)	40.25 (27.32 to 53.18)	33.97 (24.63 to 43.31)	47.51 (33.75 to 61.28)
Hospitalisations – number	Mean (CI)	0.17 (0.11 to 0.23)	0.18 (0.12 to 0.24)	0.2 (0.13 to 0.27)
Hospitalisations – cost	Mean (CI)	416 (232.8 to 598.8)	586 (310.77 to 862.17)	366 (210.66 to 521.3)
A&E – number	Mean (CI)	0.26 (0.14 to 0.38)	0.23 (0.15 to 0.31)	0.24 (0.16 to 0.32)
A&E – costs	Mean (CI)	29.65 (15.7 to 43.6)	26.1 (17.17 to 35.03)	27.2 (18.3 to 36.11)
Outpatient – number	Mean (CI)	1.52 (1.23 to 1.81)	1.5 (1.22 to 1.78)	1.37 (1.08 to 1.65)
Outpatient – costs	Mean (CI)	289 (225 to 354)	291 (229 to 352)	282 (211 to 352)
Cost of internet intervention	Mean (CI)	–	16	16
Cost of physiotherapy telephone support	Mean (CI)	–	–	45 (43 to 48)
Total cost of intervention	**Mean (CI)**	**–**	**16**	**61 (59 to 64)**
Total costs for all NHS categories	**Mean (CI)**	**953 (719 to 1191)**	**1130 (830 to 1431)**	**951 (743 to 1159)**

Outcome measures

Rates of completion of the EQ-5D-5L varied between the different time points (*Table 26*). It was complete at baseline, falling to a 71% completion rate at the 6-month follow-up. It can be seen that EQ-5D-5L scores are similar between groups and there is generally an indication of improvement between baseline and 12 months. For the intervention plus telephone-support group, it can be seen that confidence intervals between baseline and 12-month EQ-5D-5L do not overlap.

As discussed earlier, in order to estimate QALYs as originally planned, all 5 time points needed to have been completed, meaning that QALYs could only be estimated in 61% of cases. The availability of a complete QALY score differed between trial groups, with rates of 69%, 56% and 58% for usual care, intervention and intervention plus telephone-support groups respectively. It can therefore be seen that there was a difference between EQ-5D-5L completion rates by group. *Table 26* also shows QALY values when calculated using only the time points of baseline, 6 and 12 months. Two values are shown. Firstly, we limit the analysis to only those cases where a QALY was also obtainable from all 5 time points. This facilitated direct comparison between the two methods. Secondly, we present values for all cases where a QALY could be obtained using EQ-5D-5L at only 3 time points. Calculating QALYs from 3 time points meant that QALY scores were available for more cases (77%, 70% and 74% for the three groups, respectively). The number of missing QALYs scores is also more evenly distributed over the three groups.

Economic evaluation

Cost–utility and cost-effectiveness analyses results are shown in *Table 27*. These results are for the imputed data sets using seemingly unrelated regression. The base-case estimates QALYs and only considers NHS costs that were specific to back pain. The base-case analysis is shown as the first set of results and in all cases the incremental costs and incremental effects are compared to the usual care group. Compared to the usual care group, both interventions generate additional QALYs. These QALY differences are small, at around 0.01 of a QALY. Additional costs are negative for the internet intervention and are £96 for the intervention plus telephone-support group. None of these results

TABLE 26 EuroQol-5 Dimensions, five-level version scores at completion time points and QALY scores

	Usual care		Intervention		Intervention + telephone support	
Time period	*N*	Mean (95% CI)	*N*	Mean (95% CI)	*N*	Mean (95% CI)
Baseline EQ-5D-5L	274	0.65 (0.63 to 0.67)	275	0.63 (0.60 to 0.66)	276	0.63 (0.60 to 0.65)
EQ-5D-5L at 6 weeks	238	0.66 (0.64 to 0.69)	217	0.66 (0.63 to 0.69)	229	0.67 (0.65 to 0.70)
EQ-5D-5L at 3 months	218	0.66 (0.63 to 0.69)	187	0.68 (0.65 to 0.71)	192	0.71 (0.68 to 0.74)
EQ-5D-5L at 6 months	215	0.67 (0.64 to 0.70)	183	0.68 (0.64 to 0.71)	184	0.68 (0.65 to 0.71)
EQ-5D-5L at 12 months	222	0.69 (0.66 to 0.72)	215	0.68 (0.65 to 0.71)	214	0.71 (0.67 to 0.74)
QALY in follow-up (5 time points)	190	0.69 (0.66 to 0.72)	153	0.68 (0.64 to 0.71)	161	0.71 (0.69 to 0.74)
QALY in follow-up (3 time points, restricted)	190	0.69 (0.66 to 0.72)	153	0.67 (0.64 to 0.70)	161	0.72 (0.69 to 0.74)
QALY in follow-up (3 time points, all available data)	212	0.68 (0.65 to 0.71)	192	0.67 (0.64 to 0.70)	203	0.70 (0.67 to 0.72)

are significantly different from the usual care group. From the point estimates of effects, we can estimate ICERs. They follow convention in health economics and are compared to the best non-dominated alternative. Where an intervention is said to dominate, it means that it is both more effective and less costly than the intervention it is being compared to. For back-pain costs only it can be seen that the intervention-only group dominates the usual care group for both the QALY and RMDQ analyses. For the intervention with telephone-support group, the ICER compared to intervention only is £54,529. Hence, it would not seem to be cost-effective to add the telephone support to the SupportBack intervention. However, if SupportBack alone was unavailable, then the ICER for intervention + telephone support compared to usual care would be £7366 per QALY, meeting cost-effectiveness thresholds.

In addition to the base-case results presented in *Table 27*, we also present seven additional sensitivity analyses (see *Tables 27* and *28*). Sensitivity analyses are shown for the imputed analysis for all NHS costs, not just back pain. For the imputed cost/QALY analysis on total NHS costs, there is a reversal of the relative positions of the two internet interventions compared to the control group. This is caused by higher estimated costs for the intervention-only group, largely due to an increase in hospitalisation costs. Cost-effectiveness results are shown in *Table 27*, again for both LBP-related costs and all NHS costs. These present the cost per point improvement in the RMDQ between baseline and 12-month follow-up. However, for the cost per point change in RMDQ analysis, the results suggest that for the intervention-only group there is statistically significant differences with the 95% CIs not crossing zero. However, there are considerable uncertainties in all these analyses.

The same four analyses are shown in *Table 28*, this time for the CCAs only. For the cost–utility study, the results for the internet plus support group are similar to the imputed analysis. However, estimates of incremental QALYs are lower for the intervention-only group, meaning this group performs worse in the CCA compared to the imputed analysis.

For all results in *Tables 27* and *28*, the final column shows the ICER. To interpret ICERs, it is useful to consider what ICERs would be considered cost-effective. In the UK, a useful benchmark is the NICE threshold of between £20,000 and £30,000 per QALY.[68] For the cost-effectiveness analyses of cost per point change in RMDQ, there is a considerable variety of ICER estimates presented. It is also not clear how much society should be prepared to pay for a 1-point improvement in the RMDQ.

Cost-effectiveness acceptability curves

The ICERs given in *Tables 26* and *27* provide estimates of the additional cost divided by the additional effects compared to the next best non-dominated option. However, these estimates are based on the point estimates of cost and effects

TABLE 27 Economic analysis results based on regression analysis – imputed data sets

		Incremental cost	Incremental QALY gain	ICER
Base case: imputed analysis – cost/QALY (LBP costs only)	Intervention	−£16 (−128 to 95)	0.011 (−0.012 to 0.034)	Dominates control group
	Intervention + telephone support	£96 (−14 to 206)	0.013 (−0.011 to 0.037)	£54,529[a]
Imputed analysis – cost/QALY (all NHS costs)	Intervention	£138 (−221 to 497)	0.011 (−0.012 to 0.034)	Dominated by intervention + telephone-support group
	Intervention + telephone support	−£20 (−366 to 327)	0.013 (−0.011 to 0.037)	Dominates
Cost-effectiveness		Incremental cost	Change in RMDQ score	ICER
Imputed analysis – cost per change in RMDQ (LBP costs only)	Intervention	−£16 (−128 to 95)	0.94 (0.18 to 1.71)	Dominates usual care group
	Intervention + telephone support	£96 (−14 to 206)	0.57 (−0.22 to 1.36)	Dominated by intervention-only group
Imputed analysis – cost per change in RMDQ (all NHS costs)	Intervention	£138 (−221 to 497)	0.95 (0.18 to 1.71)	£423[b]
	Intervention + telephone support	−£20 (−366 to 327)	0.57 (−0.22 t6o 1.37)	Dominates usual care group

a As intervention-only group dominates usual care group, this ICER is intervention + telephone support compared to internet only. However, if intervention + telephone support is compared to usual care, the ICER is £7336.
b As intervention + telephone-support group dominates control group, this ICER is compared to the intervention + telephone-support group.

Note
As results are from the sureg regression comparing each intervention group with control, all reported incremental costs and incremental QALY gain are compared to usual care group.

from the sureg regression carried out in Stata. As estimates of both incremental costs and effects are comparatively small and there is considerable uncertainty shown in the CIs, there is the potential for the estimated ICERs to vary due to small changes in either costs or effects. To allow for parameter uncertainty, we pre-specified in the HEAP that we would estimate cost-effectiveness acceptability curves (CEACs). These show the probability that each of the interventions considered would be cost-effective at different valuations of each unit of effect. CEACs for the analyses presented in *Table 27* are shown in *Figures 6–9*

Figure 6 shows that for the base-case analysis, there is a high probability that the internet-only intervention is the most cost-effective at the NICE thresholds of between £20,000 and £30,000 per QALY. The usual care group has a probability of being cost-effective of < 10% at these values. The results for the cost-per-point improvement in RMDQ analysis for the imputed analysis are shown in *Figure 7*. This gives a similar conclusion to the base case, in that the intervention-only group is the most likely to be cost-effective at all values of a point change in the RMDQ examined. There is a difference between this and the cost/QALY analysis however, as the intervention plus telephone support has a very low chance of being the most cost-effective intervention at all values of a change in the RMDQ.

