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Using an internet intervention to support self-management of low back pain in primary care: Findings from a randomised controlled feasibility trial (SupportBack)

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ABSTRACT

Objective: To determine the feasibility of a randomised controlled trial of an internet intervention for low back pain (LBP) delivered in addition to usual primary care as: a) a stand-alone intervention, or b) with physiotherapist telephone support, compared to usual primary care.

Design and setting: A three-armed, single centre, randomised controlled feasibility trial conducted in 12 general practices in England.

Participants: Primary care patients aged over 18, with current LBP, access to the internet, and without indicators of serious spinal pathology or systemic illness.

Interventions: The 'SupportBack' internet intervention delivers a 6-week, tailored programme, focused on graded goal setting, self-monitoring, and provision of tailored feedback to encourage physical activity. Additional physiotherapist telephone support consisted of three brief telephone calls over a 4-week period, to address any concerns and provide reassurance.

Outcomes: The primary outcomes were the feasibility of the trial design including recruitment, adherence and retention at follow-up. Exploratory analyses were conducted on clinical outcomes including LBP-related disability at 3 months follow-up.

Results: 87 patients with LBP were recruited (target 60-90) within the trial timeframe, and there were 3 withdrawals. Adherence to the intervention was higher in the physiotherapist-supported arm, compared to the stand-alone internet intervention. Trial physiotherapists adhered to the support protocol. Overall follow-up rate on key clinical outcomes at three months follow-up was 84%. Exploratory analysis of LBP-related disability (Roland and Morris Disability Questionnaire (RMDQ)) at 3 months indicated that patients receiving the stand-alone internet intervention in addition to usual care improved by 0.6 RMDQ points more than usual care alone. Patients receiving the internet intervention plus physiotherapist telephone support improved by 2.4 points more than usual care.

Conclusions: This study demonstrated the feasibility of a future definitive randomised controlled trial to determine the clinical and cost effectiveness of the SupportBack intervention in primary care patients with LBP.

Trial registration: ISRCTN 31034004

Key words: Low back pain; internet intervention; self-management; primary care

STRENGHTS AND LIMITATIONS OF THIS STUDY

- This is the first feasibility trial examining an internet intervention specifically designed for patients with LBP consulting in general practice.
- This trial demonstrates that it is feasible to recruit and retain patients with LBP into a trial of low intensity interventions of internet-based and telephone support.
- Patients recruited into the trial had less severe symptoms than previous trials of interventions for LBP in primary care.
- The measure used to capture physical activity returned unreliable data, and needs to be modified for the future definitive trial.

BACKGROUND

Low back pain (LBP) causes more global disability than any other condition,[1] and has a lifetime prevalence of up to 85%.[2] The economic costs of LBP have been reported at £12.3 billion per annum in the UK alone.[3] In those who consult in primary care, pain trajectories often remain stable, with patients who report persistent-mild to persistent-severe pain, often remaining in the same pain grouping at 7-year follow-up.[3] Chronic LBP, with a prevalence of 3-10%,[4] is associated with depression, anxiety, deactivation, inability to work and substantial societal costs.[2, 5]

The recently updated National Institute for Health and Care Excellence (NICE) guidelines for managing LBP continue to state the importance of self-management and advice to remain active.[6] Identifying effective means to support behavioural self-management is becoming increasingly important; a recent review questioned the effectiveness of paracetamol for spinal pain,[7, 8] and concerns continue to grow regarding the adverse effects of prescriptions for opioid-related painkillers.[9] In primary care, General Practitioners (GPs) are unlikely to have the time or the training to deliver effective self-management support, and access to NHS services such as physiotherapy are often limited, with long waiting times for patients.[10] There is a critical need for novel interventions enabling primary care practitioners to provide their LBP patients with immediate access to evidence-based, accessible self-management advice and support.

Internet interventions are automated, structured programmes delivering tailored advice over time through text and audio-visual content.[11] They differ from simple health information webpages, which in the case of LBP are abundant and often of low quality.[12] Internet interventions may offer a useful resource for primary care practitioners to draw on. Research on internet interventions for LBP is at an early stage: A recent systematic review of nine randomised controlled trials (RCTs) of internet interventions for chronic LBP [13] concluded that despite showing some promise, many of the trials were limited by small samples sizes,[14, 15] comparisons to waiting lists or no treatment controls,[16] and researchers rarely considered healthcare resource use,[13] To our knowledge, there have been no trials of internet interventions developed specifically for patients with LBP consulting in primary care. As primary care practitioners see the full spectrum of patients with LBP, ideal interventions for this context would offer effective self-management advice for those with acute, recurrent and chronic presentations, facilitating simple implementation.

'SupportBack' is an internet intervention specifically developed by our team for patients with LBP consulting in primary care using a theory-, evidence- and person-based approach.[17] Its central focus in enabling people to manage their LBP, is to support appropriate engagement in physical activity. It is also designed to contain simple advice and behaviour change support/techniques for a range of clinical presentations (e.g. acute or subacute) through effective reassurance for common concerns (such as the misconception, hurt equals harm), as well as providing elements that those with more chronic LBP may find helpful (e.g. managing low mood, fear-avoidance, challenges with work, and poor sleep). Brief additional human support often improves outcomes when added to internet interventions [18] and SupportBack has been designed to be delivered either as a stand-alone intervention, or with additional brief telephone support from a physiotherapist.

In order to determine the effectiveness of digital approaches such as SupportBack, pragmatic trials are required that examine these interventions in addition to, and compared to, usual primary care for LBP. The aim of this study was to explore the feasibility of delivering the SupportBack intervention in addition to usual care to patients with LBP consulting in general practice, with or without brief physiotherapist telephone support, compared to usual care alone. We aimed to explore the feasibility of RCT procedures, alongside the acceptability, uptake and use of the interventions, in order to inform a future full trial.

METHOD

Design

We conducted a three-parallel arm, single centre feasibility RCT of the SupportBack internet intervention for LBP in primary care. The full details of the method and interventions can be found in the published trial protocol.[17]

Participants

Patients were included in the trial if they had current LBP (experienced pain within the last two weeks); had access to the internet; had consulted their general practice with LBP within the last 6 months; could read/understand English without assistance. Patients were excluded if they were under 18 years of age; had clinical indicators of (suspected) spinal pathology such as infection, fracture or cancer; or had taken part in

an earlier study to develop the intervention. Pregnancy was added to the exclusion criteria after the trial had begun.

Recruitment

The local Clinical Research Network (CRN) facilitated recruitment of general practices. Within practices, potentially eligible patients were identified by searching computerised lists of LBP consultations from the last 6 months. The resulting lists were screened by a practice GP who excluded patients who did not fulfil the eligibility criteria as determined from patients' notes. Practice staff sent out study packs to the remaining patients containing options for interested patients to contact the research team. Study packs were also provided to practices for opportunistic recruitment within LBP consultations. Interested patients who contacted the research team underwent a secondary telephone screen by a study manager, who asked about their current LBP and screened a list of 12 key symptoms that may indicate serious spinal pathology or systemic illness (see [17]). Patients answering yes to any symptoms were discussed with a clinician in the research team and referred back to their GP where appropriate. Those patients who remained eligible were sent a link to the study website, where they provided online consent, completed all baseline measures and were then randomised to one of the three trial arms. Recruitment opened in February 2015 and closed in September 2015. The follow-up period ended in January 2016.

