Supporting self-management of low back pain with an internet intervention with and without telephone support in primary care (SupportBack 2): a randomised controlled trial of clinical and cost-effectiveness

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Summary

Background Low back pain is prevalent and a leading cause of disability. We aimed to determine the clinical and cost-effectiveness of an accessible, scalable internet intervention for supporting behavioural self-management (SupportBack).

Methods Participants in UK primary care with low back pain without serious spinal pathology were randomly assigned 1:1:1 using computer algorithms stratified by disability level and telephone-support centre to usual care, usual care and SupportBack, or usual care and SupportBack with physiotherapist telephone-support (three brief calls). The primary outcome was low back pain-related disability (Roland Morris Disability Questionnaire [RMDQ] score) at 6 weeks, 3 months, 6 months, and 12 months using a repeated measures model, analysed by intention to treat using 97·5% CIs. A parallel economic evaluation from a health services perspective was used to estimate cost-effectiveness. People with lived experience of low back pain were involved in this trial from the outset. This completed trial was registered with ISRCTN, ISRCTN14736486.

Findings Between Nov 29, 2018, and Jan 12, 2021, 825 participants were randomly assigned (274 to usual care, 275 to SupportBack only, 276 to SupportBack with telephone-support). Participants had a mean age of 54 (SD 15), 479 (58%) of 821 were women and 342 (42%) were men, and 591 (92%) of 641 were White. Follow-up rates were 687 (83%) at 6 weeks, 598 (73%) at 3 months, 589 (72%) at 6 months, and 652 (79%) at 12 months. For the primary analysis, 736 participants were analysed (249 usual care, 245 SupportBack, and 242 SupportBack with telephone support). At a significance level of 0·025, there was no difference in RMDQ over 12 months with SupportBack versus usual care (adjusted mean difference –0·5 [97·5% CI –1·2 to 0·2]; p=0·085) or SupportBack with telephone-support versus usual care (–0·6 [–1·2 to 0·1]; p=0·048). There were no treatment-related serious adverse events. The economic evaluation showed that the SupportBack group dominated usual care, being both more effective and less costly. Both interventions were likely to be cost-effective at a threshold of £20 000 per quality adjusted life year compared with usual care.

Interpretation The SupportBack internet interventions did not significantly reduce low back pain-related disability over 12 months compared with usual care. They were likely to be cost-effective and safe. Clinical effectiveness, cost-effectiveness, and safety should be considered together when determining whether to apply these interventions in clinical practice.

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Introduction

Low back pain is the leading cause of disability globally,[1] with a prevalence of more than half a billion cases worldwide,[1] and a lifetime prevalence estimated up to 84%.[2] The economic burden of low back pain is extensive, with estimates of £1·6 billion of direct costs over a year in the UK,[3] and estimates of societal costs as high as $US81 billion in the USA.[4] Most people with low back pain are managed in primary care[5] where low back pain ranks within the top ten reasons for consultations of any type.[6] Behavioural self-management, including advice to stay active, is now a central component of recommended care; recent guidelines[7] have moved away from pharmacological and surgical management.[8] Given the scale of the problem and the fact that constrained health-care resources are under pressure, accessible, effective behavioural self-management support for low back pain is necessary to ensure these recommendations can be implemented.

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Research in context

Evidence before this study

Nicholl and colleagues published a systematic review of digital support interventions for the self-management of low back pain in 2017. This high quality systematic review was used to consider the evidence before this trial was undertaken. In this review, databases including Medline, Embase, CINAHL, PsychINFO, Cochrane Library, DoPHER and TRoPHI, Social Science Citation Index, and Science Ciation Index were searched between 2000 and March, 2016. Search terms were grouped into the following three categories: back pain, digital interventions, and self-management. Nicholl and colleagues found six completed randomised controlled trials, only one of which showed between-group differences that favoured the digital intervention. None of the trials reported harms related to the interventions. None of the trials reported on cost-effectiveness. They concluded that the evidence base for digital self-management interventions for low back pain was weak.

Added value of this study

To the best of our knowledge, this is the largest trial internationally of an internet intervention for self-management of low back pain in primary care. We found no significant differences when the SupportBack interventions were compared with usual care alone on low back pain-related disability over 12 months. The interventions were safe and likely to be cost-effective, particularly when SupportBack was delivered without physiotherapist telephone support.

Implications of all the available evidence

Although average treatment effects on low back pain-related disability are limited, internet interventions for self-management of low back pain are low-cost, safe, and have the potential to be scalable. Their use in clinical practice will require consideration of evidence on effectiveness, cost, safety, and accessibility.

Internet interventions, where content is delivered digitally through any device with access to the internet, have the potential to enable delivery of scalable behavioural interventions in primary care.[9] Systematic reviews of trials of digital interventions more broadly (including smartphone apps) for low back pain have highlighted methodological shortcomings amidst mixed results.[10,11] Research has shown that low back pain self-management could be enhanced through a smartphone plus activity monitoring wristband intervention (SelfBACK), with small reductions in low back pain-related disability compared with usual care.[12] There has not yet been an economic evaluation of digital low back pain self-management interventions in the UK,[11] despite their potential economic benefits due to being highly scalable[13] with little or no additional cost per addition of thousands of patients. It is therefore crucial to determine the clinical and cost-effectiveness of the most accessible digital format for supporting self-management of low back pain; an internet intervention delivered via a website, accessible from any device with the internet. Additionally, it remains unknown whether brief healthcare professional support enhances the effect of digital interventions for low back pain.

SupportBack is an internet intervention designed to support behavioural self-management of low back pain, through physical activity and a range of behavioural advice on topics including sleep, mood, and flare-ups.[14] It was developed with a pragmatic focus, aiming to be helpful for people who consult in primary care with acute, recurrent, or chronic low back pain.[14] This is consistent with the National Institute for Health and Care Excellence (NICE) guidelines recommending support for self-management for all with low back pain.[15] SupportBack can be used with or without accompanying physiotherapist telephone support. In this trial, we aimed to determine the clinical and cost-effectiveness of the SupportBack internet intervention delivered in addition to usual care with or without physiotherapist telephone support, in reducing low back pain-related disability over 12 months compared with usual care alone.

See Online for appendix

Methods

Study design

SupportBack 2 was a pragmatic, three-parallel group (1:1:1), multicentre randomised controlled trial, informed by a successful feasibility trial (SupportBack 1).[14] The trial was done with 179 general practices in the UK. The University of Southampton and Keele University formed the two recruiting and physiotherapist telephone support delivery centres. Each centre worked with Clinical Research Networks recruiting practices and patients from England in the south east, south west, west midlands, north west, and London. Ethical approval for the trial was granted by Hampshire B Research Ethics Committee on Aug 17, 2018 (18/SC/0388). This trial was registered with ISRCTN, ISRCTN14736486. The trial protocol has been published.[16]

People with lived experience of low back pain were involved throughout the trial, contributing to funding applications and forming a core part of the trial management group. Our public contributors provided input on all patient-facing aspects of the trial, supported with recruitment and follow-up strategies as well as contributing to interpretation of the trial findings. Two people with lived experience (FD and MW) contributed to the trial manuscript and are listed as authors. Further details on patient and public involvement can be found in the appendix (p 15).