The CEACs relating to the CCA analysis are shown in *Figures 8* and *9*. *Figure 9* shows similarities with the imputed analysis, in that the internet-only intervention is the most likely to be cost-effective at all values of a point change in

TABLE 28 Economic analysis results based on regression analysis – CCA data sets

		Incremental cost	QALY gain	ICER
CCA analysis – cost/QALY (LBP costs only)	Intervention	£14	0.000	Undefined
		(−79 to 107)	(−0.026 to 0.026)	
	Intervention + telephone support	£76	0.013	£5953[a]
		(−15 to 167)	(−0.012 to 0.038)	
CCA analysis – cost/QALY (All NHS costs)	Intervention	£292	0.000	Undefined
		(−130 to 714)	(−0.026 to 0.025)	
	Intervention + telephone support	£41	0.013	£3234[b]
		(−372 to 454)	(−0.012 to 0.038)	
Cost-effectiveness		Incremental cost	Change in RMDQ score	ICER
CCA analysis – cost per change in RMDQ (LBP costs only)	Intervention	−£12	0.68	Dominates
		(−133 to 109)	(−0.19 to 1.55)	
	Intervention + telephone support	£43	0.67	Dominated by intervention-only group
		(−77 to 162)	(−0.19 to 1.54)	
CCA analysis – cost per change in RMDQ (all NHS costs)	Intervention	£331	0.68	£51,212[c]
		(−85 to 746)	(−0.19 to 1.55)	
	Intervention + telephone support	£18	0.68	£27[d]
		(−395 to 431)	(−0.19 to 1.54)	

a This ICER is compared to the usual care group.
b This ICER is compared to the usual care group.
c This ICER is compared to the intervention + telephone-support group.
d This ICER is compared to the usual care group.

Notes
As results are from the sureg regression comparing each intervention group with control, all reported incremental costs and incremental QALY gain are compared to usual care group.
For QALY analysis *N* = 488, for RMDQ analysis *N* = 524.

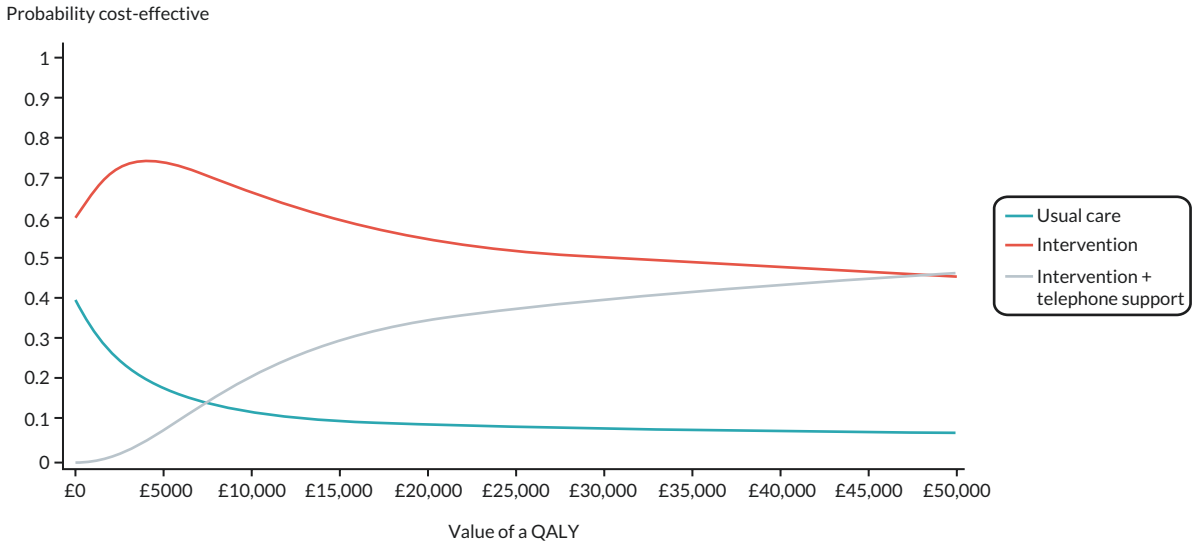

FIGURE 6 Cost-effectiveness acceptability curve showing the probability of the three interventions being cost-effective at different values of a QALY – imputed analysis.

RMDQ. Here, however, the intervention plus support arm has a higher probability of being cost-effective than the usual care group at values of a point change in RMDQ above approximately £85. The CEAC for the cost/QALY analysis for the CCA in *Figure 8* shows the biggest discrepancy between the imputed and CCAs. Here, the intervention plus telephone-support group is the most likely to be cost-effective at the NICE thresholds of between £20,000 and £30,000 per QALY. However, in both analyses, there is evidence to suggest that at least one of the interventions would be more likely to be cost-effective than the usual care group.

Discussion

Summary of main findings

The estimate of costs carried out for this analysis indicates that both internet interventions are comparatively low in cost with the cost of the intervention without support estimated at £16 per person and the intervention plus telephone support estimated to be £61 per person. When NHS costs related to care for LBP were also considered, there was no indication that total costs were different between study arms with analysis suggesting there were small cost

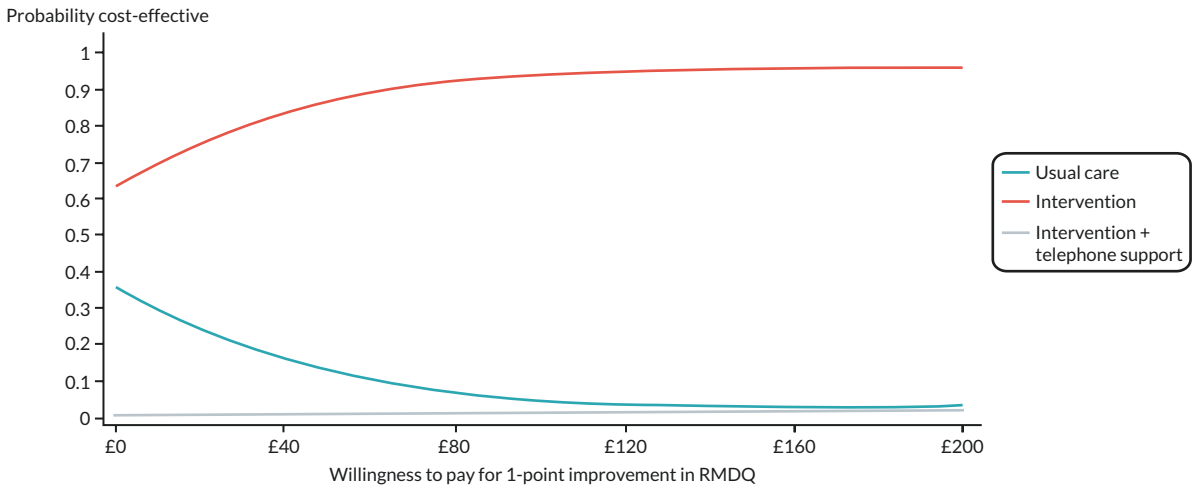

FIGURE 7 Cost-effectiveness acceptability curve showing the probability that each intervention is cost-effective at different values of a point change in the RMDQ – imputed analysis.

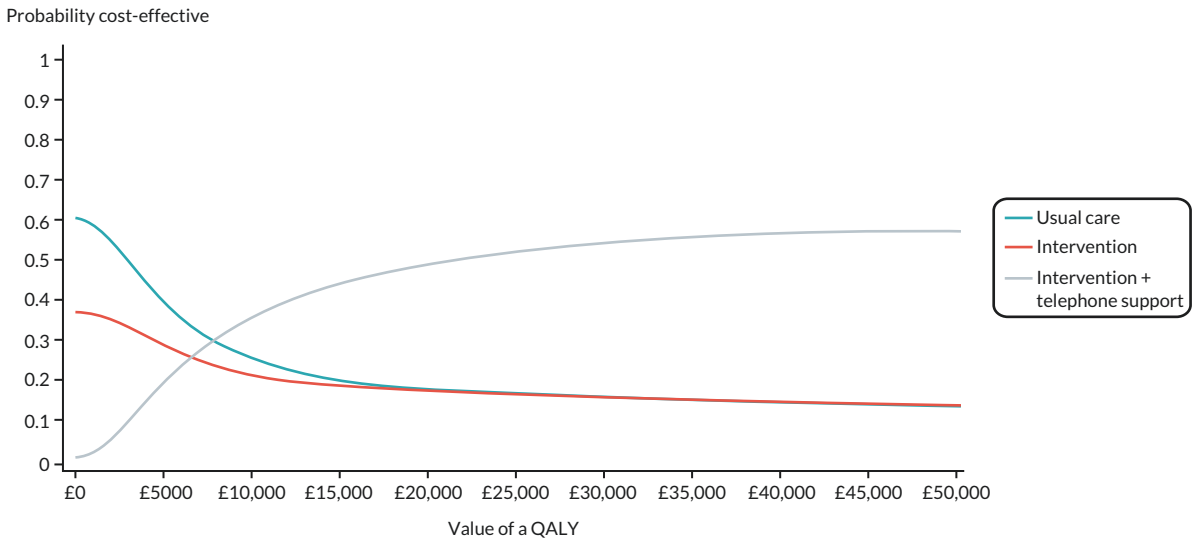

FIGURE 8 Cost-effectiveness acceptability curve showing the probability of the three interventions being cost-effective at different values of a QALY – CCA.