Interventions

Usual care:

Those patients allocated to this arm continued to receive usual care for their LBP over the trial period. This care was unrestricted and could vary substantially; for example, patients who did not re-consult at their general practice may not have received care beyond their initial consultation, whereas others may have accessed a range of treatment including physiotherapy or pain clinics.

Internet intervention plus usual care:

Patients allocated to the internet intervention arm continued to receive unrestricted usual care for LBP. In addition, patients received access to SupportBack, a tailored multi-session internet intervention designed to support self-management of LBP, developed by our team using LifeGuide software (www.lifeguideonline.org). SupportBack has been described in more detail elsewhere.[17] In brief, the intervention focuses on self-regulatory processes including goal setting, self-monitoring and tailored feedback to support physical activity. There is also a focus on cognitive reassurance

and self-efficacy for activity in the presence of pain throughout; addressing concerns with evidence-based feedback and modelling success through patient activity stories. SupportBack was developed using the Person-Based Approach [19] incorporating systematic, in-depth, qualitative research with 22 patients and community volunteers with experience of LBP.

The intervention has six sessions, and it was recommended that patients complete one session per week for six weeks. The first session introduces the rationale for physical activity being key in the self-management of LBP and allows patients to select goals for the next week. Goals options, including gentle back exercises or walking, are automatically tailored, based on how patients report their LBP is affecting their functioning at the time. Each of the following five sessions consists of patients reviewing and amending their activity goals for the coming week with automatic feedback. From session two onwards, after the goal review, patients have access to one new module per week from the SupportBack menu. The modules on the menu focus on a broad range of LBP related topics including: mood; managing pain at work; sleep; relieving pain through medication and dealing with flare-ups. Patients used SupportBack without support from a health professional in this arm of the trial. They received automated weekly email reminders to log in, and any technical difficulties were addressed by the study manager. Patients were able to access the SupportBack internet intervention at any time over the trial period and from wherever was most convenient.

Internet intervention plus physiotherapist telephone support plus usual care:
Patients in this arm continued to receive unrestricted usual care for LBP and had access to the SupportBack intervention as above. In addition, those in this arm received up to a total of 1 hour of physiotherapist telephone support, split into 3 calls, with approximately 30 minutes for call 1, and 15 minutes for calls 2 and 3. The calls were designed to be delivered approximately after week 1, between weeks 2-3 and after week 4. The purpose of the physiotherapists' calls was to provide support and encouragement to participants to use the SupportBack internet intervention, to address participants' concerns and provide additional reassurance. Two senior musculoskeletal physiotherapists (male and female, NHS Bands 6 and 7) provided the telephone support. They worked through a standardised checklist for each phone call (available on request from the corresponding author), and although they were able to address individual patient concerns, they were asked not to provide additional recommendations beyond the content of the internet intervention. Their fidelity to the

study protocol was evaluated by audio-recording a sample of 20 telephone consultations.

Outcomes and measures

The primary outcomes for this trial were descriptive, focusing on the feasibility of the trial design and intervention delivery, including: recruitment of general practices; recruitment of patients within the allocated timeframe of the trial; suitability of eligibility and screening criteria; withdrawals and retention at follow-up at 3 months; usage of the internet intervention and self-reported activity adherence; delivery and uptake of the telephone support along with any significant issues encountered.

The success criteria for the feasibility trial, as published in the protocol,[17] are listed below:

- *Recruiting a minimum of 60 patients with LBP, access to the internet and without indicators of serious spinal pathology from primary care within the allotted recruitment time period for the trial*.
- *Attrition at 3 months follow-up should be equal to or lower than 30% from all trial arms.*
- *By examining the recordings, the telephone support physiotherapists are able to deliver the telephone sessions in line with the protocol, covering approximately 2/3 of the checklist in each call.*
- *Patients should be able to access the intervention and complete measures, complete session 1 and set goals for future sessions.*
- *Qualitative and quantitative data should indicate that the intervention and trial procedures are acceptable to patients.*

All self-reported measures were collected online using LifeGuide software at baseline. At 3 months post-randomisation, measures were primarily collected online, non-response triggered additional follow-up methods including email reminders, paper questionnaires being posted, and a telephone call from a blinded independent research assistant to collect key outcomes only. Demographic data collected included gender, age, education, occupation, income and marital status. A range of LBP-related measures were collected: LBP-related physical disability was measured using the Roland and Morris Disability Questionnaire (RMDQ [20]), an outcome likely to be a primary outcome in a future full trial; pain duration was measured by asking about time

since the last pain free month;[21] pain intensity was measured using three numerical rating scales (NRS) measuring current, average and least pain over the last two weeks as well as a mean of the 3 as a pain index;[22] number of troublesome days in pain over the last month was measured with a single item;[23] risk of persistent disability was measured using the STarT Back tool;[22] fear of movement was measured using the Tampa Scale for Kinesiophobia (TSK, [24]); catastrophising beliefs were measured using the Pain Catastrophising Scale (PCS, [25]). Self-reported physical activity was measured using the International Physical Activity Questionnaire Short Form (IPAQ-SF),[26]) and questions about numbers of weeks, and times per week people did specific activities or went walking to help their back pain were asked at 3 months follow-up.

Adherence to the internet intervention was examined by using LifeGuide-generated data on SupportBack sessions started and completed. Psychological process variables including patients' expectations of positive outcome were measured using a modified brief Credibility and Expectancy Questionnaire (CEQ) [27] at baseline across all arms, and the full CEQ was completed after session one in the two internet intervention arms. Exercise self-efficacy was also measured after session one in the two internet intervention arms.[28, 29] The Problematic Experiences of Therapy Scale (PETS, [30]) was used to measure difficulties with adherence to recommended exercises.

To determine the feasibility of collecting health economic measures for a cost effectiveness analysis in a future full trial, a GP notes review was conducted and health-related quality of life was measured using the EQ-5D 3L.[31] Resource use was costed using published sources of unit cost data.[32, 33] Identified resource use was costed using 2014/15 UK pound sterling.

Sample size

The target for this trial was to recruit between 60-90 patients overall, with 20-30 per arm. Guidance for sample size in feasibility trials varies with numbers ranging from 12-30+ per arm.[34, 35] A sample of not less than 60 overall allowed for the assessment of the primary feasibility outcomes including recruitment, adherence and retention.

Randomisation and blinding

Randomisation was fully automated by the internet intervention software (LifeGuide). The randomisation sequence was generated within the software and concealed from the trial team. An automated algorithm block randomised patients to the three trial arms.

Patients were stratified by severity of physical disability (measured by the RMDQ ≥ 7). Patients were notified of their allocated arm automatically by the LifeGuide software. Due to the behavioural nature of the intervention, it was not possible to blind patients to interventions. The study manager allocated patients to physiotherapists and therefore was not blind to allocation. All telephone outcome data were collected by an independent blinded research assistant. The trial statistician remained blind until the analysis was finalised.