Participants

Eligible participants were aged 18 years or older and reporting current low back pain with or without sciatica,

and with access to the internet. Patients needed to be able to read and understand English and be able to provide written informed consent. Exclusion criteria were indicators of serious spinal pathology such as infection, malignancy, fracture, inflammatory back pain, progressive neurology or cauda equina; spinal surgery within the previous 6 months; pregnancy; or had participated in the previous SupportBack feasibility trial. Patients who had consulted with low back pain in the preceding 2 months were identified by practice staff. The resulting patient lists were screened by a general practitioner who ruled out patients based on the eligibility criteria. Alternatively, general practitioners were prompted about the trial during a consultation when entering a relevant symptom code, general practitioners then screened for eligibility and patients who were deemed as suitable had their electronic medical record tagged. A download of tagged patients was produced every 2 weeks. This method was used in practices that had the technical capacity. Practices not using this method could also identify potential participants during consultations and check eligibility.

Patients who were identified as eligible were provided with a study information pack. Interested patients responded by answering a brief screening questionnaire. The screening process consisted of questions confirming current low back pain and access to the internet. As an addition to the general practitioner screen, patients were asked brief safety questions regarding red flag symptoms (appendix p 2). If patients confirmed current low back pain and internet access, without red flag symptoms, they were considered eligible. If they answered yes to any of the safety questions regarding symptoms, a clinical physiotherapist attempted to contact them by phone to discuss the symptom and make an appropriate recommendation regarding eligibility for the trial, and advising on appropriate clinical action (eg, visiting an emergency department or contacting their general practitioner). Patients who reported a red flag symptom in this aspect of the screening or were uncontactable were considered ineligible. Eligible participants were sent a link to the trial website where they could review study information, complete informed consent online, complete baseline questionnaires (including demographics [participants were asked to either list male or female]) and be randomly assigned.

Randomisation and masking

Participants were randomly assigned to the three groups equally (a 1:1:1 allocation ratio [usual care, SupportBack, or SupportBack with telephone support]), via a fully automated process using LifeGuide software. The block randomisation was stratified by trial recruiting centre and lower level of disability on the Roland and Morris Disability Questionnaire (RMDQ; scores of less than four).[17]

Masking of participants was not possible. The majority of the follow-up data was collected online automatically using trial software. Where telephone calls were used for non-response, callers were masked to allocation. The statisticians conducting the analyses were masked to allocation. The health economist conducted the majority of analyses masked to allocation. However, estimates of total cost required the addition of costs specific to the provision of interventions, therefore the health economist was un-masked at this point of the analysis.

Procedures

Participants randomly assigned to receive usual care had access to unrestricted usual care for low back pain, including both primary care and secondary care referrals. The UK NICE guidance for low back pain recommends assessment to rule out specific spinal pathology, alongside use of stratification tools[15] and guidance and information to support self-management and keep active. Guidance recommends limited pharmacotherapy, and non-pharmacological care includes referrals to physiotherapists, pain clinics, or psychological interventions as available. As we kept our eligibility criteria broad, we expected a high degree of variance in the usual care received. Participants assigned to receive usual care plus the SupportBack internet intervention could continue with unrestricted usual care while accessing SupportBack. SupportBack has been described in detail elsewhere.[18–20] In brief, SupportBack is an interactive, automated multisession internet intervention that provides participants with behavioural support and advice to guide effective self-management of low back pain, focusing on increasing physical activity. Participants are supported to develop expertise in managing their low back pain through graded activity goal setting, self-monitoring, and tailored feedback (drawing on self-efficacy and self-regulatory theory). SupportBack provided six sessions, once per week with emails to encourage adherence. Session one stressed the importance of physical activity in managing low back pain, and supported setting goals to increase walking or gentle back exercises. The weekly sessions featured self-monitoring, feedback on progress, and opportunities for goal adjustment. After session one, a weekly module could be unlocked on topics including mood, work, sleep, and flare-ups. SupportBack could be accessed from any device with the internet and used where most convenient. Participants assigned to receive usual care plus SupportBack with the addition of physiotherapist telephone support also had up to three calls with a physiotherapist. The calls were up to 1 h in total (one 30 min call, two 15 min follow-up calls), and delivered within the 6 week interactive period with SupportBack. Physiotherapists encouraged use of SupportBack, provided reassurance regarding physical activity with low back pain, supported goal setting, and addressed concerns. The 12 physiotherapists involved in delivering the support attended a 2 h training session. Although physiotherapists could address individual concerns, they were asked to avoid assessment and

For more on the **LifeGuide software** see www.lifeguideonline.org

treatment recommendations beyond what was offered in SupportBack.

Follow-up data were collected at 6 weeks, 3 months, 6 months, and 12 months after randomisation. The majority of data were collected automatically online. At 6 weeks and 12 months, non-response to online data collection emails was followed by sending a postal questionnaire, non-response to postal questionnaires triggered a phone call from a masked research assistant to collect primary outcome data. At the 3-month and 6-month time points, non-response to follow-up emails led to a follow-up with a postal questionnaire only. All participants were provided with a £5 voucher at 6 months and a £10 voucher at 12 months to encourage completion of later follow-up measures (unconditionally). Potential serious adverse event data were reported by lead GPs at participating practices, telephone physiotherapists, and participants over the course of the trial. Adverse events judged as serious were assessed for relatedness by a lead clinician at the practice or by a clinical delegate from the trial team.

Outcomes

The primary outcome was low back pain-related disability over 12 months, as measured by the RMDQ at 6 weeks, 3 months, 6 months, and 12 months (using a repeated measures model). The RMDQ is measured on a scale of 0 to 24 with higher scores indicating worse physical disability.[17] Secondary outcomes were low back pain-related disability measured with the RMDQ at each of the four follow-up time points,[21] back pain intensity (on a scale of 0 [none] to 10 [worst]), number of troublesome days in pain over the last 4 weeks, risk of persistent disabling pain (StarT Back risk score on a scale of 0 [lowest] to 9 [highest] risk of persistent disability due to back pain; StarT Back risk group patients are allocated to the high-risk group if the StarT Back psychosocial subscale score is ≥4, the remaining patients are allocated to the low-risk group if the overall StarT Back score is <4 and to the medium risk group if the overall StarT Back score is ≥4), kinesiophobia (Tampa Scale for Kinesiophobia; scale of 11 to 44 with higher scores indicating greater fear of movement), pain catastrophising (on a scale of 0 to 52 with higher scores indicating more negative orientation towards pain), pain self-efficacy (Pain Self Efficacy Questionnaire; on a scale of 0 to 60, higher scores indicate greater confidence to manage pain), self-efficacy for low back pain (on a scale of 0 [not at all] to 4 [extremely]), symptoms of depression and anxiety (PHQ-4 scores; rated as normal [0–2], mild [3–5], moderate [6–8], and severe [9–12]), enablement (Patient Enablement Index; on a scale of 1 [strongly disagree] to 7 [strongly agree] with higher scores indicating greater ability to cope with the condition), satisfaction with care for back pain (on a scale of 0 [not at all satisfied] to 4 [very satisfied]), general physical activity (Godin physical activity scale; <14 [insufficiently active), 14–23 [moderately active], >24 [active]), back-related physical activity (physical activity over the last week with the aim of helping the back), self-reported medication use, numbers of GP, physiotherapist, and secondary care consultations, back pain related prescriptions, and time off work due to low back pain (see the published protocol for full details[15]). When developing the statistical analysis plan, an additional analysis was included focusing on the number of patients reaching a within-person minimally clinically important difference on the RMDQ within each group. The within person minimally clinically important difference for the RMDQ was defined as a change of 30% between baseline and follow-up at 12 months.[21] This analysis was added to provide an indication of the extent of meaningful change at the individual level, although we acknowledge the need to interpret this with caution due to change from baseline consisting of regression to the mean, placebo effects, and measurement error, as well as the intervention effect.