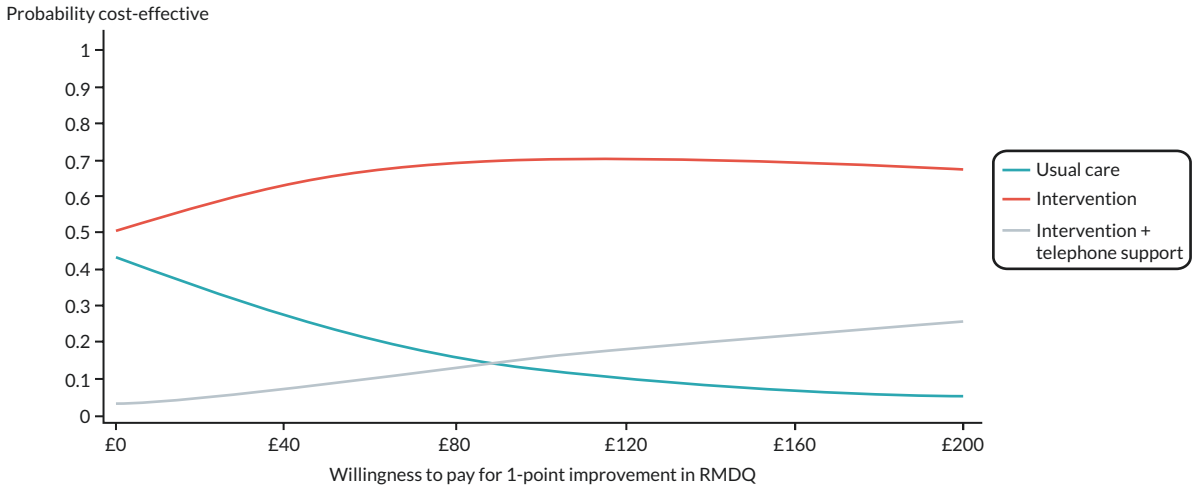

FIGURE 9 Cost-effectiveness acceptability curve showing the probability that each intervention is cost-effective at different values of a point change in the RMDQ – CCA analysis.

differences compared to the usual care group and CIs which crossed 0. For the base-case analyses using imputed data to estimate cost/QALY, the results would indicate that the internet intervention group would be preferred. However, both interventions could be considered cost-effective compared to the usual care group. Analysis taking account of the uncertainty around these estimates suggests the internet intervention without support is the most likely to be cost-effective at values of a QALY below approximately £50,000 per QALY. Similar results are shown when we look at the cost per point change in RMDQ with the internet intervention without telephone-support group appearing to be the most likely to be cost-effective at all values of the effectiveness measures. These results provide support for the internet intervention without support being more widely adopted in the NHS.

Strengths of the study

The economic analysis was conducted alongside a large, well-conducted clinical trial and hence it was able to collect a variety of data. The resource data presented here were drawn from a review of general practice records and hence had a high degree of completion. There may also have been advantages in separating out costs related to LBP from all costs. Where costs were missing, this was largely related to some practices not providing costs and hence missingness is not likely to be related to patient characteristics, such as LBP symptoms on participant engagement with the project. Considerable effort was devoted to ensuring a high completion of data, particularly at baseline and 12-month follow-up.

The interventions evaluated in this study would be ones where it was very feasible to scale up to large-scale provision and hence there would be good opportunities for implementing the findings more widely. This is particularly true of the internet-only intervention where costs per person may even be lower than those indicated here if the intervention was rolled out to the wider population of individuals with LBP.

Limitations of the study

The economic evaluation found comparatively small differences in outcomes (both QALY and RMDQ change) and small differences in cost. Although there may be a good likelihood that an intervention that brings positive benefits would be cost-effective if it is associated with low costs of implementation, there is likely to be an issue with the required sample size required to show these differences. Also, potentially a much larger sample would have been needed to show statistically significant differences in costs and outcomes. This is likely to be even more of an issue where total NHS costs were considered, not just back pain-specific ones. In this case, the internet-only group was the costliest because of higher non-LBP-related costs. A small difference in the number of complex inpatient stays, for example, hip replacements, would very likely have affected these estimates.

Another limitation of the study was the discrepancy between groups in the proportion of missing data for QALYs. There is often an issue related to missing data for QALY estimates, and data from a number of time periods are needed. In this trial, with EQ-5D-5L estimates at baseline, 6 weeks, 3, 6 and 12 months, there were issues with missing data as

the probability of having a missing value for total QALYs increased with the number of EQ-5D-5L values obtained. Also, considerable effort was put into ensuring that the data be as complete as possible. However, it was necessary to target this effort at certain time points, for example, final data collection. This was compounded by missingness in other variables, for example, cost estimates. This meant that if QALYs were estimated from all 5 time points, then the CCA would only have included around 50% of participants. For this reason, we estimated QALYs based on EQ-5D-5L at 3 time points, baseline, 6 weeks and 12 months, where response rates were highest. *Table 26* indicates that estimated QALYs were very similar between the two methods but that QALYs were obtainable on more participants when only 3 time points were used. Using QALY estimated at 3 time points meant that the CCA now comprised approximately 60% of cases. However, this was still a considerable amount of missing data, and for this reason the imputed analysis was adopted as the base case.

In this study, we found inconsistencies between the conclusions of the imputed analysis and the CCA. In both cases, there would be a low probability that the usual care group would be the most cost-effective at different values of a QALY. However, there were differences between the imputed analysis and the CCA in which intervention would be the most likely to be preferred, with the imputed analysis showing that the intervention-only group had the highest probability of being cost-effective and the CCA showing the intervention plus telephone support showing the highest probability of being cost-effective between the thresholds of £20,000 and £30,000 per QALY.

Conclusion

Although only the outcome of change in RMDQ for the internet intervention without support appeared to be significantly different from the control, we found that this intervention had a high probability of being the most likely intervention to be cost-effective at all values of the outcome measure used. Although this is an intervention that is associated with comparatively small changes in QALYs, it is also associated with low additional costs. And therefore, there is justification from the current economic evaluation in considering its wider implementation.

Chapter 8 General discussion

Summary of findings

We believe this to be one of the largest trials internationally of an internet intervention to support the self-management of LBP in primary care. For our primary outcome, we found small non-significant reductions in LBP-related disability over 12 months for both intervention arms, compared to usual care. These changes of around half a point on the RMDQ fell below our specified minimally important (between-group) clinical difference of 1.5 on the RMDQ. Our sensitivity analyses (both CACE and imputation models) replicated these small reductions of around half a point over 12 months, compared to usual primary care. Pre-specified subgroup analyses on risk of persistent disability (STarT Back risk group), pain duration and deprivation at baseline did not show any differences between arms on our primary outcome. Cost-effectiveness analyses showed that the internet intervention without support dominated usual care, being both more effective and less costly. Both interventions were likely to be cost-effective compared to usual care at the threshold of £20.000.

Secondary outcome analyses showed that when splitting RMDQ by time point, the internet intervention with support arm stayed consistently around −0.7 points below usual care (i.e. in favour of the internet intervention with support arm). The internet intervention alone arm appeared to improve over time, with a statistically significant improvement of −1.1 below usual care on the RMDQ by 12 months. Significantly more of those allocated to the intervention arms reached a 30% reduction from baseline on the RMDQ at 12 months, compared to usual care. This translates to a NNT of 10 for both interventions. While few differences were found in pain intensity over time, participants in both intervention arms reported a day less in pain per month over the 12-month period compared to usual care. At 6 weeks, both interventions significantly improved pain self-efficacy and satisfaction with care for back pain. At 12 months there were small but significant reductions in kinesiophobia in both intervention arms, compared to usual care. With regard to physical activity, there were no significant differences reported in leisure time activity at 12 months; however, participants in the internet intervention plus support arm reported small but significant increases in days per week doing physical activity for their back pain, over 12 months. There were no related SAEs reported in either intervention arm.

Interpretation considering related research

Clinically, our primary outcome result is similar to that of the selfBACK trial.[17] In our trial, we report between-group differences of −0.5 and −0.6 on the RMDQ over 12 months. The research team that led the selfBACK trial reported a −0.79 reduction in the RMDQ compared to usual care at their primary outcome time point of 3 months. There were important differences in eligibility criteria between the two trials. Entry into the selfBACK trial required at least 6 out of a maximum of 24 on the RMDQ at baseline and thus their sample had higher levels of pain-related disability at entry to their trial. In our trial we had no minimum cut-off on baseline disability levels, reflecting our pragmatic approach. We sought to determine the effectiveness of internet-based intervention on all those with LBP in primary care who were willing to be randomised. Additionally, we choose a more challenging time point for our primary outcome. The selfBACK team selected RMDQ at 3 months as their primary outcome point, whereas we examined the effect of the interventions on RMDQ over the full 12 months of follow-up, including RMDQ scores at 6 weeks, 3, 6 and 12 months in our primary outcome model. Nevertheless, our different digital approaches to supporting patients with LBP in primary care appear to have produced similar small improvements in LBP-related disability, both falling below pre-specified between group MCIDs. However, some secondary outcomes in both trials showed significant differences: in SB2, small significant reductions in LBP-related disability compared to usual care at 12 months were reported for those accessing SupportBack without support. In selfBACK, significant reductions in pain as well as improvements in global perceived effects were reported for the intervention arm compared to their control arm. In both trials, the digital interventions led to significant increases in numbers (around 10%) reaching within person MCIDs on LBP-related disability compared with usual care.

Broadly, the finding of small differences for rigorously developed and thoroughly trialled digital interventions in LBP[17,25] mirrors the consistent findings of small between-group differences of a wide range of more intensive interventions for LBP.[15] This highlights the often-noted complexity in demonstrating substantial, significant benefits over usual care in this heterogeneous condition.[69] However, although the small differences we have shown might be similar to previous non-digital interventions, the potential ease of implementation differs greatly. SupportBack, offered without support, could be provided to those with LBP via a web platform at scale and low cost.