Nested qualitative study

A nested qualitative study was undertaken to explore patients' perceptions of the intervention conditions and taking part in the trial more generally. Both trial physiotherapists that provided the telephone support were also interviewed. The qualitative results of this trial will be reported elsewhere.

Analysis

The primary analysis for this trial focused on a description of the key feasibility outcomes including numbers of general practices recruited; patient eligibility and recruitment rates; withdrawals; response to follow-up at 3 months. Use of the internet intervention was described by reporting numbers of sessions started and completed per arm. Delivery of physiotherapist telephone support was described in terms of the number of calls successfully made and mean/modal calls per patient.

Exploratory quantitative analyses were conducted on patients' clinical, activity and psychological process measures. Descriptive statistics were used to identify any floor or ceiling effects. Means and/or medians, standard deviations and 95% confidence intervals were reported for the measures. Linear regression models, controlling for baseline covariates (each outcome at baseline, gender, age, marital status, employment status, income, ethnicity and age left education), were used to explore between group differences in continuous outcome measures and logistic regression models were used for binary outcome measures. The analysis was undertaken on an intention to treat basis, analysing participants in the group to which they had been randomised, and comprised complete cases only. Correlations were used to explore the relationship between psychological process measures such as expectancy and exercise self-efficacy on LBP-related disability and adherence to physical activity.

RESULTS

Recruitment and retention

The CRN received expressions of interest to take part in the trial from 27 practices, of which 4 were initially approached and recruited, this was increased to 12 following close monitoring of initial recruitment rates. 1263 trial invitation letters were sent from the 12 participating practices to potentially eligible patients. 160 responses were received. Of these, 87 patients with LBP met the eligibility criteria after further telephone screening and were randomised over a 6-month period. This translated to a recruitment rate of 14-15 patients per month, and approximately 7 patients randomised per practice over a total of 6 months. Three patients withdrew over the course of the trial: 1 from the internet intervention plus usual care arm (no reason given), 2 from the internet intervention plus physiotherapist support arm (1. due to illness, 2. due to family bereavement). The overall follow-up rate for the key clinical outcomes was 84% (73/87) at 3 months, and varied between arms: usual care = 93%, internet intervention plus usual care = 83%, internet intervention plus physiotherapist support = 76%. See Figure 1 for patient flow through the trial.

[INSERT FIGURE 1 ABOUT HERE]

Patient characteristics

Eighty-four participants provided baseline data. Table 1 shows participant characteristics across the three trial arms. Demographic characteristics were generally similar across the arms, with some exceptions including greater numbers of retired participants in the usual care alone arm. With regard to clinical variables at baseline, LBP-related disability (measured by the RMDQ) was similar across arms. Taken together, the RMDQ, pain numerical rating scales and STarT back scores indicate slightly higher severity in those randomised to the internet intervention plus physiotherapist support arm. Pain duration, measured as time since last pain free month, was similar across arms. Number of troublesome days in pain over the last four weeks differed substantially; from a median of 10 in the usual care alone arm to 18 in the internet intervention plus physiotherapist support arm.

Table 1. Baseline characteristics

Variable	Usual care (n=27)	Internet intervention plus usual care (n=29)	Internet intervention plus physiotherapist support (n=27)
Female	15 (55.6%)	19 (65.2%)	17 (63.0%)
Age	60.3 (16.3)	54.5 (13.7)	59.3 (10.4)
Marital Status			
- Married/partner	23 (85.2%)	19 (65.5%)	22 (81.5%)
- Single	3 (11.1%)	4 (13.8%)	2 (7.4%)
- Divorced/separated	0	5 (17.2%)	1 (3.7%)
- Widow/widower	1 (3.6%)	1 (3.6%)	2 (7.4%)
White ethnicity	27 (100%)	26 (92.9%)	27 (100%)
Age left education	17.6 (2.7)	17.3 (1.7)	17.6 (2.8)
Employment status			
- Full time	7 (25.9%)	12(41.8%)	6 (22.2%)
- Part time	2 (7.4%)	4 (13.8%)	8 (29.6%)
- Retired	13 (48.2%)	6 (20.7%)	8 (29.6%)
- Self-employed	2 (7.4%)	3 (10.3%)	4 (14.8%)
- Sickness/disability	2 (7.4%)	2 (6.9%)	1 (3.7%)
- Other	1 (3.7%)	2 (6.9%)	0
Annual income (up to £)			
- 10,000	2 (7.4%)	4 (14.3%)	3 (11.5%)
- 20,000	7 (25.9%)	6 (21.4%)	3 (11.5%)
- 40,000	9 (33.3%)	9 (32.1%)	10 (38.5%)
- > 40, 000	9 (33.3%)	9 (32.1%)	10 (38.5%)
Expectations re improvement in LBP	5.86 (1.88)	5.22 (2.06)	5.74 (2.19)
Expected percentage improvement in LBP (Item from the CEQ)	43.21% (25.53)	41.92% (21.17)	37.40% (25.50)
Median days of pain in the last 4 weeks (IQR) (Item from the CEQ)	10 (6, 25)	10 (4, 21)	18 (5, 28)
Time since you had a whole month without pain			
- Less than 3 months	5 (17.2%)	6 (21.4%)	5 (19.2%)
- 3-6 months	1 (3.5%)	2 (7.1%)	4 (15.4%)
- 7-12 months	5 (17.2%)	4 (14.3%)	6 (23.1%)
- 1-2 years	7 (24.1%)	4 (14.3%)	5 (19.2%)
- 3-5 years	4 (13.8%)	4 (14.3%)	3 (11.5%)
- 6-10 years	2 (6.9%)	4 (14.3%)	3 (11.5%)
- Over 10 years	5 (17.2%)	4 (14.3%)	0
LBP-related disability (RMDQ) mean (SD)	6.8 (4.9)	6.6 (4.6)	7.7 (4.7)
STarT Back risk group			
- Low	16 (57.1%)	19 (67.9%)	14 (51.9%)
- Medium	11 (39.3%)	6 (21.4%)	12 (44.4%)
- High	1 (3.8%)	3 (10.7%)	1 (3.7%)

Adherence outcomes

Table 2 shows the percentages of participants starting and completing sessions of the SupportBack internet intervention. Both the percentages starting and completing sessions tended to be higher in the internet intervention plus telephone support arm. For all sessions, those starting a session tended to complete it, with the exception of the internet intervention plus usual care arm in session 1. Overall, 11.1% (3/27) of those in the internet intervention plus telephone support arm and 29.6% (8/27) of patients in the internet intervention plus usual care arm partially completed session 1 and did not return to the internet intervention over the duration of the trial.

At follow-up, participants were also asked about activities they engaged with to help their LBP (walking or back exercises). All participants provided this data, serving as an indication of self-reported activity adherence in the internet intervention arms, and providing data about levels of activity in the usual care alone arm. The responses are tabulated in Table 3. Most participants regardless of arm allocation reported spending 9-12 weeks going for walks or doing back exercises and did so regularly (4+ days per week).