For more on **StarT Back risk group** see https://startback.hfac.keele.ac.uk/

Health economic analysis

The SupportBack 2 trial also included a parallel economic evaluation. The perspective of the analysis presented here was that of the UK National Health Service (NHS).

Resources required to provide the internet intervention and the telephone support were recorded. These included the cost of hosting the web platform and user support, as well as physiotherapist time to provide telephone support. Physiotherapists kept a log of all telephone contacts. We also recorded duration of contacts for a subset of 50 participants, from this sample the estimate of duration of the three scheduled contacts was 25, 14, and 13 min and contact time was costed using data from a published source.[22] Details of NHS service use by participants were recorded using a health-care records review at participating general practices. This included both primary and secondary health-care contacts and covered both general health care use in addition to low back pain-specific health care; however, only low back pain-specific health-care resource use is reported here. The following resource types were collected: general practitioner based contacts; other primary care; pain related medicines; low back pain-related physiotherapy; hospital admissions; accident and emergency contacts; and outpatient visits (including imaging). Data were collected in the 12-month follow-up period. We also collected data on primary care costs in the 3-months before recruitment to test for differences in baseline resource use. All resources identified were costed using appropriate local and national data.[22–24] For hospital based inpatient and outpatient care a description of the hospital speciality was requested and was used to match to appropriate NHS reference costs. Where this was not possible a weighted average cost for either inpatient or outpatient was used. Costs were valued in

2020–21 UK pounds sterling. As the time frame of the study was 1 year, neither costs nor outcomes were discounted.

Two outcome measures were used in the economic analysis. The base case analysis estimated quality adjusted life years (QALYs) using the EQ-5D-5L,[25] valued

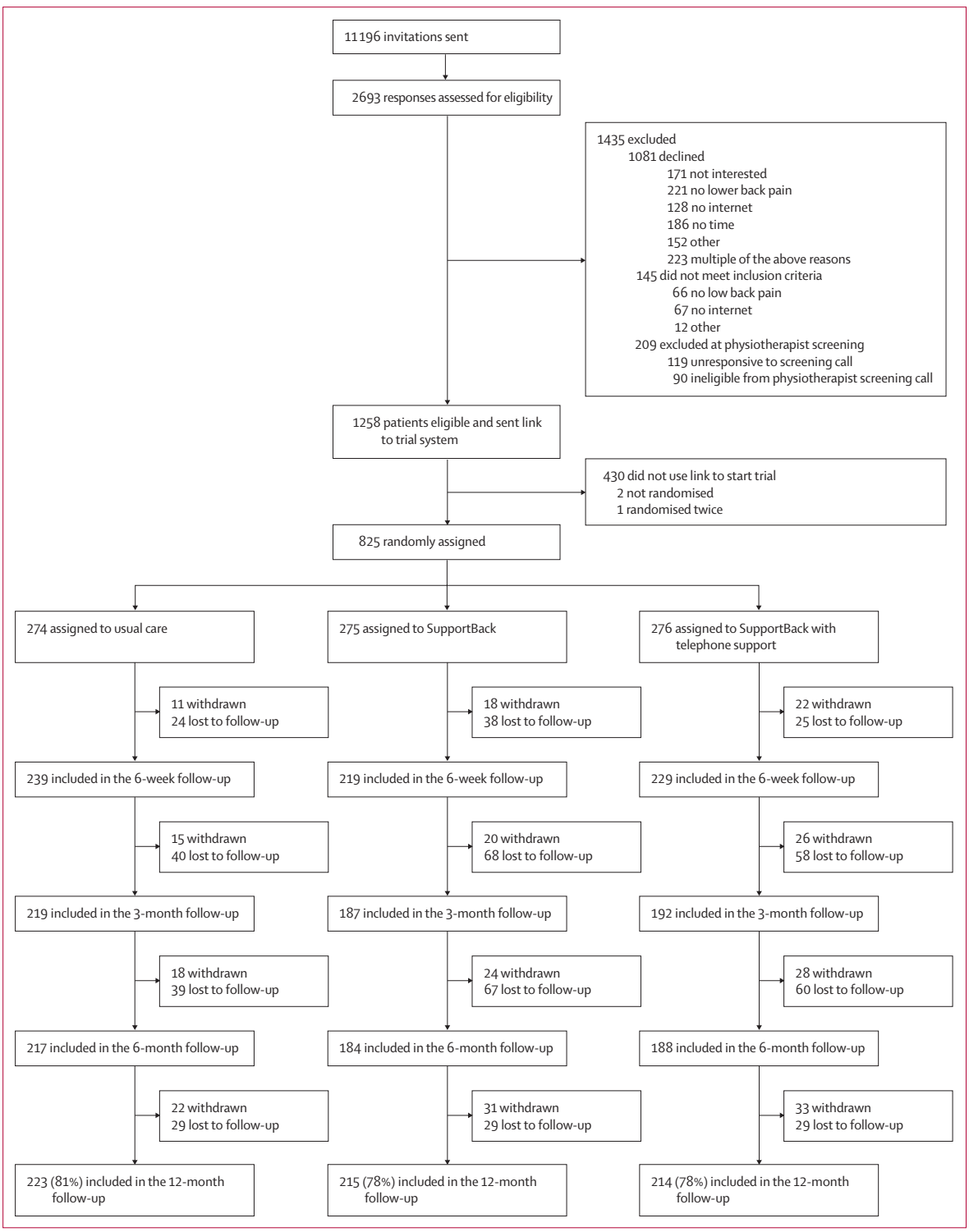

***Figure 1*: Trial profile**
Note the denominator for each follow-up point is the total number randomised to that group.

	Usual care (n=274)	SupportBack (n=275)	SupportBack and telephone support (n=276)
Sex			
Female	158/273 (58%)	154/273 (56%)	167/275 (61%)
Male	115/273 (42%)	119/273 (44%)	108/275 (39%)
Age, years	54·5 (15·0), n=271	53·5 (16·1), n=271	54·6 (15·2), n=276
Ethnicity			
White	199/212 (94%)	196/213 (92%)	196/216 (91%)
Asian or Asian British	7/212 (3%)	4/213 (2%)	8/216 (4%)
Black, African, Caribbean, or Black British	0/212	5/213 (2%)	3/216 (1%)
Mixed or multiple	4/212 (2%)	6/213 (3%)	2/216 (1%)
Other	2/212 (1%)	2/213 (1%)	7/216 (3%)
Marital status			
Single	51 (19%)	36 (13%)	49 (18%)
Married	155 (57%)	169 (61%)	165 (60%)
Partner	30 (11%)	36 (13%)	26 (9%)
Divorced	22 (8%)	13 (5%)	17 (6%)
Separated	5 (2%)	2 (1%)	4 (1%)
Widowed	9 (3%)	14 (5%)	12 (4%)
Prefer not to answer	2 (1%)	5 (2%)	3 (1%)
Age left full time education	19·0 (5·0), n=264	18·6 (3·9), n=265	18·8 (4·5), n=266
Highest qualification			
No formal educational qualifications	26 (9%)	31 (11%)	26 (9%)
GCSE/O Levels	54 (20%)	56 (20%)	69 (25%)
A Levels	34 (12%)	30 (11%)	39 (14%)
Diploma (non-degree)	40 (15%)	39 (14%)	33 (12%)
Degree	55 (20%)	52 (19%)	51 (18%)
Higher Degree	11 (4%)	18 (7%)	13 (5%)
Postgraduate degree	32 (12%)	26 (10%)	24 (9%)
Other	20 (7%)	17 (6%)	21 (8%)
No response	2 (1%)	6 (2%)	0
Employment status			
Full-time	98 (36%)	97 (35%)	85 (31%)
Part time	41 (15%)	39 (14%)	44 (16%)
Self-employed (full time)	10 (4%)	15 (5%)	11 (4%)
Self-employed (part time)	9 (3%)	16 (6%)	14 (5%)
Homemaker	5 (2%)	7 (3%)	6 (2%)
Retired	84 (31%)	70 (25%)	86 (31%)
Not in employment due to disability	8 (3%)	2 (1%)	12 (4%)
Not in employment due to long-term sickness	5 (2%)	10 (4%)	6 (2%)
Unemployed	7 (3%)	8 (3%)	9 (3%)
Student	4 (1%)	7 (3%)	3 (1%)
No response	3 (1%)	4 (1%)	0
Household income			
Up to £10 000	33 (12%)	28 (10%)	27 (10%)
£10 001–£20 000	49 (18%)	50 (18%)	55 (20%)
£20 001–£40 000	87 (32%)	85 (31%)	91 (33%)
≥£40 001	97 (35%)	103 (37%)	93 (34%)
No response	8 (3%)	9 (3%)	10 (4%)
Index of multiple deprivation decile*	7 (5–9), n=273	6 (4–9), n=270	7 (4–9), n=270
Median RMDQ score	7 (3–11)	7 (3–12)	7 (3–12)