The provision of healthcare professional (HCP) support with digital interventions has been reported as important for increased effectiveness.[19] This is the case in mental health conditions such as depression, where 'unguided' digital interventions have been consistently shown to be less effective than those with remote guidance from a HCP.[18] For interventions with a physiotherapy focus, previous research on chronic dizziness and asthma has shown both digital interventions and booklet-based interventions could produce significant benefits compared to usual care without HCP support.[21,22] Consequently, when determining the effectiveness of internet interventions for LBP, the necessity of HCP support was an important question to be addressed. In the present trial, the effect on the primary outcome, LBP-related disability over 12 months, was similar in both the supported and unsupported arms. The numbers reporting ≥ 30% reduction in LBP-related disability at 12 months were also very similar. When breaking down the LBP-related disability outcome by time point, those in the supported arm reported greater benefit more quickly, showing significant improvements at 6 weeks compared to usual care. For participants in the unsupported arm, benefits were more gradual, being similar to usual care at 6 weeks, 3 and 6 months but by 12 months improvements were greater than those in the supported arm. This finding of greater long-term benefits for unguided self-management support has been reported previously in a trial of physical rehabilitation for chronic dizziness.[70] It is possible that mechanisms underlying this effect may differ between arms. Benefits in the supported arm could stem more from processes such as reassurance from an expert in musculoskeletal/spinal health.[71] In the unsupported arm, the gradual improvements may stem from ongoing application of the activity-based strategies leading to gradual improvement. However, the complexities of this potential application of activity that seemed apparent from interviews were not picked up by our quantitative measures. One reason why this might have been the case is a dynamic relationship between pain and activity, for example, more use *when* in pain. Whereas our quantitative measures were designed to pick up more generic, average increases in physical activity. Further research is needed to explore this possible hypothesis.

Process evaluation

The mixed-methods process studies that comprised our process evaluation showed that our interventions were implemented as intended. The majority of those in the intervention arms accessed the core elements of the digital material. Over 70% of those in the internet intervention plus support arm received at least two telephone support calls from physiotherapists. Regarding context and moderating factors, there was no evidence from the trial subgroup analysis that baseline risk of persistent disability (STarT Back group) or pain duration differentially affected the impact of the interventions compared to usual care. This finding was also supported in the nested qualitative study; throughout the interviews with intervention participants there was no apparent relationship between reported LBP history, including described severity, and reported perceptions of benefit or not. Lower-intensity self-management focused interventions are often recommended for those at low risk of persistent disability.[34] Although not powered to address this specifically, data from our trial suggest that where benefits did occur, they were not limited to just those in low-risk groups.

We did not find any indication that higher levels of use (completion of intervention sessions) were related to larger reductions in LBP-related disability. Previous research has demonstrated greater use of internet interventions is associated with greater benefit in clinical outcomes.[72] However, more recent research has emphasised the complexity of interpreting usage data. Effective engagement, that is engagement to the point of benefit for the individual,[10] is likely to be highly variable. Our qualitative study suggested that people who reported benefit used the intervention in different ways. Some logged in to early sessions, wrote down or saved material, and did not return to the website. Others used all sessions when they had the e-mail reminders. This variety of use demonstrates the limitations inherent in using a simple quantitative, count-based measure when exploring engagement. Additionally, we suggested in our protocol[25] that the most important session is likely to be session 1. This session contained the key rationales regarding the importance activity for LBP and guided through core activities and goal-setting processes. Although completion of this session was

higher in the internet intervention plus support arm, the majority of participants in both arms started and may have accessed this core material. Consequently, those who completed one to three sessions, and those who completed four to six sessions, all received what we defined as the minimum 'dose' in this case. This could also contribute to the lack of difference seen in outcomes for high and low users. We also found that greater use was not related to higher pain self-efficacy at the 6-week time point. This lack of a linear relationship may also be related to the complexity of the pain self-efficacy construct. What is necessary to enhance pain self-efficacy is likely to be different between individuals, thus not captured simply by testing for relationship between the pain self-efficacy scale total and a session count variable.

There was no indication that quantitative measures of pain self-efficacy or physical activity worked as mediators of the effect of the internet intervention without support on RMDQ score at 6 months. It is possible that this is due to the inadequacy of the brief quantitative measures to accurately capture dynamic and complex processes related to outcome.[73] In the qualitative data, participants who described the benefit from the intervention often attributed it to using physical activity to manage their LBP. Similarly, participants described increases in confidence related to improvements, as well as 'mastery experiences' (e.g. experiencing pain reduction following SupportBack recommended activity), all of which map on to self-efficacy as a construct.[74] This highlights the importance of qualitative process studies for exploring possible mechanisms of action, particularly when complex interventions have been used to address complex conditions such as LBP. If quantitative measures of potential mediators are to be used, it will be important to carefully ensure the construct that will be measured maps directly on the proposed processes underlying the specific intervention. For instance, the pain self-efficacy scale has a focus on confidence in doing activities despite pain. While this would have been relevant for some of our participants who had low levels of confidence about their ability to go about their everyday activities with LBP, it may have been less relevant for others such as those with already high levels of confidence, or those focusing on using activity to reduce their pain.

Strengths and limitations

We took a pragmatic approach to eligibility for this trial. We decided that all those who had consulted in primary care with LBP (acute, recurrent, persistent) and still reporting current LBP could take part. We did not set any cut-off on our back-related disability scale for eligibility. This increases the generalisability of our findings when considering possible implementation. Our trial arms were well balanced at baseline, and we believe this to be one of the first large-scale trials of a digital intervention to include a full health economic evaluation. The SupportBack intervention was developed through a robust person-based approach (PBA) working systematically with those with LBP throughout development and feasibility evaluation.[24] Including three arms also allowed us to determine the benefit of a pragmatic telehealth approach to physiotherapist support. Not setting a threshold for disability to enter the trial meant that those with mild problems as well as those with more severe problems were included. While this meant it would be more challenging to demonstrate superiority of the interventions, we favoured this inclusive approach, as self-management advice and education is recommended for all those with LBP. Additionally, our participants were actively seeking health care in general practices for LBP; thus, all were highly likely to be considered suitable to be offered the SupportBack intervention if it was available beyond the trial in the future. This means the results of the trial are likely to be a useful representation of the effectiveness of SupportBack when offered to the heterogeneous population that seek primary care in the UK. We had a relatively low 7% invitation to randomisation rate; this is common in primary care trials using similar recruitment methodologies.[22,70] The sample were predominately white, and ethnicity data collection was limited. Ethnicity data were collected post randomisation (75% of participants provided ethnicity data). The sample was generally older, with a reasonably high number of retirees (29%). However, this is consistent with prevalence data showing LBP increasing with age and peaking between 80 and 89 years old.[2]

The COVID-19 pandemic commenced when we were over halfway through recruitment to this trial. As our follow-up period was over 12 months, the majority of our participants would have experienced the lockdown restrictions as part of their time during the trial. Our qualitative study suggested the pandemic had a mixed effect on participants, with some reporting more physical activity, some less and some the same as pre pandemic. Additionally, our quantitative analysis did not indicate any meaningful variation in RMDQ scores before or after the beginning of the pandemic. Nevertheless, the COVID-19 pandemic should be considered when reflecting on the societal context of this trial.

Recommendations for future research

Researchers should focus on understanding if and how the effectiveness of widely accessible, internet-based, self-management support for LBP can be improved. SB2 has shown that the effectiveness of an internet intervention over 1 year is not clearly improved with the addition of remote physiotherapist support. Future research should focus on identifying those unlikely to benefit from unsupported digital interventions and determining whether it is possible to appropriately scale up their support for self-management to an effective level. There were no clear indications that 'responders' could be identified from baseline pre-specified subgroups in SB2. We also did not see patterns between described LBP histories and talk of benefits in the nested qualitative study. However, we did find that those who generally reported benefit from the programme overall described positive shifts in pain and increased activity after trying suggestions from the internet intervention, in their interviews. These associations appeared to lead to longer-term behaviour change. We were unable to confirm such changes in physical activity using the more linear quantitative measures of physical activity in this trial. Adaptive self-management programmes where remote live support could be activated and scaled up based on early participant feedback may be useful to explore. In such systems, the greatest support would be provided to those struggling with self-management in real time, rather than based on prognostic indicators at baseline.

Implications for healthcare practice

When considering the implications of this trial for practice, it is useful to reflect on the current landscape of care for LBP generally. NICE guidance for LBP, published in 2016 and updated in 2020,[5] placed a strong emphasis on support for self-management as a core treatment recommendation. Recently published NICE guidance on management of chronic primary pain, which includes LBP, also emphasises encouragement of physical activity.[75] Importantly, chronic primary pain guidance does not recommend many common medications including NSAIDs, paracetamol, opioids or gabapentinoids.[75] There remains a need for accessible behavioural self-management support that could be provided easily by HCPs in primary care. Our trial has shown that adding internet-based support for self-management leads to only limited effects on LBP-related disability, that do not differ from usual primary care, when measured over time. Our trial has also shown that the majority of patients offered the internet intervention engage with the core aspects of the intervention, typically engaging in three to four internet sessions. We showed that the interventions led to a significant 10% increase in number of those reporting substantial improvements in LBP-related disability at the 12-month point, and were safe, with no related SAEs reported. Additionally, the NNT of 10 we report is similar to NNTs for antidepressants used for chronic pain (ranging from 7 to 12[76]). Antidepressants are one of the only medications still recommended by NICE for chronic primary pain.[75]

Overall, the implications regarding the provision of physiotherapist telephone support require consideration. In the trial, providing physiotherapist telephone support led to small improvements more rapidly than the unsupported intervention. Given the substantial organisation required to deliver telephone calls at scale, and the likely small additional benefit of the supported intervention, implementing the unsupported intervention may represent the most sensible option. The very low cost of the unsupported intervention and the potential ease of delivery (e.g. provision of a web link/module) may mean clinicians still view it as a useful option to recommend to their patients, when considering clinical effectiveness and cost-effectiveness, accessibility and safety findings together. It is important to note that we did have a safety screen in place, and participants were recruited based on a recent consultation with primary care. Therefore, to align with the context of the trial, the unsupported intervention would need to be offered by clinicians (whether GP or physiotherapist), following assessment.