Table 2. Percentages starting (S) and completing (C) internet intervention sessions (SS)

	S SS1	**C SS1**	**S SS2**	**C SS2**	**S SS3**	**C SS3**	**S SS4**	**C SS4**	**S SS5**	**C SS5**	**S SS6**	**C SS6**
Int. interven*	89%	54%	61%	57%	54%	50%	46%	43%	36%	36%	32%	32%
Int. interven+ support**	82%	70%	85%	70%	82%	78%	59%	56%	48%	48%	41%	41%

* Internet intervention plus usual care
** Internet intervention plus physiotherapist support

Table 3. Tabulation of self-reported LBP-related activities

	Usual care alone (n=14)	**Internet intervention plus usual care (n=16)**	**Internet intervention plus telephone support (n=19)**
How many weeks spent doing back exercises or going for walks?			
• Never started	2 (14.3%)	0	0
• 1 week	0	0	0
• 1-2 weeks	0	1 (6.3%)	1 (5.3%)
• 3-5 weeks	3 (21.4%)	6 (37.5%)	4 (21.1%)
• 6-8 weeks	1 (7.1%)	2 (12.5%)	5 (26.3%)
• 9-12 weeks	8 (57.1%)	7 (43.7%)	9 (47.4%)
How many times a week did you do back exercises or go for walks?			
• Never started	2 (14.3%)	0	0
• 1 day	1 (7.1%)	2 (12.5%)	1 (5.3%)
• 2-3 days	2 (14.3%)	5 (31.3%)	2 (10.5%)
• 4-5 days	5 (35.7%)	4 (25.0%)	7 (36.8%)
• Every day	4 (28.6%)	5 (31.3%)	9 (47.4%)
Did you stop because you no longer experienced pain			
• Yes	3 (21.4%)	1 (6.3%)	1 (5.3%)

Note. Numbers are lower as these variables were not part of minimum data collection over the telephone at 3 months follow-up with telephone follow-up

Physiotherapist telephone support

Support telephone calls were made to 25/29 (86%) participants who were randomised to this arm. For those that did not receive calls, 3 participants were uncontactable despite multiple call attempts made by the physiotherapists (2 of 3 continued to use the internet intervention alone), and 1 participant was not allocated a physiotherapist due to an administrative error. This was discovered at the end of the trial through the qualitative interview with this participant. This individual continued to use the internet intervention alone.

For the 25 patients receiving physiotherapist support calls, the mean number of calls made was 2.4 (*SD* = 1.03, mode = 3). Mean call durations were 17.3 minutes (*SD* = 8.5) for call 1, and 11.5 (*SD* = 6.2) and 11.9 (*SD* = 6.2) minutes for calls 2 and 3 respectively. From the 65 connected calls made, a random sample of 20 calls (30%) were selected to examine fidelity using verbatim transcripts of the calls and physiotherapist completed call check sheets. At least two thirds of the recommended topics were covered in 19 of the calls checked (95%).

Clinical outcomes/measures

Mean physical disability measured by RMDQ score, was 6.9 *(SD* = 5.5) across the trial arms at baseline. From the 84 participants who provided RMDQ data at baseline, 73 (84%) provided a response at 3 months follow-up. Of these, 27 (34.2%) were contacted by telephone or completed a paper questionnaire follow-up pack. Exploratory analysis of RMDQ scores showed, on average, participants in all three arms improved between baseline and follow-up (see Table 4). The internet intervention plus usual care arm improved by 0.6 points more than usual care alone, whilst the internet intervention plus physiotherapist support support arm improved by 2.4 points, after controlling for baseline score and covariates. When those with a lower RMDQ at baseline (< 4) were excluded, the results remained similar with participants allocated to the internet intervention plus usual care improving by 0.4, and those allocated to internet intervention plus physiotherapist support improving by 2.0 more than usual care alone on the RMDQ. A minimal clinically important difference (MCID) was classified as a reduction of 2 points on the RMDQ compared to usual care alone.[36] The proportions achieving this MCID were higher in the internet intervention plus physiotherapist support arm (13/22, 59.1%), than the internet intervention plus usual care (8/26, 31.0%) and usual care alone (10/25, 40.0%) arms.

Table 4. Clinical and physical activity measures at baseline and follow-up.

	Baseline	**3 months follow-up**	**Difference at follow-up controlling for baseline**	**Difference at follow-up controlling for baseline and other covariates**
LBP related disability (RMDQ) (n=73)				
Usual care alone	6.8 (4.9)	6.3 (5.1)		
Internet intervention plus usual care	6.6 (4.6)	5.8 (4.5)	-0.71 (-2.77, 1.35)	-0.64 (-3.10, 1.83)
Internet intervention plus physiotherapist support	7.7 (4.7)	5.1 (5.1)	-1.34 (-3.49, 0.81)	-2.38 (-5.00, 0.25)
LBP related disability (RMDQ) - Excluding those with a score below 4 (n=51)				
Usual care alone	8.5 (4.3)	7.3 (5.4)		
Internet intervention plus usual care	9.0 (3.9)	7.4 (4.9)	-.03 (-2.73, 2.82)	-0.41 (-3.08, 3.11)
Internet intervention plus physiotherapist support	9.5 (3.6)	6.4 (5.4)	-0.80 (-3.64, 1.99)	-2.02 (-4.98, 0.94)
Pain intensity (NRS) – Index average (n=72)				
Usual care alone	3.76 (2.27)	3.63 (2.09)		
Internet intervention plus usual care	3.88 (1.97)	3.18 (2.24)	-0.76 (-1.60, 0.07)	-0.49 (-1.47, 0.49)
Internet intervention plus physiotherapist support	4.19 (2.18)	3.08 (2.02)	-0.66 (-1.53, 0.21)	-0.76 (-1.78, 0.25)
Pain intensity (NRS) 1 – current (n=72)				
Usual care alone	3.57 (3.06)	3.96 (2.45)		
Internet intervention plus usual care	4.00 (2.61)	3.60 (2.48)	-0.85 (-1.86, 0.16)	-0.63 (-1.82, 0.56)
Internet intervention plus physiotherapist support	4.52 (2.57)	3.10 (2.32)	-1.35 (-2.40, -0.29)	-1.02 (-2.25, 0.21)