(Table 1 continues on next page)

using a published scoring system.[26] The EQ-5D-5L was collected at baseline, 6 weeks, 3 months, 6 months, and 12 months. Due to lower response rates at the timepoints not followed-up by telephone, we estimated QALYs based on EQ-5D-5L at baseline, 6 weeks, and 12 months. This provided response rates of 77%, 70%, and 74% for the three groups with less disparity between groups in QALY responses. A comparison of QALY values derived using both five and three timepoints (for those with complete data for both methods) showed very similar results (appendix p 11). A secondary analysis used differences between RMDQ at 12 months and baseline.

Statistical analysis

The reported minimally clinical important difference for the RMDQ varies. A between group minimally clinically important difference of two or three points is often reported. However, a difference of 1·5 between groups could still be important,[27] particularly for low intensity interventions like SupportBack. We chose a between-group difference of at least 1·5 to be a meaningful difference given the low intensity nature of SupportBack. For our repeated primary outcome measures, 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[14] gave an effect size of 0·30. Alpha was set to 0·025 to allow both SupportBack groups to be independently compared with the usual care alone group. Using four repeated measures (6 weeks, and 3, 6 and 12 months), and assuming a correlation between repeated measures of 0·7 and 90% power, the study required 215 participants per group. Allowing for 20% loss to follow-up, a total sample size of 806 was required.

Quantitative analysis followed 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 done using a multilevel mixed model framework with observations at 6 weeks and 3, 6, and 12 months (level one) nested within participants (level two), adjusting for stratification factors (baseline RMDQ and trial centre) and pre-specified confounders (previous pain duration, STarT Back risk group, and age). The primary outcome analysis was reported at a 2·5% significance level to align with the sample size calculation (in the statistical analysis plan we suggested a 5% level). The model used all the observed data and assumed that missing RMDQ scores were missing at random given the observed data. A treatment–time interaction was modelled, but was not included as this was not significant (ie, treatment effect was not significantly varying over time). The assumption of practice level (cluster) effect was tested by comparing a fixed effect model with 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 sensitivity analyses based on data imputed using a multiple imputation model were carried out.

Analysis of secondary outcomes was done using linear regression for continuous outcomes and logistic regression for dichotomous outcomes, again controlling for baseline outcome, baseline RMDQ, recruitment centre, previous pain duration, STarT Back risk group, and age. Secondary outcomes were reported at a 5% significance level. If there was no significant treatment by time interaction, only the main effect from the repeated measures model was presented. All primary and secondary analyses were analysed on an intention-to-treat basis (ie, as randomised). We also did a complier-average causal effect analysis,[28] which compared compliant participants in each SupportBack intervention group with those in the usual care alone group who would have complied with the intervention, given the opportunity to do so. The complier-average causal effect was estimated using an instrumental variables regression of the repeated measures RMDQ, with compliance as the endogenous variable and randomised group as the instrument. Compliance for these analyses in the SupportBack groups was defined as completing at least session one of the internet intervention. Session one contains the central rationale for the intervention and the goal setting exercise that is revisited throughout the sessions. In the physiotherapist telephone support group, compliance was defined as receiving at least two of the three planned phone calls in addition to at least session one of the internet intervention, indicating that support was delivered over time. To explore the possible impact of COVID-19, RMDQ scores at baseline and 6 weeks were summarised descriptively by group before and after the onset of the pandemic. Stata version 17 was used for all analyses.

Cost-effectiveness was evaluated using regression-based methods. For QALYs, results were adjusted for baseline EQ-5D-5L, stratification factors, pain duration, STarT Back risk group, and age. The same baseline characteristics were used to estimate improvement in RMDQ except that baseline RMDQ was added. For costs, results were adjusted for primary care costs in the preceding 3 months, stratification factors, pain duration, STarT Back risk group, and age. Missing data can lead to bias in economic evaluations.[29] For this reason, multiple imputation with chained equations ("mi impute chained" command in Stata) was used to impute missing data in the base case analysis. As we had completed data for both costs and QALYs for approximately 60% of individuals we created 40 data sets. The multiple imputation model included study group, EQ5D-5L scores at all timepoints, RMDQ baseline score, RMDQ difference (between baseline and 12 months), costs in the 3 months before recruitment, costs in the 12 month study period, age, STarT Back risk group, pain duration, and stratification factors. The health economic analysis was carried out in Stata 17. Guidelines on handling missing data were followed.[29] Cost-effectiveness acceptability curves were estimated to show the effects of uncertainty.

	Usual care (n=274)	SupportBack (n=275)	SupportBack and telephone support (n=276)
(Continued from previous page)			
Mean RMDQ score	7·7 (5·2)	8·1 (5·5)	7·9 (5·4)
Pain intensity			
Current pain	3·6 (2·1)	3·9 (2·2)	4·1 (2·1)
Least pain over past two weeks	2·9 (2·2)	3·1 (2·4)	3·4 (2·3)
Average pain over past two weeks	4·6 (1·9)	4·9 (2·1)	5·0 (2·0)
Days in pain over past 4 weeks	14 (6–28)	12 (6–25)	15 (7–28)
Time since whole month without pain			
Less than 3 months	48 (18%)	48 (17%)	47 (17%)
3–6 months	38 (14%)	24 (9%)	48 (17%)
7–12 months	43 (16%)	53 (19%)	44 (16%)
1–2 years	46 (17%)	33 (12%)	36 (13%)
3–5 years	41 (15%)	49 (18%)	38 (14%)
6–10 years	18 (7%)	28 (10%)	24 (9%)
Over 10 years	38 (14%)	38 (14%)	37 (13%)
No response	2 (1%)	2 (1%)	2 (1%)
STarT Back risk group			
Low risk	125/250 (50%)	127/256 (50%)	118/257 (46%)
Medium risk	74/250 (30%)	71/256 (28%)	94/257 (37%)
High risk	51/250 (20%)	58/256 (23%)	45/257 (18%)
STarT Back score	3·8 (2·3)	3·8 (2·4)	4·0 (2·2)
Pain Self Efficacy Questionnaire	42 (29–50)	40 (31–49)	41 (30–49)
Self-efficacy for lower back pain	2·4 (1·0), n=267	2·3 (1·0), n=260	2·3 (1·0), n=264
Godin physical activity scale	21 (10–42), n=249	21 (10–41), n=250	22 (11–42), n=254
Insufficiently active	81/249 (33%)	81/250 (32%)	74/254 (29%)
Moderately active	49/249 (20%)	51/250 (20%)	56/254 (22%)
Active	119/249 (48%)	118/250 (47%)	124/254 (49%)
Back related physical activity			
0 days	49 (18%)	53 (19%)	46 (17%)
1–2 days	71 (26%)	82 (30%)	73 (26%)
3–4 days	55 (20%)	67 (24%)	78 (28%)
5+ days	99 (36%)	73 (27%)	79 (29%)
Tampa Scale for Kinesiophobia	24·0 (7·4), n=253	24·0 (7·1), n=262	24·2 (6·9), n=257
Pain Catastrophising Scale	14 (6–24), n=252	13 (5–26), n=243	13 (6–26), n=252
PHQ-4 category			
Normal	152/266 (57%)	162/266 (61%)	152/273 (56%)
Mild	64/266 (24%)	60/266 (23%)	63/273 (23%)
Moderate	26/266 (10%)	27/266 (10%)	36/273 (13%)
Severe	24/266 (9%)	18/266 (7%)	22/273 (8%)
PHQ-4 Anxiety	56/268 (21%)	52/272 (19%)	63/275 (23%)
PHQ-4 Depression	52/270 (19%)	48/269 (18%)	61/274 (22%)