Patient and public involvement

We have been working closely with public contributors with experience of LBP throughout the SupportBack projects, including the development, feasibility and randomised trial and the present main trial. Linda Leigh, Hazel Patel and Jenny Magee formed our public contributor advisory group from the start of this trial. For various reasons, over the

course of the trial Linda, Hazel and Jenny moved on, and they were replaced by Malcolm White and Firoza Davies, two new public contributors with experience of LBP.

The public contributors we have worked with have been active members of the trial management group, joining and contributing to trial meetings as well forming separate meetings to discuss and support with specific issues. Our public contributors reviewed and contributed to all patient-facing materials in the setup of trial (e.g. patient information sheets). They were also central when we worked on ensuring adequate follow-up. We discussed and agreed amendments to our follow-up strategies, wordings were reviewed, and the impact of adjustments was monitored together. When the COVID pandemic began in March 2020, we again worked closely with our public contributors on how best to inform our participants that the trial would continue, and that their answers to our questionnaires were still critically important. The support we had from our public contributors helped us continue with recruitment and follow-up with minimal delays. As the pandemic unfolded, we continued to work as a team to address issues to keep the trial running through this difficult period.

Our public contributors have also been closely involved with our nested qualitative process study, particularly, the patient process study. The public contributors reviewed and adjusted the interview schedules, including highlighting the importance of hearing the participant pain stories/narratives in the early part of the interview. As the qualitative study included interviews at different time points (post 3, 6 and 12 months), before the 12 months' interviews started, we met with the academic team and the public contributors, to discuss early data from the 3- and 6-month interviews together. We then agreed additions to the interview schedule for post 12 months' interviews. Amendments focused on questions addressing the potential long-term impacts of the interventions. As the qualitative study progressed, and data were analysed, we met again with our public contributors to discuss an early version of the analysis. The team made important points and contributed on the emphasis given to aspects in the analysis, such as the balance in the tone of the comments. They also advised in the presentation of the findings; for example, advising against the use of synonyms, to avoid bias in name types. They will continue to be involved as the qualitative analyses are developed for separate publications.

Our public contributors have an important role to play in supporting the implementation of our dissemination strategy. They will support us in how best to share the findings of this trial with the public. Particularly, they will help us develop the key 'take-home' message based on our results and process analyses. This will need to be easily understood by the public.

Equality, diversity and inclusion

Participant representation

Our intervention materials were developed using the PBA. The PBA includes the application of systematic qualitative research with users, iteratively, to continually improve intervention materials to ensure they are accessible, engaging and motivating. We worked very closely with people with LBP both through patient and public involvement (PPI) and qualitative research to ensure the intervention was as accessible and usable as possible. Additionally, our PPI group advised and amended participant-facing documents to support accessibility and inclusion.

We recruited participants from a wide range of areas in the UK including Wessex (comprising Dorset, Hampshire, South Wiltshire and the Isle of White), the West of England (comprising City of Bristol, Bath, North East Somerset, Swindon Gloucestershire, North Somerset), North Thames (comprising north-east and north-central London, Hertfordshire, Bedfordshire and Essex), Ken, Surrey and Sussex, North West Coast (including South Cheshire and South Cumbria) and the West midlands (comprising Shropshire, Staffordshire, County of the West Midlands, Warwickshire, Worcestershire, Herefordshire). This represents broad geographical representation within the UK for a RCT sample.

Regarding age, our sample was inclusive and ranged from 18 to 92 years of age. Our gender split was relatively well balanced with 58% of the sample identifying as female and 42% as male. Having two options for gender was a limitation. In future trials we will increase the options available for gender, so participants can self-identify with a gender category they feel most appropriate.

The ethnicity data we have were limited, as these data were collected post baseline. We acknowledge this limitation in our data and will ensure ethnicity data are collected fully in all future trials. Ethnicity data were provided by 75% of the sample. Of these participants, 92% identified as 'white'. Based on the 2021 Census data, where 82% identified as 'white', this suggests that we under-recruited from non-white groups. As above, while work was done to ensure the trial materials and the interventions were as accessible as possible, we need to do more to ensure future trial samples reflect the ethnic diversity in the UK population. We will do this by funding specific work packages alongside trials to work with diverse community groups to remove as many barriers as possible to participating.

As a trial of a digital intervention (e.g. primarily a text-based intervention), we recruited a diverse sample with regard to educational qualifications, with over 30% reporting General Certificate of Secondary Education/O levels or no formal educational qualifications as their 'highest qualification'. This is important. It suggests our findings are likely to apply to people with diverse educational backgrounds. Considering deprivation, the sample recruited had a median IMD decile of seven which is slightly higher than the UK population. In an a priori subgroup analysis, there was no evidence that deprivation impacted on the primary outcome.

Reflection on research team and wider involvement

Our research team was diverse with regard to gender, age, career stage, research and clinical background. Ethnic diversity was limited, and we aim to improve on this as we build teams for future projects. Development opportunities were provided, including supporting a research colleague as they progressed their PhD. All those who were included in our public contributor advisory group over the trial had lived experience of LBP, and were diverse in age, gender and ethnicity.

Overall conclusion

In the SB2 trial we showed that adding an internet intervention, designed to support self-management of LBP, with and without brief physiotherapy-telephone support did not significantly reduce LBP-related disability over 12 months compared to usual primary care alone. However, both the unsupported and supported interventions were likely to be cost-effective, with the internet intervention without support being both less costly and more effective than usual care over 12 months. There were a number of secondary outcomes where the interventions resulted in significant improvements compared to usual care alone. These included the number of those reporting a 30% reduction in LBP-related disability at 12 months, both intervention arm participants reporting a day less in pain per month, increased satisfaction with care and pain self-efficacy at 6 weeks and reductions in kinesiophobia at 12 months. The interventions were found to be safe. In a UK healthcare context where access to recommended support for behavioural self-management is limited, HCPs will need to balance our findings on clinical effectiveness, cost-effectiveness, safety and accessibility when considering offering the SupportBack interventions.

Additional information

Contributions of authors

Adam W A Geraghty (https://orcid.org/0000-0001-7984-8351) (Associate Professor of Psychology and Behavioural Medicine) was chief investigator and led the SupportBack 2 trial.

Taeko Becque (https://orcid.org/0000-0002-0362-3794) (Senior Research Fellow in Statistics) conducted the statistical analysis and wrote up all statistical analysis for the report.

Lisa C Roberts (https://orcid.org/0000-0003-2662-6696) (Clinical Professor of Musculoskeletal Health) was a co-applicant who led the training of the trial support physiotherapists, supported the qualitative analysis and contributed to trial oversight.

Jonathan Hill (https://orcid.org/0000-0001-6246-1409) (Professor in Physiotherapy) was a co-applicant who contributed musculoskeletal trial oversight.

Nadine E Foster (https://orcid.org/0000-0003-4429-9756) (Professor and Director of STARS Education and Research Alliance) was a co-applicant who contributed expert musculoskeletal trial oversight.

Lucy Yardley (https://orcid.org/0000-0002-3853-883X) (Professor of Health Psychology) was a co-applicant who contributed to trial oversight from a behavioural perspective.

Beth Stuart (https://orcid.org/0000-0001-5432-7437) (Professor of Medical Statistics and Clinical Trials) was a co-applicant who developed the statistical analysis plan for the trial and provided senior statistical oversight for all aspects of the analysis.

David A Turner (https://orcid.org/0000-0002-1689-4147) (Associate Professor in Health Economics) was a co-applicant who designed, conducted analysis and wrote the health economic evaluation chapter.

Gareth Griffiths (https://orcid.org/0000-0002-9579-8021) (Professor of Clinical Trials and Director of Southampton Clinical Trials Unit) was a co-applicant who provided senior clinical trials oversight.

Frances Webley (https://orcid.org/0000-0001-7341-5379) (Senior Trial Manager) provided oversight for all aspects of trial management.

Lorraine Durcan (https://orcid.org/0000-0002-8890-2134) (Trial Manager) provided trial management supporting recruitment and follow-up.

Alannah Morgan (https://orcid.org/0000-0002-0262-3135) (Trial Co-ordinator) assisted with trial recruitment and management.

Stephanie Hughes (https://orcid.org/0000-0003-4801-8245) (Senior Research Associate) assisted with all digital elements of the trial and conducted qualitative interviews and supported qualitative analysis.

Sarah Bathers (https://orcid.org/0009-0004-0239-8769) (Senior Trial Manager) assisted with recruitment at the Keele centre.

Stephanie Butler-Walley (https://orcid.org/0009-0002-9260-3636) (Trial Co-ordinator) assisted with recruitment at the Keele centre.

Simon Wathall (https://orcid.org/0000-0002-7107-5785) (Health Informatics Specialist) assisted with the health informatics related to recruitment.

Gemma Mansell (https://orcid.org/0000-0002-5479-2678) (Lecturer in Psychology) assisted with the process evaluation.

Malcolm White (Public Contributor) provided public input to many aspects of the trial and qualitative analysis.

Firoza Davies (https://orcid.org/0009-0005-9218-8702) (Public Contributor) provided public input to many aspects of the trial and qualitative analysis.

Paul Little (https://orcid.org/0000-0003-3664-1873) (Professor of Primary Care Research) was a co-applicant who provided senior primary care trials oversight.

Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

Data-sharing statement

Pseudonymised individual participant data (IPD) within the clinical study data set will be available for sharing via controlled access by authorised Southampton CTU staff (as delegated to Southampton CTU by the study sponsor). Data access can be requested via a Southampton CTU Data Release application form (available from www.southampton.ac.uk/ctu/about/index.page) after the trial is published. Please e-mail the completed form to the Southampton CTU Data Release Committee Coordinator at ctu@soton.ac.uk.