Pain intensity (NRS) – least pain last 2 weeks (n=72)				
Usual care alone	3.18 (2.52)	2.81 (2.08)		
Internet intervention plus usual care	3.14 (2.09)	2.3 2.3094	-0.72 (-1.60, 0.16)	-0.59 (-1.46, 0.29)
Internet intervention plus physiotherapist support	2.89 (2.68)	2.29 (2.12)	-0.04 (-0.97, 0.89)	0.19 (-0.71, 1.08)
Pain intensity (NRS) – average last 2 weeks (n=72)				
Usual care alone	4.57 (2.03)	4.08 (2.13)		
Internet intervention plus usual care	4.50 (2.06)	3.64 (2.51)	-0.51 (-1.56; 0.54)	-0.39 (-1.54, 0.76)
Internet intervention plus physiotherapist support	5.15 (2.11)	3.43 (1.69)	-0.86 (-1.96, 0.25)	-0.82 (-2.07, 0.44)
Fear avoidance (TSK) (n=59)				
Usual care alone	37.75 (6.22)	35.04 (6.40)		
Internet intervention plus usual care	37.51 (7.44)	36.06 (8.12)	0.66 (-2.52, 3.84)	0.14 (-3.02, 3.29)
Internet intervention plus physiotherapist support	35.52 (6.83)	34.32 (7.47)	0.86 (-2.30, 4.02)	-0.56 (-3.65, 2.53)
Negative orientation towards pain (PCS) (n=57)				
Usual care alone	13.71 (12.79)	14.00 (11.36)		
Internet intervention plus usual care	13.53 (10.00)	12.83 (8.96)	-1.49 (-6.37, 3.40)	-3.48 (-9.70, 2.74)
Internet intervention plus physiotherapist support	13.59 (9.38)	18.63 (8.47)	4.16 (-0.58, 8.90)	3.74 (-1.78, 9.27)
Modified Enablement Scale (n=58)				
Usual care alone	26.50 (8.37)	27.86 (10.53)		
Internet intervention plus usual care	25.14 (8.48)	25.35 (9.66)	-1.98 (-8.51, 4.55)	-1.34 (-8.69, 6.01)

Internet intervention plus physiotherapist support	26.12 (7.84)	28.26 (9.31)	0.12 (-6.19, 6.43)	-0.27 (-6.63, 6.08)
Days in pain				
Usual care alone	10 (6, 25)	6 (2,20)		
Internet intervention plus usual care	10 (4,21)	4 (0,15)	-0.69 (-9.20, 7.87)	-1.60 (-10.36, 7.16)
Internet intervention plus physiotherapist support	18 (5, 28)	10 (3,20)	0.33 (-8.71, 9.38)	1.14 (-8.62, 10.90)
Physical activity (IPAQ)	**Median (IQR)**	**Median (IQR)**		
Usual care alone	3139.5 (466.1, 5385)	2277.5 (912, 6105)		
Internet intervention plus usual care	1178.5 (480, 4131)	1130.5 (693, 2826)	-64.92 (-2796.15, 2666.32)	331.82 (-2360.85, 3024.50)
Internet intervention plus physiotherapist support	3168 (396, 7413)	990 (396, 3226.5)	-668.04 (-3347.32, 2011.25)	-408.04 (-2757.56, 1941.50)

The STarT Back tool [22] was used at baseline and 3 months follow-up to describe the proportions of participants at low, medium, or high risk of persistent disability (see Table 5). There was an increase in the proportion of patients classed at low risk in both the internet intervention plus usual care (60% to 70%) and the internet intervention plus physiotherapist support arms (33% to 74%). The proportion of patients classified at high risk reduced to zero in the internet intervention plus physiotherapist support arm. There was little change in the risk proportions in the usual care alone arm from baseline to 3 months follow-up.

Additional pain-related measures are also shown in Table 4. There were small reductions in pain intensity (NRS) in all arms from baseline to 3 months, although greater change occurred in the internet intervention plus physiotherapist support arm in comparison with internet intervention plus usual care arm and usual care alone. There were small reductions in fear avoidance beliefs across all arms. With regard to pain catastrophising, there were small increases in the usual care alone arm and unexpectedly, in the internet intervention plus physiotherapist support arm (13.6 to 18.6). However, this finding should be interpreted with caution in light of small numbers and the norms for the PCS; a score of 20 is average on the PCS among those with

injury, a score of 30 is considered clinically relevant;[25] our sample had a mean of 13.6 suggesting low levels of catastrophising at baseline. Although caution is required with regard to the measure of troublesome days in pain, as it was not balanced across the arms at baseline, changes were in the expected direction: at 3 months, those in the internet intervention plus physiotherapist support arm reported 8 less days in pain, internet intervention plus usual care arm reported 6 less days in pain and those in usual care alone reported 2 less days in pain over the last 4 weeks. Finally, patient enablement showed small increases across all three arms.

Table 5. STarT Back subgroups at baseline and follow-up for all trial arms.

Arm	**Baseline**			**Follow up**		
	Low risk	Medium risk	High risk	Low risk	Medium risk	High risk
Usual care alone	15 (51.7%)	11 (37.9%)	3 (10.3%)	11 (47.8%)	10 (43.5%)	2 (8.7%)
Internet intervention plus usual care	17 (60.7%)	8 (28.6%)	3 (10.7%)	12 (70.6%)	3 (17.7%)	2 (11.8%)
Internet intervention plus physiotherapist support	9 (33.3%)	15 (55.6%)	3 (11.1%)	14 (73.7%)	5 (11.8%)	0

Physical activity

The IPAQ-SF data were converted to MET/mins per week and compared using medians, as the distribution of energy expenditure is known to be non-normal in many populations. Scores can be found in Table 4. The median at baseline for the sample was 2343 (IQR= 480, 5544). It is important to note that the American Heart Association recommends 450-750 MET/per week or approximately, moderate exercise for 30 minutes per day, 5 days a week.[37] A baseline median of 2343 is unexpected, and brings into question the reliability of this self-report measure of physical activity. The seeming reduction in exercise reported by the internet intervention plus physiotherapist support arm is also surprising. We advise considering these findings with caution.

Process variables for the full trial

An exploration of psychological process data collected after session one for those in the internet intervention arms revealed associations in the expected direction. 37 patients completed the Credibility and Expectancy Questionnaire (CEQ) and the

exercise self-efficacy questionnaire (ESE) (66%). There was a weak negative correlation between the CEQ score and the RMDQ score at follow up (r=-0.16), suggesting those with higher expectations regarding the internet interventions after session one reported a lower RMDQ score at 3 months. Although there was no association between ESE and RMDQ score at 3 months, there was a positive association between ESE and number of weeks spent engaging in back-related exercise reported at 3 months (r =.36). The Problematic Experiences of Therapy Scale (PETS) was completed by 67% (18) of patients in the internet intervention plus usual care and 70% (19) of the internet intervention plus physiotherapist support arm. The PETS is used to explore the relationship between its scores and quantitative adherence (both to the internet intervention and recommended exercises) data in large samples. As the numbers are small our main focus is on completion rates, which suggest the PETS is suitable for inclusion in a full trial.

Health economic outcomes

The hosting cost of providing access to SupportBack was assumed to be £12.50 per person, this based on predicted costs of server provision and website maintenance. Physiotherapist support was estimated at £38 per person. This gives a total intervention cost of £12.50 and £50.50 in the internet intervention plus usual care and internet intervention plus physiotherapist support arm respectively. NHS related costs were estimated from computer records in participating general practice for 79 participants where data were provided, see Table 6. These costs were recorded over the 3 month follow-up period. The total mean cost for all 79 participants was £270, of which £107 (43%) was related to back pain; indicating that use of NHS services were an important cost for this group of patients. Our sample showed 66% of total NHS costs and 78% of back pain related costs occurred in secondary care. Due to delays related to referring and attending secondary care appointments it is likely that costs would occur after the 3 month period used in this study. As this was a small-scale feasibility trial, there was considerable uncertainty caused by a small number of high cost items such as inpatient stays. A fully powered trial with longer follow-up will enable more accurate estimates of any cost differences that may exist between arms.