Data are n (%), n/n (%), mean (SD), or median (IQR). PHQ=Patient Health Questionnaire. RMDQ=Roland Morris Disability Questionnaire. *Index of multiple deprivation decile, 1=most deprived to 10=least deprived (based on individual postcodes at the Lower layer Super Output Area level).

Table 1: **Baseline characteristics**

Role of the funding source
The funder had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Nov 29, 2018, and Jan 12, 2021, 11 196 invitation packs were sent out to potentially eligible participants, of whom 2693 (24%) responded. After patients who declined to participate or failed screening were removed, 1258 (11%) of 11 196 were eligible and were sent the link to the trial website for randomisation. Of these 1258 people, 825 (66%) used the link and were randomly assigned into the trial: 274 to usual care alone, 275 to SupportBack, and 276 to SupportBack with telephone-support (figure 1). Follow-up was completed by Feb 22, 2022. As we used a repeated measures model, 736 (89%) of 825 participants were included in the primary analysis (249 on usual care alone, 245 on SupportBack, and 242 on SupportBack with telephone-support). Of the additional 134 telephone calls made to obtain a primary outcome, the caller was unmasked to treatment allocation on three occasions.

At baseline, most participants had low-to-moderate levels of low back pain-related disability with a median score of 7 on the RMDQ (IQR 3–12). The mean pain intensity over the previous 2 weeks was 4·8 (SD 2·0; on a 0–10 scale), and 426 (52%) of 819 participants reported that their current low back pain episode had lasted 1 year or more. Participants had a mean age of 54 (SD 15), 479 (58%) of 821 were women and 342 (42%) were men (gender data were missing for 4 participants), and 591 (92%) of 641 were White (table 1). In the SupportBack group a mean of 2·4 (SD 2·4) internet sessions (of six) were completed, and 182 (66%) of 275 participants completed at least the first session. Use of the intervention was higher in the SupportBack with telephone-support group with a mean of 3·4 (SD 2·2) sessions completed and 236 (86%) of 276 participants completing at least the first session; 196 (71%) participants received at least two calls with a physiotherapist.

The repeated measures primary outcome of the RMDQ score at 6 weeks and 3, 6, and 12 months showed a small reduction in the RMDQ score in both the SupportBack and the SupportBack with telephone-support groups compared with usual care alone (adjusted mean difference –0·5 [97·5% CI –1·2 to 0·2; p=0·085] for SupportBack *vs* usual care; –0·6 [–1·2 to 0·1; p=0·048] for SupportBack with telephone-support *vs* usual care). These differences were not significant at the pre-specified significance level of 0·025 for the primary repeated measures outcome (table 2, figure 2). For secondary outcomes, small mean differences in RMDQ were seen at each of the four follow-up points (table 2). There were statistically significant reductions in the RMDQ score in the SupportBack with telephone-support group versus usual care alone at 6 weeks (0·7 [95% CI –1·3 to –0·02). At 12 months, the RMDQ score was statistically significantly lower in the SupportBack group versus usual care alone (–1·1 [–1·9 to –0·3]).

In repeated measures models over 12 months, there were statistically significant differences on a numerical rating scale measuring least pain intensity in the last 2 weeks, showing less pain for those in SupportBack with telephone-support versus usual care alone. A statistically significant reduction in troublesome days in pain over the past 4 weeks of just over 1 day per month was seen with both SupportBack and SupportBack with telephone-support versus usual care alone. A brief measure of back-related physical activity in the last week was statistically significantly higher in the SupportBack with telephone-support group by approximately 1 day per week compared with usual care alone (table 2). There were no statistically significant differences in repeated measures models used to examine pain intensity (numerical rating scale current pain, average pain over the past 2 weeks), nor a single item on back-pain related self-efficacy score between both SupportBack groups versus usual care. Pain self-efficacy was statistically significantly higher in both SupportBack groups versus usual care at 6 weeks, as was satisfaction with care for back pain. At 12 months, both SupportBack groups showed small statistically significant reductions in kinesiophobia versus usual care. There were no statistically significant differences between either SupportBack groups versus usual care on pain self-efficacy, catastrophising, leisure time physical activity, or enablement at 12 months.

A higher percentage of participants were in the low risk STarT Back group at 12 months compared with baseline, and percentages were broadly similar across intervention groups. There were also no statistically significant differences between groups in reported time off work at 6 and 12 months, nor in general practitioner, physiotherapy, or secondary care referrals, or prescriptions for back pain-related medication, and counts of self-reported over-the-counter medication for pain did not differ between groups. The SupportBack group was more likely to have symptoms of depression versus usual care alone at 12 months. Following investigation, this seemed best explained by attrition bias rather than a direct negative effect of the intervention: a higher proportion of the intervention group who had symptoms of depression at baseline were missing PHQ-4 depression scores at 12 months (29 [60%] of 48) compared with usual care alone (26 [43%] of 61). A post hoc analysis using imputed data showed that this effect on depression was not statistically significant (appendix p 6).

The proportion of participants who had a 30% reduction from baseline in the RMDQ was statistically significantly higher in the SupportBack group versus the usual care group (61·2% *vs* 50·5%, adjusted odds ratio [OR] 1·8 [95% CI 1·2–2·7]), and similarly for the SupportBack with telephone support group (61·4% *vs*