Ethics statement

This study received full approval from an NHS Research Ethics Committee (REC) and the Health Research Authority. The South Central – Hampshire B Research Ethics Committee granted approval on 17 August 2023 (REC REF: 18/SC/0388).

Information governance statement

The University of Southampton is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

Under the Data Protection legislation, the University of Southampton is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.southampton.ac.uk/hr/services/data-protection/data-protection.page

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GDPS2418.

Primary conflicts of interest: Adam W A Geraghty, Paul Little, Lucy Yardley, Lisa C Roberts, Beth Stuart, Jonathan Hill, Nadine E Foster, David A Turner and Gareth Griffiths received grant funding to their employer universities from the NIHR to carry out this study and other research. Nadine Foster is a member of the NIHR Research Professors Selection Panel. Nadine E Foster was supported through an NIHR Research Professor (2012–7; NIHRRP-011-015) and NIHR Senior Investigator award. Nadine E Foster is funded through an Australian National Health and Medical Research Council (NHMRC) Investigator Grant (ID: 2018182).

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Appendix 1 Screening questions

Please read each question carefully and circle the answer that applies to you

SupportBack 2 Screening Questions: Answering 'Yes' is needed to include you in the study			
1.	Do you have access to the internet and an e-mail address?	Yes	No
2.	Do you have low back pain at the moment (or have had pain in the last week)?	Yes	No

Safety Questions: Answering 'Yes' may exclude you from the study			
1.	Since your back problem started have you found it MORE difficult to move your foot or toes up and down?	No	Yes
2.	*Do you have numbness or altered feeling or pins/needles around your back passage or genitals (e.g. wiping after being at the toilet)? * *IF YOU HAVE THESE SYMPTOMS, IT MAY INDICATE A RARE BUT SERIOUS CONDITION AND YOU SHOULD CONTACT A DOCTOR IMMEDIATELY (GP or A&E)*	No	Yes
3.	*Do you have a new or recent loss of control of your bladder and/or your bowels? * *IF YOU HAVE THESE SYMPTOMS, IT MAY INDICATE A RARE BUT SERIOUS CONDITION AND YOU SHOULD CONTACT A DOCTOR IMMEDIATELY (GP or A&E)*	No	Yes

Appendix 2 Unrelated hospitalisations as listed in the notes reviews

Key:

Group A = Usual care + internet intervention + support;

Group B = Usual care + internet intervention;

Group C = Usual care

TABLE 29 Image of an excel table of hospitalisations listed in the notes reviews

SAE Criteria:
*** Results in Death**
*** Is Life Threatening**
*** Requires Hospitalisation**
*** Results in Persistent or Significant Disability or Incapacity**
*** Is a Congenital Anomaly or Birth Defect**
*** Other Important Event**

Data from GP 12 Months Notes Review						Clinical Reviewer to Complete			
							If Yes:		
Subject	Randomisation group	Site	Site number	Reason for stay	Was this related to back pain?	Do you think this event might meet the SAE criteria?	Which criteria does it meet? (If more than one, please state in comments)	Is this related to study treatment?	Comments
K0070	Group C	Moss Grove Surgery (Kingswinford)	5041	Bilateral si joint injections	No	Yes	Requires hospitalisation	Not related	
K0093	Group A	Whiteacres Medical Group (Worcester)	5061	R l4 nerve root block	Yes	Yes	Requires hospitalisation	Not related	
K0108	Group C	Central Surgery (Rugby)	5064	Right-hand stt joint pain	No	Yes	Requires hospitalisation	Not related	
K0123	Group A	Whiteacres Medical Group (Worcester)	5061	L 4/5 image-guided epidural	Yes	Yes	Requires hospitalisation	Not related	
K0139	Group C	Haresfield and Kempsey Surgery (Worcester)	5073	Worsening sciatica with leg weakness	Yes	Yes	Requires hospitalisation	Not related	
K0141	Group B	Spring Gardens (Worcester)	5070	Colonoscopy	No	Yes	Requires hospitalisation	Not related	
K0141	Group B	Spring Gardens (Worcester)	5070	Eua rectum and removal of anal polyp	No	Yes	Requires hospitalisation	Not related	
K0178	Group B	Salters Medical Practice (Droitwich)	5077	Arthroscopy of right knee	No	Yes	Requires hospitalisation	Not related	
K0196	Group A	Winyates Health Centre (Redditch)	5072	Endoscopy	No	Yes	Requires hospitalisation	Not related	
K0328	Group A	Central Surgery (Rugby)	5064	Gastric balloon complication	No	Yes	Requires hospitalisation	Not related	
K0328	Group A	Central Surgery (Rugby)	5064	Prostate cancer	No	Yes	Requires hospitalisation	Not related	

continued

TABLE 29 Image of an excel table of hospitalisations listed in the notes reviews (*continued*)

SAE Criteria:
*** Results in Death**
*** Is Life Threatening**
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*** Results in Persistent or Significant Disability or Incapacity**
*** Is a Congenital Anomaly or Birth Defect**
*** Other Important Event**

Data from GP 12 Months Notes Review						Clinical Reviewer to Complete			
							If Yes:		
Subject	Randomisation group	Site	Site number	Reason for stay	Was this related to back pain?	Do you think this event might meet the SAE criteria?	Which criteria does it meet? (If more than one, please state in comments)	Is this related to study treatment?	Comments
K0446	Group A	Glebedale Medical Practice (Stoke)	5107	Sign of ulnar neuropathic symptoms with tennis elbow	No	Yes	Requires hospitalisation	Not related	
K0446	Group A	Glebedale Medical Practice (Stoke)	5107	Ankle weakness	No	Yes	Requires hospitalisation	Not related	
K0446	Group A	Glebedale Medical Practice (Stoke)	5107	Shoulder and wrist pain	No	Yes	Requires hospitalisation	Not related	
K0481	Group C	Budbrooke Medical Centre	5102	Af ablation	No	Yes	Requires hospitalisation	Not related	
K0504	Group A	Whiteacres Medical Group (Worcester)	5061	Colonoscopy	No	Yes	Requires hospitalisation	Not related	
K0510	Group C	Spring Gardens (Worcester)	5070	Left phacoemulsification + iol	No	Yes	Requires hospitalisation	Not related	
K0510	Group C	Spring Gardens (Worcester)	5070	Colonoscopy	No	Yes	Requires hospitalisation	Not related	
K0531	Group C	Spring Gardens (Worcester)	5070	Hyperkalaemic	No	Yes	Requires hospitalisation	Not related	
K0570	Group A	Golden Valley Practice (Peterchurch)	5117	Haemorrhoid treatment	No	Yes	Requires hospitalisation	Not related	
K0618	Group C	Central Surgery (Rugby)	5064	Fall, right weber b ankle fracture – external fixator placed	No		ALREADY REPORTED AS AN SAE		
K0645	Group A	Moss Grove Surgery (Kingswinford)	5041	Radical cholecystectomy and extrahepatic bile duct resection	No	Yes	Requires hospitalisation	Not related	

K0784	Group B	Moss Grove Surgery (Kingswinford)	5041	Gynae procedure	No	Yes	Requires hospitalisation	Not related
K0784	Group B	Moss Grove Surgery (Kingswinford)	5041	Gynae clinic	No	Yes	Requires hospitalisation	Not related
K0784	Group B	Moss Grove Surgery (Kingswinford)	5041	Gynae scan	No	Yes	Requires hospitalisation	Not related
K0802	Group B	Winyates Health Centre (Redditch)	5072	Right shoulder decompression and removal of metalwork from humeral head	No	Yes	Requires hospitalisation	Not related
K0802	Group B	Winyates Health Centre (Redditch)	5072	Non-diabetic ketoacidosis	No	Yes	Requires hospitalisation	Not related
K0816	Group B	Albany House (Worcester)	5085	Obstetrics	No	Yes	Requires hospitalisation	Not related
K0816	Group B	Albany House (Worcester)	5085	Gynaecology	No	Yes	Requires hospitalisation	Not related
K0838	Group A	Whiteacres Medical Group (Worcester)	5061	Punch biopsies	No	Yes	Requires hospitalisation	Not related
S0004	Group B	Lordshill Health Centre (Southampton)	5024	Left-sided facet joint injection	Yes	Yes	Requires hospitalisation	Not related
S0009	Group A	Lordshill Health Centre (Southampton)	5024	Dvt	No	Yes	Requires hospitalisation	Not related
S0009	Group A	Lordshill Health Centre (Southampton)	5024	Post-thrombotic syndrome	No	Yes	Requires hospitalisation	Not related
S0047	Group A	Liphook and Liss Surgery	5002	Epidural injection	Yes	Yes	Requires hospitalisation	Not related
S0048	Group B	Liphook and Liss Surgery	5002	Panic attack hypokalaemia	No	Yes	Requires hospitalisation	Not related
S0073	Group A	Swanage Medical Practice (Swanage)	5009	Colonoscopy	No	Yes	Requires hospitalisation	Not related
S0074	Group C	Liphook and Liss Surgery	5002	Cataract operation	No	Yes	Requires hospitalisation	Not related

continued

TABLE 29 Image of an excel table of hospitalisations listed in the notes reviews (*continued*)