Two outcomes measures would be used in the economic evaluations alongside any future full trial; change in LBP-related disability (RMDQ) and the quality adjusted life year (QALY) evaluated using the EQ-5D 3L.[38] However, because of the variability in costs any estimates of cost-per point change in these measures would be subject to considerable uncertainty and so are not reported here. The EQ-5D was found to be

strongly negatively correlated with RMDQ at both baseline and follow-up, with respective Pearson correlations of -0.594 and -0.560 (ps<0.01). This provides some support for the use of the EQ-5D in a future full trial of SupportBack for LBP. For QALYs there were only 57 cases with baseline and follow-up data for the EQ-5D and 54 that also had cost data. This was lower than response rate for RMDQ and other clinical measures. The EQ-5D was one of the last questionnaires participants completed, additionally, it was not part of the minimum data-set collected by telephone at 3 months. The cost-effective analysis will form a critical component of a future full trial, thus in the full trial the EQ-5D will be collected after the RMDQ and included in the minimum data-set phone calls. A follow-up period of 3 months is likely to be insufficient to capture the full QALY effects of LBP and its treatment. In a full trial, follow-up will occur at regular intervals over a 12-month period.

Table 6. NHS costs (£, Mean (SD)) derived from computer records at participating general practices at 3 months follow-up

	Usual care alone (N=26)	Internet intervention plus usual care (N=28)	Internet intervention plus physiotherapist support (N=25)	All (excluding intervention costs) (N=79)
Intervention costs	0	12.5	50.5	
All NHS costs				
Primary Care costs*	96 (142)	85 (114)	108 (136)	96 (130)
Secondary Care - A&E	-	14 (42)	11 (53)	8 (39)
Secondary Care - O/P	116 (279)	48 (83)	87 (106)	83 (178)
Secondary Care - inpatient	59 (299)	129 (564)	101 (391)	97 (432)
Secondary Care Total	175 (490)	191 (586)	198 (483)	188 (517)
Total Costs	**271 (492)**	**289 (650)**	**357 (553)**	**284 (564)**
Back pain Costs Only				
Primary Care costs – back pain only	15 (40)	30 (73)	35 (75)	26 (64)
Secondary Care - A&E	-	-	11 (53)	3 (30)
Secondary Care - O/P	76 (251)	25 (62)	32 (69)	44 (153)
Secondary Care - inpatient	26 (132)	24 (129)	101 (391)	49 (244)
Secondary Care Total	102 (325)	50 (158)	143 (482)	96 (340)
Total Costs – Back pain only	**116 (327)**	**92 (178)**	**228 (535)**	**123 (367)**

* Primary care costs refer to GP consultations (at the surgery/home/phone.); practice nurse consultations (at the surgery/home/phone); use of other person in surgery (mainly phlebotomist); any other primary care related costs (walk in centre or phlebotomist); and costs of back pain relevant prescribing.

Harms

Six hospital admissions were reported: 2 (internet intervention plus physiotherapist support arm), 2 (internet intervention plus usual care), 2 (usual care alone). One case of suspected cauda equina was detected towards the end of the trial in the physiotherapist support arm (immediate clinical treatment was received, L5/S1 discectomy performed), and 5 admissions were identified from patient general practice medical record reviews: 1 for a facet joint injection, 1 for a haemoarthrosis, 1 for lumbar screening and injection, 1 for an epidural steroid injection, and 1 unrelated serious adverse event. We think it is very unlikely that the gentle activity advice offered by the internet intervention would lead to any of the above, but it is not possible to rule out; all Serious Adverse Reactions were reported to the trials' Research Ethics Committee.

DISCUSSION

We believe this is the first trial of an internet intervention specifically designed for patients with LBP consulting in general practice. Overall, the trial design was found to be feasible and the success criteria [17] were met; the target number of patients were recruited within the trial timeframe; the majority of patients were exposed to core active internet intervention content; the telephone support physiotherapists adhered to the protocol, and acceptable levels of retention were achieved for the key clinical outcomes at 3 months follow-up. Caution is required when interpreting the exploratory analysis of clinical outcomes as, due to the feasibility aims of this trial, it was not powered to determine effectiveness. Nonetheless, the reduction of 2.4 points on the RMDQ for the internet intervention plus physiotherapist support arm compared to usual care alone at 3 months follow-up, suggests the potential importance of additional remote, brief healthcare professional support for primary care patients with LBP. Reductions in LBP-related disability compared to usual care alone were smaller when the internet intervention was delivered stand-alone.

The trial design had a number of strengths. The internet intervention was provided in addition to and compared with unrestricted usual care. This pragmatic design will enable evaluation of the incremental value of the interventions in addition to the existing full range of LBP healthcare available. Use of outcomes recommended as core outcome domains for LBP [39] will enable comparison with other non-digital interventions; previous studies of internet interventions for LBP have used a heterogeneous range of outcome measures.[13] To our knowledge this is the first trial

to integrate brief physiotherapist telephone support with an internet intervention specifically designed for LBP patients. Physiotherapists are ideally placed to support LBP interventions with a central focus on physical activity, and this trial demonstrates the feasibility of a guided digital approach for the management of a prevalent musculoskeletal condition in primary care.

We identified some limitations to be addressed in the full trial: Encouraging physical activity was a core focus of SupportBack. The high median MET minutes of physical activity reported by patients at baseline on the IPAQ-SF appears to reflect a substantial overestimation, severely limiting the scales potential for detecting change in physical activity over the course of the trial. Despite the IPAQ-SF remaining the most widely used self-report measure of physical activity,[40] overestimation is frequently reported.[41] Objective measures such as accelerometers can be intrusive, costly when needed in large numbers, and there are still questions over accuracy.[42] Consequently, for the full trial it may be best to provide additional support for accurate reporting on the IPAQ-SF at baseline (e.g. through providing worked examples). Our sample had a lower mean RMDQ score than other trials for LBP in primary care,[43] with approximately 30% reporting an RMDQ score of ≥4 at baseline. This may be a function of the 6 month recruitment window from patients' LBP consultation, our broad inclusion criteria (experience of LBP in the last two weeks) and the low intensity nature of the interventions on offer. For the full trial we will amend our recruitment strategy to recruit patients closer to their consultation at participating practices. We will also amend our recruitment procedure aiming at improving efficiency, working to ensure more of those invited are screened and more of those screened are eligible. Follow-up rates differed between the 3 arms, with the lowest rates in the internet intervention plus telephone support arm. In the main trial follow-up rates will be closely monitored to ensure they remain above 80% across all 3 arms. Finally, the randomisation was unbalanced on some demographic and clinical variables. This was likely a function of the small numbers in each arm, and would be expected to balance out with the numbers required (approx. 200+ per arm) for a full trial.