	Usual care		SupportBack		SupportBack and telephone support		SupportBack versus usual care adjusted intervention effect	SupportBack and telephone support versus usual care adjusted intervention effect
	n	Mean (SD) or n (%)	n	Mean (SD) or n (%)	n	Mean (SD) or n (%)		
Primary outcome								
RMDQ (repeated measures)	249	5·6 (5·6)	245	4·9 (5·4)	242	4·7 (5·1)	MD (97·5% CI): −0·5 (−1·2 to 0·2)	MD (97·5% CI): −0·6 (−1·2 to 0·1)
Secondary outcomes								
RMDQ								
6 weeks	239	6·7 (5·5)	219	6·7 (5·5)	229	6·0 (5·5)	MD (95% CI): −0·4 (−1·0 to 0·3)	MD (95% CI): −0·7 (−1·3 to −0·02)*
3 months	219	5·9 (5·4)	187	5·9 (5·6)	192	5·0 (4·9)	MD (95% CI): −0·3 (−1·1 to 0·5)	MD (95% CI): −0·7 (−1·5 to 0·1)
6 months	217	5·7 (5·6)	184	5·6 (5·6)	188	4·9 (4·7)	MD (95% CI): −0·5 (−1·3 to 0·3)	MD (95% CI): −0·7 (−1·5 to 0·1)
12 months	223	5·6 (5·6)	215	4·9 (5·4)	214	4·7 (5·1)	MD (95% CI): −1·1 (−1·9 to −0·3)*	MD (95% CI): −0·6 (−1·4 to 0·2)
Pain intensity (repeated measures)								
Current pain	249	3·0 (2·5)	245	3·0 (2·4)	242	2·7 (2·3)	MD (95% CI):−0·26 (−0·52 to 0·01)	MD (95% CI): −0·26 (−0·52 to 0·01)
Least pain	249	2·5 (2·5)	245	2·3 (2·2)	242	2·1 (2·0)	MD (95% CI): −0·18 (−0·43 to 0·08)	MD (95% CI): −0·30 (−0·55 to −0·05)*
Average pain	249	3·6 (2·5)	245	3·4 (2·5)	242	3·1 (2·2)	MD (95% CI): −0·20 (−0·46 to 0·07)	MD (95% CI): −0·22 (−0·49 to 0·05)
Days in pain over past 4 weeks	249	11·0 (10·2)	245	9·8 (9·8)	242	9·0 (9·5)	MD (95% CI): −1·2 (−2·4 to −0·01)*	MD (95% CI): −1·3 (−2·5 to −0·2)*
Self-efficacy for low back pain	249	2·8 (1·0)	245	2·8 (1·0)	242	2·9 (1·1)	MD (95% CI): 0·06 (−0·06 to 0·19)	MD (95% CI): 0·06 (−0·06 to 0·19)
Back related physical activity (days over past week)	246	3·0 (2·3)	236	3·5 (2·1)	237	3·4 (2·2)	MD (95% CI): 0·3 (−0·1 to 0·6)	MD (95% CI): 0·8 (0·5 to 1·1)*
Pain Self Efficacy Questionnaire at 6 weeks	230	42·0 (14·2)	206	43·5 (12·8)	211	43·7 (13·0)	MD (95% CI): 1·8 (0·1 to 3·5)*	MD (95% CI): 2·4 (0·7 to 4·1)*
Pain Self Efficacy Questionnaire at 12 months	206	43·8 (14·4)	202	45·1 (13·9)	202	46·0 (13·8)	MD (95% CI): 1·3 (−0·9 to 3·4)	MD (95% CI): 1·6 (−0·6 to 3·8)
Tampa Scale of Kinesiophobia at 12 months	176	22·5 (8·1)	162	20·9 (7·2)	163	20·7 (6·7)	MD (95% CI): −2·0 (−3·3 to −0·8)*	MD (95% CI): −1·3 (−2·6 to −0·1)*
Pain Catastrophising Scale at 12 months	174	11·5 (12·1)	159	11·0 (11·9)	161	10·5 (10·9)	MD (95% CI): −0·5 (−2·5 to 1·6)	MD (95% CI): −0·7 (−2·7 to 1·4)
Patient Enablement Index at 6 weeks	216	4·1 (1·6)	205	4·3 (1·6)	214	4·8 (1·5)	MD (95% CI): 0·1 (−0·2 to 0·4)	MD (95% CI): 0·7 (0·4 to 1·0)*
Patient Enablement Index at 12 months	182	4·4 (1·6)	166	4·4 (1·7)	168	4·5 (1·7)	MD (95% CI): 0·05 (−0·3 to 0·4)	MD (95% CI): −0·03 (−0·4 to 0·3)
Satisfaction at 6 weeks	204	2·1 (1·1)	154	2·4 (1·1)	181	3·1 (0·9)	MD (95% CI): 0·3 (0·1 to 0·6)*	MD (95% CI): 1·0 (0·8 to 1·2)*
Godin physical activity moderately active or active at 12 months	140	104 (74%)	115	87 (76%)	111	81 (73%)	OR (95% CI): 1·2 (0·6 to 2·4)	OR (95% CI): 0·8 (0·4 to 1·7)
PHQ-4 anxiety at 12 months	193	33 (17%)	171	34 (20%)	171	28 (16%)	OR (95% CI): 1·6 (0·8 to 3·2)	OR (95% CI): 1·3 (0·7 to 2·6)
PHQ-4 depression at 12 months	190	31 (16%)	171	33 (19%)	174	27 (16%)	OR (95% CI): 2·2 (1·1 to 4·7)*	OR (95% CI): 1·0 (0·4 to 2·0)
STarT Back risk group at 12 months								
Low risk	179	119 (66%)	168	111 (66%)	164	118 (72%)	..	..
Medium risk	179	39 (22%)	168	37 (22%)	164	33 (20%)	..	..
High risk	179	21 (12%)	168	20 (12%)	164	13 (8%)	..	..
Over the counter medication at 6 months								
Never	214	74 (35%)	180	73 (41%)	184	69 (38%)	..	..
Occasionally	214	44 (21%)	180	31 (17%)	184	43 (23%)	..	..
Once a week	214	37 (17%)	180	28 (16%)	184	36 (20%)	..	..
2 to 4 per week	214	14 (7%)	180	9 (5%)	184	10 (5%)	..	..
Every day	214	45 (21%)	180	39 (22%)	184	26 (14%)	..	..
Over counter medication at 12 months								
Never	194	74 (38%)	173	69 (40%)	170	55 (32%)	..	..
Occasionally	194	33 (17%)	173	36 (21%)	170	47 (28%)	..	..
Once a week	194	40 (21%)	173	34 (20%)	170	39 (23%)	..	..
2 to 4 per week	194	15 (8%)	173	9 (5%)	170	8 (5%)	..	..
Every day	194	32 (16%)	173	25 (14%)	170	21 (12%)	..	..
Time off work due to back pain at 6 months	131	30 (23%)	107	25 (23%)	101	21 (21%)	OR (95% CI): 1·3 (0·6 to 2·8)	OR (95% CI): 1·0 (0·5 to 2·2)
Time off work due to back pain at 12 months	109	12 (11%)	103	12 (12%)	100	13 (13%)	OR (95% CI): 1·1 (0·4 to 3·1)	OR (95% CI): 1·5 (0·5 to 4·1)

(Table 2 continues on next page)

	Usual care		SupportBack		SupportBack and telephone support		SupportBack versus usual care adjusted intervention effect	SupportBack and telephone support versus usual care adjusted intervention effect
	n	Mean (SD) or n (%)	n	Mean (SD) or n (%)	n	Mean (SD) or n (%)		
(Continued from previous page)								
GP consultation for back pain	228	83 (36%)	237	87 (37%)	236	86 (36%)	OR (95% CI): 1·0 (0·7 to 1·5)	OR (95% CI): 0·9 (0·6 to 1·4)
Physiotherapist consultation	223	40 (18%)	221	42 (19%)	226	43 (19%)	OR (95% CI): 1·0 (0·6 to 1·7)	OR (95% CI): 1·0 (0·6 to 1·6)
Secondary care consultation	244	32 (13%)	249	37 (15%)	246	36 (15%)	OR (95% CI): 1·1 (0·7 to 1·9)	OR (95% CI): 1·1 (0·7 to 1·9)
Back pain-related prescriptions	220	1·8 (4·0)	229	1·9 (3·3)	230	1·8 (3·7)	IRR (95% CI): 0·9 (0·6 to 1·4)	IRR (95% CI): 0·8 (0·6 to 1·2)

Data are n, n (%), or mean (SD), unless otherwise stated. Comparison values are adjusted for baseline outcome score, recruiting centre, age, pain duration, and STarT Back risk group. IRR=incidence rate ratio. MD=mean difference. OR=odds ratio. PHQ=Patient Health Questionnaire. RMDQ=Roland Morris Disability Questionnaire. *p<0·05.