SAE Criteria: *** Results in Death** *** Is Life Threatening** *** Requires Hospitalisation** *** Results in Persistent or Significant Disability or Incapacity** *** Is a Congenital Anomaly or Birth Defect** *** Other Important Event**									
Data from GP 12 Months Notes Review						**Clinical Reviewer to Complete**			
							If Yes:		
Subject	**Randomisation group**	**Site**	**Site number**	**Reason for stay**	**Was this related to back pain?**	**Do you think this event might meet the SAE criteria?**	**Which criteria does it meet? (If more than one, please state in comments)**	**Is this related to study treatment?**	**Comments**
S0090	Group A	Emsworth Surgery	5067	Left and right lacrimal puncto-plasty (ophthalmology dept)	No	Yes	Requires hospitalisation	Not related	
S0096	Group C	Phoenix Health Group (Cirencester)	5062	Thyroidectomy	No	Yes	Requires hospitalisation	Not related	
S0115	Group C	Phoenix Health Group (Cirencester)	5062	Coronary vasospasm	No	Yes	Requires hospitalisation	Not related	
S0159	Group C	Trafalgar Medical Group (Southsea)	5069	Removal of lr7 and ul7 (for gross dental caries)	No	Yes	Requires hospitalisation	Not related	
S0169	Group B	Pioneer Medical Group (Bristol)	5074	Appendicitis	No	Yes	Requires hospitalisation	Not related	
S0175	Group A	Old Fire Station Surgery, Woolston (Southampton)	5021	Injection around spinal facet of spine	Yes	Yes	Requires hospitalisation	Not related	
S0183	Group C	Vine Medical Group (Waterlooville)	5006	L5/s1 prolapse	Yes	Yes	Requires hospitalisation	Not related	
S0183	Group C	Vine Medical Group (Waterlooville)	5006	Discectomy	Yes	Yes	Requires hospitalisation	Not related	
S0229	Group B	Tyntesfield Medical Group (Nailsea)	5079	Facet joint injection	Yes	Yes	Requires hospitalisation	Not related	
S0230	Group C	Tyntesfield Medical Group (Nailsea)	5079	Fracine?? Clavice	No		ALREADY REPORTED AS AN SAE		
S0305	Group B	Westbury-on-Trym Primary Care Centre (Westbury-on-Trym)	5098	Damaged foot	No	Yes	Requires hospitalisation	Not related	

S0330	Group A	Rendcomb Surgery	5087	Lumbar facet medial branch block	Yes	Yes	Requires hospitalisation	Not related
S0341	Group B	Beechwood Medical Practice (Bristol)	5093	Urticaria, angio-odema, abdominal pain	No	Yes	Requires hospitalisation	Not related
S0385	Group C	Price's Mill Surgery (Gloucester)	5104	Cataract surgery	No	Yes	Requires hospitalisation	Not related
S0396	Group B	Nicholstown (Southampton)	5109	Hernia repair	No	Yes	Requires hospitalisation	Not related
S0410	Group B	Mendip Vale Medical Practice (Langford)	5103	Left lateral femoral cutaneous-nerve block under ultrasound guidance	Yes	Yes	Requires hospitalisation	Not related
S0410	Group B	Mendip Vale Medical Practice (Langford)	5103	Right lateral femoral cutaneous nerve pulsed radio frequency	Yes	Yes	Requires hospitalisation	Not related
S0421	Group A	Old Fire Station Surgery, Woolston (Southampton)	5021	Skin lesion removed (one stop surgery). No letter received on procedure, but from notes this was between march 2020 and april 2020	No	Yes	Requires hospitalisation	Not related
S0448	Group B	Beechwood Medical Practice (Bristol)	5093	Colposcopy	No	Yes	Requires hospitalisation	Not related
S0514	Group A	Eastville Medical Practice	5115	Removal of intrauterine contraceptive device and polyp removal	No	Yes	Requires hospitalisation	Not related
S0518	Group C	Eastville Medical Practice	5115	Incision and drainage for sebaceous cyst on sternum	No	Yes	Requires hospitalisation	Not related
S0539	Group A	Emsworth Surgery	5067	Gastro referral, required sigmoidoscopy	No	Yes	Requires hospitalisation	Not related
S0542	Group B	Pioneer Medical Group (Bristol)	5074	Ectopic pregnancy/left salpingectomy	No	Yes	Requires hospitalisation	Not related
S0566	Group B	Pioneer Medical Group (Bristol)	5074	Colonoscopy and removal of polyp	No	Yes	Requires hospitalisation	Not related
S0569	Group C	Fireclay Health	5113	Endoscopy	No	Yes	Requires hospitalisation	Not related
S0569	Group C	Fireclay Health	5113	Spinal injection for sciatica	Yes	Yes	Requires hospitalisation	Not related

continued

TABLE 29 Image of an excel table of hospitalisations listed in the notes reviews (*continued*)

SAE Criteria:
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*** Is a Congenital Anomaly or Birth Defect**
*** Other Important Event**

Data from GP 12 Months Notes Review						Clinical Reviewer to Complete			
							If Yes:		
Subject	Randomisation group	Site	Site number	Reason for stay	Was this related to back pain?	Do you think this event might meet the SAE criteria?	Which criteria does it meet? (If more than one, please state in comments)	Is this related to study treatment?	Comments
S0651	Group B	Pioneer Medical Group (Bristol)	5074	Amputation of toe right foot	No	Yes	Requires hospitalisation	Not related	
S0679	Group C	Heart of Bath Medical Partnership (Bath)	5091	Urosepsis	No	Yes	Requires hospitalisation	Not related	
S0696	Group B	The Old School Surgery (Bristol)	5118	Audiology implants		Yes	Requires hospitalisation	Not related	
S0771	Group B	Oaks Healthcare (Waterlooville)	5007	Total left hip replacement	No	Yes	Requires hospitalisation	Not related	
S0771	Group B	Oaks Healthcare (Waterlooville)	5007	Total right hip replacement	No	Yes	Requires hospitalisation	Not related	
S0792	Group B	The Andover Health Centre (Andover)	5012	Para-umbilical hernia repair	No	Yes	Requires hospitalisation	Not related	
S0805	Group A	Pioneer Medical Group (Bristol)	5074	Vaginal hysterectomy and anterior repair	No	Yes	Requires hospitalisation	Not related	
S0805	Group A	Pioneer Medical Group (Bristol)	5074	Intra-op fluoroscopy-guided left l5/s1 microdiscectomy	Yes	Yes	Requires hospitalisation	Not related	
S0815	Group A	Pioneer Medical Group (Bristol)	5074	Trial without catheter post prostatectomy	No	Yes	Requires hospitalisation	Not related	
S0815	Group A	Pioneer Medical Group (Bristol)	5074	Prostatectomy for prostate cancer	No		ALREADY REPORTED AS AN SAE		
S0822	Group B	Tile House Surgery (Brentwood)	5133	Skin biopsy	No	Yes	Requires hospitalisation	Not related	

S0836	Group B	Cranleigh Medical Centre (Cranleigh)	5132	Mua + injection right hallux mtp joint	No	Yes	Requires hospitalisation	Not related
S0836	Group B	Cranleigh Medical Centre (Cranleigh)	5132	Right cataract surgery	No	Yes	Requires hospitalisation	Not related
S0839	Group C	Oaks Healthcare (Waterlooville)	5007	Cytoscopy	No	Yes	Requires hospitalisation	Not related
S0842	Group A	The Lighthouse Medical Practice (Eastbourne)	5134	Maxillofacial	No	Yes	Requires hospitalisation	Not related
S0843	Group A	Brockwood Medical Practice (Brockham)	5136	Denervation right wrist	No	Yes	Requires hospitalisation	Not related
S0843	Group A	Brockwood Medical Practice (Brockham)	5136	Colonoscopy	No	Yes	Requires hospitalisation	Not related
S0843	Group A	Brockwood Medical Practice (Brockham)	5136	Right side l4/5 transforaminal injection	Yes	Yes	Requires hospitalisation	Not related
S0844	Group C	Tile House Surgery (Brentwood)	5133	Excision biopsy right cheek	No	Yes	Requires hospitalisation	Not related
S0851	Group A	Tile House Surgery (Brentwood)	5133	Left eye injection	No	No	Requires hospitalisation	Not related
S0851	Group A	Tile House Surgery (Brentwood)	5133	Caudal epidural facet joint injection	Yes	Yes	Requires hospitalisation	Not related
S0851	Group A	Tile House Surgery (Brentwood)	5133	Left eye injection	No	Yes	Requires hospitalisation	Not related
S0884	Group A	The Fishponds Family Practice	5114	Excision of lesion	No	Yes	Requires hospitalisation	Not related
S0884	Group A	The Fishponds Family Practice	5114	Incision and biopsy of skin	No	Yes	Requires hospitalisation	Not related
S0893	Group B	Pioneer Medical Group (Bristol)	5074	Spontaneous pneumothorax	No	Yes	Requires hospitalisation	Not related
S0897	Group A	Brockwood Medical Practice (Brockham)	5136	Cystoscopy	No	Yes	Requires hospitalisation	Not related
S0915	Group B	Newton Place Surgery (Faversham)	5146	Zolendronate infusion	No	Yes	Requires hospitalisation	Not related
S0980	Group C	Vine Medical Group (Waterlooville)	5006	Left thumb nail bed graft	No	Yes	Requires hospitalisation	Not related

continued

TABLE 29 Image of an excel table of hospitalisations listed in the notes reviews (*continued*)

SAE Criteria:
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*** Results in Persistent or Significant Disability or Incapacity**
*** Is a Congenital Anomaly or Birth Defect**
*** Other Important Event**

Data from GP 12 Months Notes Review						Clinical Reviewer to Complete			
							If Yes:		
Subject	Randomisation group	Site	Site number	Reason for stay	Was this related to back pain?	Do you think this event might meet the SAE criteria?	Which criteria does it meet? (If more than one, please state in comments)	Is this related to study treatment?	Comments
S0982	Group A	Park Surgery (Horsham)	5150	Microdiscectomy	Yes	Yes	Requires hospitalisation	Not related	
S0984	Group C	Park Surgery (Horsham)	5150	Backache (no recent injury)	Yes	Yes	Requires hospitalisation	Not related	
S0992	Group A	Heart of Bath Medical Partnership (Bath)	5091	L4/5 transforaminal nerve block	Yes	Yes	Requires hospitalisation	Not related	
S0992	Group A	Heart of Bath Medical Partnership (Bath)	5091	Nerve block follow-up	Yes	Yes	Requires hospitalisation	Not related	
S0996	Group B	Newton Place Surgery (Faversham)	5146	Sacroiliac joint injections bilateral	Yes	Yes	Requires hospitalisation	Not related	
S0999	Group B	Pioneer Medical Group (Bristol)	5074	T2 fracture non-displaced after fall from horse	No	Yes	Requires hospitalisation	Not related	
S0999	Group B	Pioneer Medical Group (Bristol)	5074	Abdominal pain	No	Yes	Requires hospitalisation	Not related	
S1016	Group A	Heart of Bath Medical Partnership (Bath)	5091	Mri spine	Yes	Yes	Requires hospitalisation	Not related	
S1022	Group C	Pioneer Medical Group (Bristol)	5074	Acute exacerbation of asthma secondary to chest infection	No	Yes	Requires hospitalisation	Not related	
S1022	Group C	Pioneer Medical Group (Bristol)	5074	Shoulder arthroscopy decompression	No	Yes	Requires hospitalisation	Not related	
S1043	Group A	Cranleigh Medical Centre (Cranleigh)	5132	Ent day case	No	Yes	Requires hospitalisation	Not related	