Health economic evaluations of digital health interventions can be complex. A recent paper has discussed these complexities inherent in costing digital health interventions, such as SupportBack, highlighting the importance of considering ongoing costs and benefits of digital interventions.[44] For costing future implementation it would be important to identify any hosting costs as well as documenting any additional development costs needed and whether any of these would be ongoing (to keep the

intervention up to date). We would also propose sensitivity analysis to allow for different assumptions as to the number of people who will use the intervention as this affects the estimate of unit cost. Finally, potential future benefit should be considered and assessed where possible beyond the perspective of the trial timeframe; since LBP tends to be recurrent coping strategies learned from SupportBack might help prevent or manage back pain recurrence.

To conclude, digital approaches with and without healthcare professional support have the potential to offer an accessible means of effectively supporting behavioural self-management. We have shown that the SupportBack intervention is acceptable to patients with LBP presenting to primary care, and demonstrated the feasibility of a future definitive randomised controlled trial aimed at determining its clinical and cost effectiveness.

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Ethics approval: NHS Research Committee, REC Reference: 13/SC/020

Contributors: LY, AWAG and PL conceived the idea for the study. AWAG, LY, PL, LR, NEF, EMH and JCH designed the trial and secured funding. RS and AWAG developed the internet intervention with LY and LR, with further input from NEF, JCH, EMH, PL and LL. LY, AG, LR, JCH, NEF, developed the physiotherapy telephone support package. RS managed the trial on a day-to-day basis with oversight from AG, PL, LR, LY and input from NEF, JCH, EMH and LL. BS, DT, WM planned and carried out the statistical and health economic analysis. AWAG drafted the manuscript with input from all authors, AWAG is the guarantor for the data.

REFERENCES

1. Hoy D, March L, Brooks P et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. *Ann Rheum Dis* 2014;73:968-974.
2. Andersson GB. Epidemiological features of chronic low-back pain. *Lancet* 1999;354:581-585.
3. Maniadakis N, Gray A. The economic burden of back pain in the UK. *Pain* 2000;84:95-103.
4. Freburger JK, Holmes GM, Agans RP et al. The rising prevalence of chronic low back pain. *Arch Intern Med* 2009;169:251-258.
5. Gore M, Sadosky A, Stacey BR, Tai KS, Leslie D. The burden of chronic low back pain: clinical comorbidities, treatment patterns, and health care costs in usual care settings. *Spine (Phila Pa 1976)* 2012;37:E668-77.
6. National Institute for Health and Care Excellence. Low back pain: Early management of persistent non-specific low back pain. Clinical Guideline 134. London: Nice; 2009
7. Machado GC, Maher CG, Ferreira PH et al. Efficacy and safety of paracetamol for spinal pain and osteoarthritis: systematic review and meta-analysis of randomised placebo controlled trials. *BMJ* 2015;350:h1225.
8. Mallen C, Hay E. Managing back pain and osteoarthritis without paracetamol. *BMJ* 2015;350:h1352.
9. Crofford LJ. Adverse effects of chronic opioid therapy for chronic musculoskeletal pain. *Nat Rev Rheumatol* 2010;6:191-197.
10. Salisbury C, Foster NE, Hopper C et al. A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of 'PhysioDirect' telephone assessment and advice services for physiotherapy. *Health Technol Assess* 2013;17:1-157, v.
11. Current Issues and Future Directions for Research Into Digital Behavior Change Interventions. *Am J Prev Med* 2016;51(5):814.
12. Butler L, Foster NE. Back pain online: a cross-sectional survey of the quality of web-based information on low back pain. *Spine (Phila Pa 1976)* 2003;28:395-401.
13. Garg S, Garg D, Turin TC, Chowdhury MF. Web-Based Interventions for Chronic Back Pain: A Systematic Review. *J Med Internet Res* 2016;18:e139.
14. Buhrman M, Faltenhag S, Strom L, Andersson G. Controlled trial of Internet-based treatment with telephone support for chronic back pain. *Pain* 2004;111:368-377.
15. Buhrman M, Nilsson-Ihrfeldt E, Jannert M, Strom L, Andersson G. Guided internet-based cognitive behavioural treatment for chronic back pain reduces pain catastrophizing: a randomized controlled trial. *J Rehabil Med* 2011;43:500-505.

16. Carpenter KM, Stoner SA, Mundt JM, Stoelb B. An online self-help CBT intervention for chronic lower back pain. *Clin J Pain* 2012;28:14-22.

17. Geraghty AWA, Stanford R, Little P et al. Using an internet intervention to support self-management of low back pain in primary care: protocol for a randomised controlled feasibility trial (SupportBack). *BMJ Open* 2015;5:e009524.

18. Andersson G, Cuijpers P. Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. *Cogn Behav Ther* 2009;38:196-205.

19. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behavior change interventions. *J Med Internet Res* 2015;17:e30.

20. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine (Phila Pa 1976)* 2000;25:3115-3124.

21. Dunn KM, Croft PR. The importance of symptom duration in determining prognosis. *Pain* 2006;121:126-132.

22. Hill JC, Dunn KM, Lewis M et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Rheum* 2008;59:632-641.

23. Little P, Lewith G, Webley F et al. Randomised controlled trial of Alexander technique lessons, exercise, and massage (ATEAM) for chronic and recurrent back pain. *BMJ* 2008;337:a884.

24. Goubert L, Crombez G, Van Damme S, Vlaeyen JW, Bijttebier P, Roelofs J. Confirmatory factor analysis of the Tampa Scale for Kinesiophobia: invariant two-factor model across low back pain patients and fibromyalgia patients. *Clin J Pain* 2004;20:103-110.

25. Sullivan M, Bishop SR, Pivik J. The pain catastrophizing scale: User manual. 2009

26. Craig CL, Marshall AL, Sjostrom M et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc* 2003;35:1381-1395.

27. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry* 2000;31:73-86.

28. Resnick B, Palmer MH, Jenkins LS, Spellbring AM. Path analysis of efficacy expectations and exercise behaviour in older adults. *J Adv Nurs* 2000;31:1309-1315.

29. Tijou I, Yardley L, Sedikides C, Bizo L. Understanding adherence to physiotherapy: findings from an experimental simulation and an observational clinical study. *Psychol Health* 2010;25:231-247.

30. Kirby S, Donovan-Hall M, Yardley L. Measuring barriers to adherence: validation of the problematic experiences of therapy scale. *Disabil Rehabil* 2014

31. Brooks R, Rabin R, De Charro F. The measurement and valuation of health status using EQ-5D: a European perspective: evidence from the EuroQol BIO MED research programme. Berlin: Springer Science & Business Media; 2003

32. Curtis L, Burns A. Unit costs of health and social care. 2015. Retrieved from http://www.pssru.ac.uk/project-pages/unit-costs/2015/index.php

33. Department of Health. NHS Reference costs 2014-15. 2014. Retrieved from https://www.gov.uk/government/publications/nhs-reference-costs-2014-to-2015

34. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics* 2005;4:287-291.

35. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301-308.

36. Stratford PW, Binkley JM, Riddle DL, Guyatt GH. Sensitivity to change of the Roland-Morris Back Pain Questionnaire: part 1. *Phys Ther* 1998;78:1186-1196.