Table 2: **Primary and secondary outcomes**

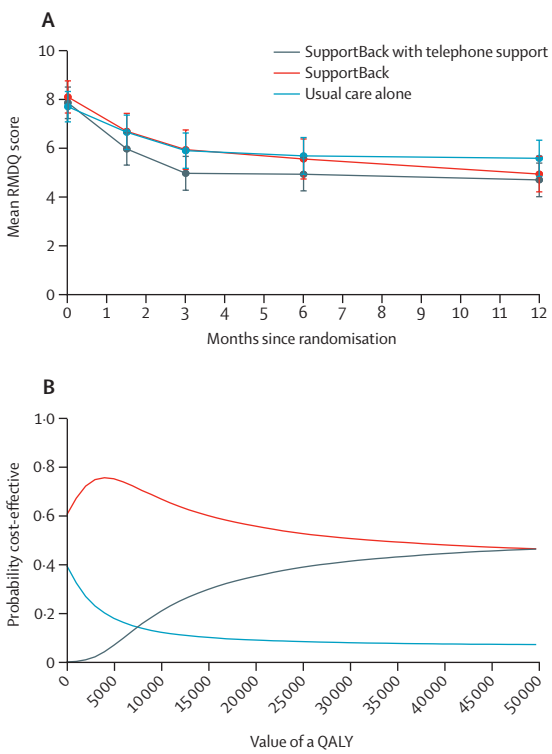

Figure 2: **RMDQ score over 12 months (A) and cost-effectiveness acceptability curve of each intervention at different valuations of a QALY (B)**
RMDQ=Roland Morris Disability Questionnaire. QALY=quality adjusted life year.

50·5%, adjusted OR 1·5 [1·0–2·3]). This corresponds to a number needed to treat of 10 (95% CI 6–82) in the SupportBack group and a number needed to treat of 10 (5–72) in the SupportBack with telephone-support group. In sensitivity analyses for the primary outcome, an adherence adjusted analysis gave complier average causal effect estimates slightly larger than the intention-to-treat estimates, that were not significantly different between intervention groups on the RMDQ at a significance level of 0·025 (SupportBack *vs* usual care –0·8 [97·5% CI –1·7 to 0·1], p=0·049; SupportBack with telephone-support *vs* usual care –0·7 [–1·6 to 0·1], p=0·050). Additional sensitivity analyses for missing data, using both imputed data with the assumption of missingness at random, along with assuming missing RMDQ scores were on average 1·5 points better or worse than those observed led to similar estimates as the primary outcome analysis. Assuming missing RMDQ outcome data were on average 1·5 points worse than the observed data reduced the estimates slightly. Assuming missing RMDQ outcome data were on average 1·5 points better than observed data increased the estimate slightly (appendix p 5). Pre-specified subgroup analyses by STarT Back risk group and pain duration at baseline did not show statistically significant treatment effects for the SupportBack interventions versus usual care (appendix p 4). Supplementary quantitative analysis did not show differences in RMDQ scores before or after the COVID-19 pandemic onset (appendix p 7).

There were seven unrelated serious adverse events reported during the trial; three in the usual care group, one in the SupportBack group, and three in the SupportBack with telephone-support group (table 3). These serious adverse events included an unrelated death in the SupportBack with telephone-support group. 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 and 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).

In the economic evaluation, we found that costs in the 3 months before recruitment were very similar between study groups, and were £38 per person for the usual care alone and SupportBack plus telephone-support group and £41 per person for the SupportBack group. Total back pain-related costs in the follow-up period were

£178 (with usual care alone), £182 (with SupportBack), and £280 (with SupportBack with telephone-support). Important drivers of cost were inpatient stays, outpatient visits, and physiotherapy-related costs. These values include the costs of the intervention, which was £16 per person for the SupportBack intervention and £45 per person for telephone support (a total of £61 per person for SupportBack with telephone support). A breakdown of costs by category for low back pain-related costs are in the appendix (pp 12–14).

Using EQ-5D-5L scores at baseline, 6 weeks, and 12 months, we obtained QALY estimates for 607 (74%) of all 825 participants (212 with usual care alone, 192 with SupportBack, and 203 with SupportBack with telephone-support; appendix p 11). Using seemingly unrelated regression on an imputed data set, both the cost-per-QALY and the cost-per-point improvement in RMDQ analyses show that the SupportBack group dominated usual care, this means they were both more effective and less costly than usual care alone (table 4). Both SupportBack interventions show small gains in QALYs and small cost differences compared to usual care alone. For the SupportBack with telephone-support group it was estimated that this intervention gives an additional cost per QALY of £54529 when compared with the SupportBack group. However, if SupportBack alone was unavailable, SupportBack with telephone-support would cost £7366 per additional QALY when compared with usual care, again meeting cost-effectiveness thresholds. For change in RMDQ the SupportBack with telephone-support group is dominated by SupportBack. Figure 2 provides cost-effectiveness acceptability curves for the three intervention groups, showing the probability that each intervention is cost-effective at various values of a QALY. SupportBack without telephone-support is the most likely to be cost-effective at each QALY value below £50000 per QALY. The usual care group is only estimated to be the most cost-effective intervention in less than 10% of cases between the values of £20000 to £30000 per QALY, indicating that providing SupportBack would likely represent a good use of health-care resources compared with usual care.

	Usual care alone (N=274)	SupportBack (N=275)	SupportBack and telephone support (N=276)
Serious adverse events*			
Left inferior pubic rami fracture and left clavicle fracture	1 (<1%)	0	0
Prostatectomy	0	0	1 (<1%)
Fracture to right ankle	1 (<1%)	0	0
L3/L4 foraminal compression	1 (<1%)	0	0
Lumbar microdiscectomy for L5-SI disc prolapse and nerve root compression	0	0	1 (<1%)
COVID-19 pneumonitis	0	1 (<1%)	0
Death	0	0	1 (<1%)
Non-serious adverse events			
Non-serious operations	0	2 (1%)	3 (1%)
Back pain following car accident	0	1 (<1%)	0
Leg pain	0	0	1 (<1%)

*All serious adverse events were deemed unrelated to the intervention.

Table 3: **Adverse events**

	Incremental cost	Change	ICER
Base-case: Imputed analysis - Cost/QALY (low back pain costs only)			
SupportBack	–£16 (–128 to 95)	QALY gain: 0·011 (–0·0014 to 0·039)	Dominates
SupportBack and telephone support	£96 (–14 to 206)	QALY gain: 0·013 (–0·011 to 0·037)	£54529*
Imputed analysis - Cost per change in RMDQ (low back pain costs only)			
SupportBack	–£16 (–128 to 95)	Change in RMDQ score†: 0·94 (0·18 to 1·71)	Dominates
SupportBack and telephone support	£96 (–14 to 206)	Change in RMDQ score†: 0·57 (–0·22 to 1·36)	Dominated by SupportBack group

Imputed analysis includes full trial sample. ICER=incremental cost-effectiveness ratio. RMDQ=Roland and Morris Disability Questionnaire. QALY=quality adjusted life years. *ICER here is presented compared with the SupportBack group. When compared with the control group the ICER was £7336. †As reductions in the RMDQ represent improvements the sign on difference between follow-up and baseline has been changed to represent this as an improvement.