S1057	Group A	Tile House Surgery (Brentwood)	5133	Gynaecology outpatient phone call	No	Yes	Requires hospitalisation	Not related
S1066	Group A	Greenway Community Practice (Bristol)	5131	Total knee replacement	No	Yes	Requires hospitalisation	Not related
S1066	Group A	Greenway Community Practice (Bristol)	5131	Dvt and tachycardia	No	Yes	Requires hospitalisation	Not related
S1067	Group C	Hampstead Group Practice (Hampstead)	5155	Fracture of tibial plateau	No	Yes	Requires hospitalisation	Not related
S1087	Group B	Cotswold Medical Practice	5090	Diagnostic laparoscopy	No	Yes	Requires hospitalisation	Not related
S1088	Group B	Tile House Surgery (Brentwood)	5133	Right total hip replacement	No	Yes	Requires hospitalisation	Not related
S1089	Group A	Tile House Surgery (Brentwood)	5133	Gastroscopy	No	Yes	Requires hospitalisation	Not related
S1097	Group B	Lancaster Medical Practice (Lancaster)	5158	Covid-19-positive pneumonitis respiratory failure	No		ALREADY REPORTED AS AN SAE	
S1108	Group C	Mathukia Surgery (Ilford)	5154	Oesophageal varices	No	Yes	Requires hospitalisation	Not related
S1111	Group A	Marine Lake Medical Practice (Wirral)	5157	Back pain? Cauda equina syndrome, mri scan excluded	Yes	Yes	Requires hospitalisation	Not related
S1122	Group B	Tile House Surgery (Brentwood)	5133	Colonoscopy	No	Yes	Requires hospitalisation	Not related
S1152	Group C	Marine Lake Medical Practice (Wirral)	5157	Fluroscopic hip injection	No	Yes	Requires hospitalisation	Not related
S1152	Group C	Marine Lake Medical Practice (Wirral)	5157	Abdominal pain	No	Yes	Requires hospitalisation	Not related
S1158	Group C	Lancaster Medical Practice (Lancaster)	5158	Elective total knee replacement	No	Yes	Requires hospitalisation	Not related
S1159	Group C	Pioneer Medical Group (Bristol)	5074	Abdominal pain	No	No	Requires hospitalisation	Not related

continued

TABLE 29 Image of an excel table of hospitalisations listed in the notes reviews (*continued*)

SAE Criteria:
*** Results in Death**
*** Is Life Threatening**
*** Requires Hospitalisation**
*** Results in Persistent or Significant Disability or Incapacity**
*** Is a Congenital Anomaly or Birth Defect**
*** Other Important Event**

Data from GP 12 Months Notes Review						Clinical Reviewer to Complete			
							If Yes:		
Subject	Randomisation group	Site	Site number	Reason for stay	Was this related to back pain?	Do you think this event might meet the SAE criteria?	Which criteria does it meet? (If more than one, please state in comments)	Is this related to study treatment?	Comments
S1176	Group C	Marine Lake Medical Practice (Wirral)	5157	Campylobacter	No	No	Requires hospitalisation	Not related	
S1181	Group C	Oakenhurst Medical Practice (Blackburn)	5163	Msk chest pain	No	Yes	Requires hospitalisation	Not related	
S1181	Group C	Oakenhurst Medical Practice (Blackburn)	5163	Aki 2nd to nsaid use. Transferred to rph.	Yes	Yes	Requires hospitalisation	Not related	
S1181	Group C	Oakenhurst Medical Practice (Blackburn)	5163	Neutropenic sepsis. Multiple myeloma	No	No	Requires hospitalisation	Not related	
S1182	Group A	Oakenhurst Medical Practice (Blackburn)	5163	Prostate biopsy	No	No	Requires hospitalisation	Not related	
S1182	Group A	Oakenhurst Medical Practice (Blackburn)	5163	Prostate biopsy	No	No	Requires hospitalisation	Not related	
S1188	Group A	West Walk Surgery (Bristol)	5097	L4/5 lumbar decompression	Yes	Yes	Requires hospitalisation	Not related	
S1197	Group B	Vine Medical Group (Waterlooville)	5006	Sigmoid diverticular disease	No	Yes	Requires hospitalisation	Not related	
S1198	Group C	Vine Medical Group (Waterlooville)	5006	Biopsy of prostatic urethral lesion	No	Yes	Requires hospitalisation	Not related	

S1203	Group B	Heart of Bath Medical Partnership (Bath)	5091	Elective surgery for pre-existing condition	No	Yes	Requires hospitalisation	Not Related
S1205	Group B	Marine Lake Medical Practice (Wirral)	5157	Revision of hip prosthesis	No	Yes	Requires hospitalisation	Not related
S1206	Group A	Oakenhurst Medical Practice (Blackburn)	5163	Cataract surgery	No	Yes	Requires hospitalisation	Not related
S1206	Group A	Oakenhurst Medical Practice (Blackburn)	5163	Cataract surgery	No	Yes	Requires hospitalisation	Not related
S1211	Group A	Station House Surgery (Kendal)	5162	Colonoscopy	No	Yes	Requires hospitalisation	Not related
S1222	Group B	Heart of Bath Medical Partnership (Bath)	5091	Acute constipation	No	Yes	Requires hospitalisation	Not related
S1222	Group B	Heart of Bath Medical Partnership (Bath)	5091	Abdominal pain	No	Yes	Requires hospitalisation	Not related
S1255	Group C	Andover Medical Centre (London)	5135	Endometrial biopsy	No	Yes	Requires hospitalisation	Not related

Appendix 3 Logic model for the SupportBack intervention

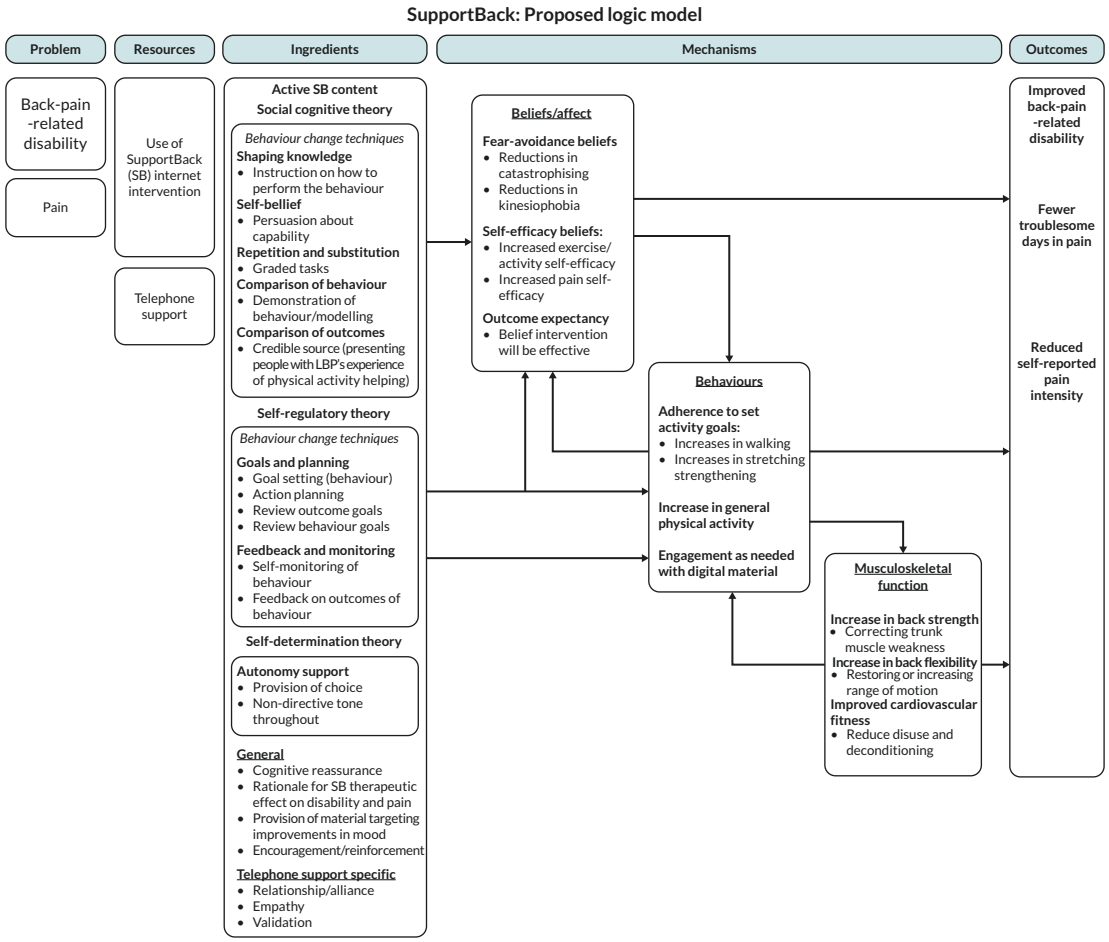

FIGURE 10 Logic model for the SupportBack intervention.

EME
HSDR
HTA
PGfAR
PHR

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