Table 4: **Cost per QALY and cost per point improvement in RMDQ**

Discussion

The addition of the SupportBack intervention, with or without physiotherapist telephone-support did not significantly reduce low back pain-related disability compared with usual care alone over 12 months. The mean reductions in RMDQ on the primary outcome ranged from –0·5 to –0·7, smaller between-group differences than our pre-specified minimally clinically important difference of –1·5. The secondary and additional analyses showed a mixed pattern of results; although some secondary outcomes favoured either of the SupportBack interventions, the majority did not. There were no serious adverse events related to the interventions. In the cost-effectiveness analyses, the SupportBack intervention without telephone-support dominated, being both less costly and more effective than usual primary care. Both interventions, when compared with usual primary care were likely to be cost-effective at a QALY threshold of £20000.

It is not uncommon in trials to find a non-significant primary outcome together with evidence of cost-effectiveness.[30] Raftery and colleagues[30] stress the importance of plausibility when considering an intervention where the primary outcome (usually a clinical outcome) and cost-effectiveness findings differ. It might at least be plausible to favour the SupportBack interventions when considering the pattern across the secondary or additional outcomes that did significantly favour the interventions compared with usual care (eg, differences in the RMDQ at 6 weeks and 12 months,

greater percentage of patients reaching the minimally clinically important difference at 12 months, fewer troublesome days in pain per month, and reductions in kinesophobia). Additionally, the reduction in disability (RMDQ) following the SupportBack intervention is similar to the reduction in disability in a recent large trial of an app-based self-management intervention for low back pain (SelfBack);[12] Sandal and colleagues[12] reported a reduction of –0·79 on the RMDQ compared with usual care at 3 months, which did meet their threshold for statistical significance. Ultimately, interpretation of complex intervention trials with mixed outcomes requires balancing clinical effectiveness, cost-effectiveness, and safety findings along with the likely accessibility and availability of the interventions.[31] Conclusions are likely to differ depending on the weight attributed to these aspects.

The patterns in the reductions in disability over time differed for the two SupportBack interventions. Although the small reductions in disability following the offer of SupportBack with physiotherapist-telephone support occurred up to 3 months and were then maintained, the reductions following the SupportBack intervention appeared to occur more gradually, diverging from reductions seen in usual care between 6 and 12 months. These findings also reinforce the conclusions for the economic analysis, for if there are benefits that persist after the 12-month follow-up period then the current analysis could understate total long-term effects and hence cost-effectiveness. However, this would be difficult to quantify as it is not clear how long differences would persist for. Finding longer-term benefit following unguided self-management interventions is consistent with findings from a similar behavioural self-management intervention for chronic dizziness.[32] It is possible that the unsupported, ongoing application of the activity-based strategies leads to more gradual improvement, compared with steeper improvements that might occur initially with greater reassurance and motivational support from a physiotherapist. Adherence to the internet intervention also differed between intervention groups, with greater adherence in the supported intervention. However, average use of the SupportBack website was relatively low in both groups. Interpreting usage data for digital interventions is complex, as the relationship between use and impact is often non-linear.[33] Qualitative process analyses (that will be published separately) suggest that some who used the SupportBack internet intervention infrequently, still engaged regularly with activity suggestions in their day-to-day lives.

This trial has several strengths. We took a pragmatic approach to eligibility by including patients with acute, chronic, and recurrent low back pain reflecting the range of presentations in primary care. To increase external validity, we did not set lower limits on disability scales for eligibility; we wanted to evaluate this approach in all primary care consulters with low back pain, rather than a more select, severe group of people with low back pain with high pain interference, as we believe that this type of internet intervention would be most likely offered to all primary care consulters with low back pain in the future. We used a conservative primary outcome of low back pain-related disability over time, including data from 6 weeks, and 3, 6, and 12 months in the repeated measures model. To our knowledge, SupportBack 2 is one of the first large-scale trials of a digital intervention for low back pain to include a health economic evaluation. The weaknesses of the trial include a relatively low (7%) invitation to randomisation rate; although this is common in primary care trials using similar recruitment strategies.[32] The study participants were predominately White, and ethnicity data were limited as they were collected post-randomisation (78% of participants provided ethnicity data). Study participants were generally older, with a reasonably high proportion of retirees (29%). Aligning with the increasing prevalence of low back pain with older age,[1] our particpants were older adults who were also internet users. Internet access and use is lower in older populations (although use is growing).[34] Therefore, if SupportBack were to be offered more generally, the wider economic impact might vary while access and use of the internet in older adults continues to grow. The COVID-19 pandemic began during this trial. The remote delivery of the intervention allowed us to continue the trial.

Future research should focus on improving the effectiveness of highly accessible digital interventions for low back pain. Our process evaluation focusing on mechanisms will be published separately. Such mechanistic analyses will be important for determining necessary amendments to improve effectiveness.

To conclude, adding the SupportBack internet intervention, with or without physiotherapist-telephone support to usual care, did not significantly reduce low back pain-related disability compared with usual care alone over 12 months. The internet interventions were safe and likely to be cost-effective compared with usual care alone. SupportBack without support is simple to deliver. Clinicians will need to balance these mixed findings in light of the high prevalence of low back pain and currently limited access to behavioural support in primary care.

Contributors

AWAG, PL, LY, LCR, JCH, NEF, EH, BS, DAT, and GG conceived the trial. AWAG, PL, LCR, JCH, NEF, LY, EH, BS, DAT, and GG secured funding for the trial. AWAG led the development of the internet intervention with LY and LR, with further input from NEF, JCH, EH, PL, LY, AWAG, LCR, JCH, and NEF developed the physiotherapy telephone support package. FW, LD, AM, SH, SB, SB-W, and SW managed and coordinated all aspects of the trial and data acquisition, with oversight from AWAG, PL, LCR, JCH, NEF, LY, EH, BS, DAT, and GG. BS wrote the statistical analysis plan with input from AWAG, PL, LCR, JCH, NEF, LY, EH, and GM. DT wrote the health economic plan with input from AWAG and NEF. TB conducted the statistical analysis, and drafted statistical aspects of the paper with input from BS. TB and BS have

directly accessed and verified the underlying data reported in this manuscript. DAT conducted the economic analysis and drafted the health economic sections of the paper. MW and FD are public contributors who have contributed substantially to resolving trial issues and interpretation of the data. AWAG drafted the manuscript with revision and input from PL, JCH, NEF, LCR, DAT, EH, GG, FW, LD, AM, SH, SB, SB-W, SW, BS, MW, FD, and GM. AWAG is the guarantor. All authors were permitted access to all the data in the study and all authors accept responsibility to submit the manuscript for publication.

Declaration of interests

LCR reports an educational grant from Pfizer held by their institute; consulting fees from the Musculoskeletal Association of Chartered Physiotherapists; and meeting support from Eurospine. All other authors declare no competing interests.

Data sharing

Individual participant data will be made available, including data dictionaries, for approved data sharing requests. Individual participant data will be shared that underlie the results reported in this article, after deidentification and normalisation of information (text, tables, figures, and appendices). Anonymised data will be available beginning 3 months after and ending 10 years after publication of this article to researchers who provide a completed Data Sharing Agreement that describes a methodologically sound proposal for the purpose of the approved proposal. Proposals should be directed to ctu@soton.ac.uk. Data will be shared once all relevant parties approve and sign the Data Sharing Agreement. Data sharing requests are available for 10 years via the Southampton Clinical Trials Unit website.

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