37. Haskell WL, Lee IM, Pate RR et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. *Med Sci Sports Exerc* 2007;39:1423-1434.

38. Brooks R. EuroQol: the current state of play. *Health Policy* 1996;37:53-72.

39. Chiarotto A, Deyo RA, Terwee CB et al. Core outcome domains for clinical trials in non-specific low back pain. *Eur Spine J* 2015;24:1127-1142.

40. Lee PH, Macfarlane DJ, Lam TH, Stewart SM. Validity of the International Physical Activity Questionnaire Short Form (IPAQ-SF): a systematic review. *Int J Behav Nutr Phys Act* 2011;8:115.

41. Hallal PC, Gomez LF, Parra DC et al. Lessons learned after 10 years of IPAQ use in Brazil and Colombia. *J Phys Act Health* 2010;7 Suppl 2:S259-64.

42. Napolitano MA, Borradaile KE, Lewis BA et al. Accelerometer use in a physical activity intervention trial. *Contemporary Clinical Trials* 2010;31:514-523.

43. Hill JC, Whitehurst DG, Lewis M et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *Lancet* 2011;378:1560-1571.

44. McNamee P, Murray E, Kelly MP et al. Designing and Undertaking a Health Economics Study of Digital Health Interventions. *Am J Prev Med* 2016;51:852-860.

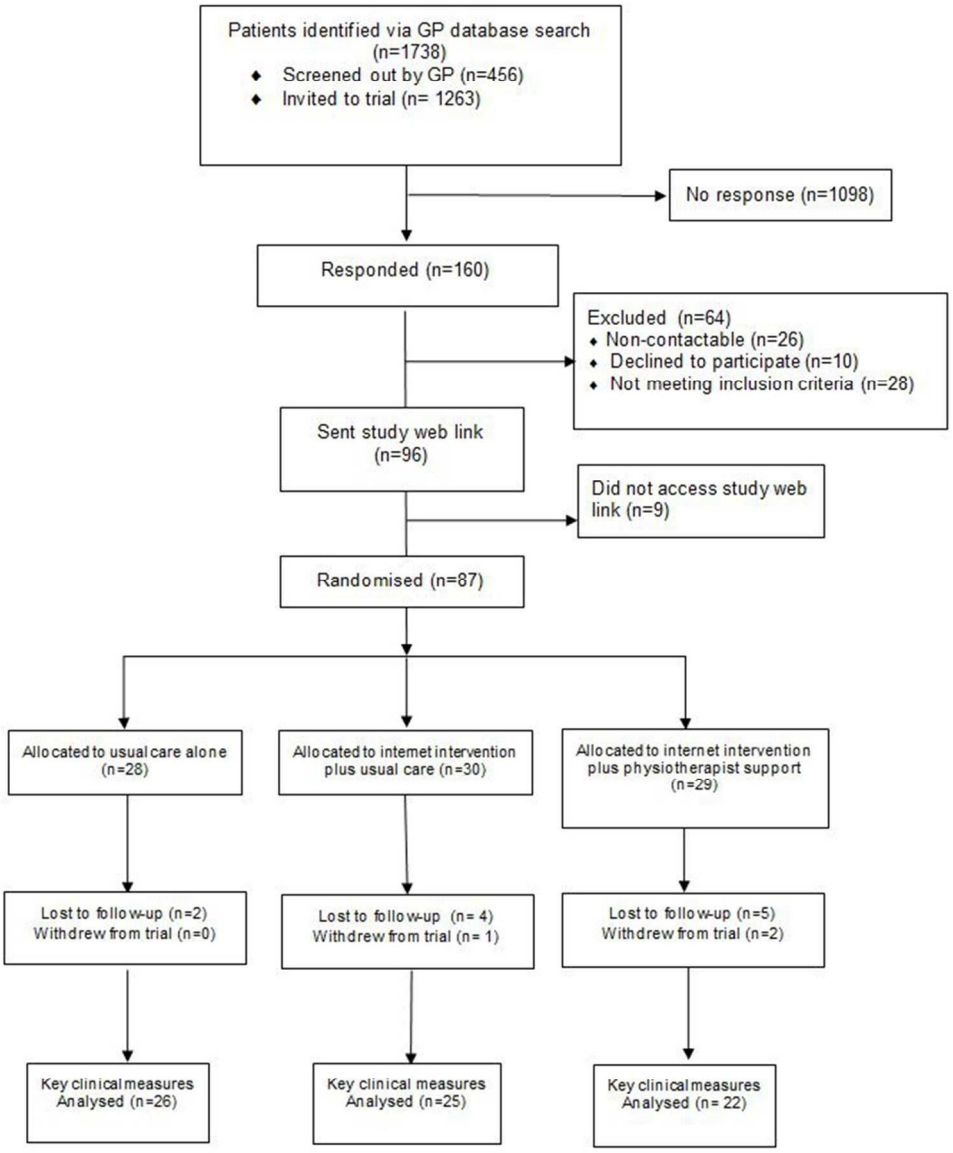

Figure 1. Participant flow through the trial

185x221mm (96 x 96 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9-10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9-10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9-10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9-10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	9-10

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6-7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	28
	13b	For each group, losses and exclusions after randomisation, together with reasons	28
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16-18
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16-18
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	16-18
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	19-20
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	22
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	23
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	23
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	23
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Using an internet intervention to support self-management of low back pain in primary care: Findings from a randomised controlled feasibility trial (SupportBack)

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Using an internet intervention to support self-management of low back pain in primary care: Findings from a randomised controlled feasibility trial (SupportBack)

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ABSTRACT

Objective: To determine the feasibility of a randomised controlled trial of an internet intervention for low back pain (LBP) using 3 arms: 1) usual care, 2) usual care plus an internet intervention or 3) usual care plus an internet intervention with additional physiotherapist telephone support.

Design and setting: A three-armed randomised controlled feasibility trial conducted in 12 general practices in England.

Participants: Primary care patients aged over 18, with current LBP, access to the internet, and without indicators of serious spinal pathology or systemic illness.

Interventions: The 'SupportBack' internet intervention delivers a 6-week, tailored programme, focused on graded goal setting, self-monitoring, and provision of tailored feedback to encourage physical activity. Additional physiotherapist telephone support consisted of three brief telephone calls over a 4-week period, to address any concerns and provide reassurance.

Outcomes: The primary outcomes were the feasibility of the trial design including recruitment, adherence and retention at follow-up. Secondary descriptive and exploratory analyses were conducted on clinical outcomes including LBP-related disability at 3 months follow-up.

Results: Primary outcomes: 87 patients with LBP were recruited (target 60-90) over 6 months, and there were 3 withdrawals. Adherence to the intervention was higher in the physiotherapist-supported arm, compared to the stand-alone internet intervention. Trial physiotherapists adhered to the support protocol. Overall follow-up rate on key clinical outcomes at three months follow-up was 84%.

Conclusions: This study demonstrated the feasibility of a future definitive randomised controlled trial to determine the clinical and cost effectiveness of the SupportBack intervention in primary care patients with LBP.

Trial registration: ISRCTN 31034004

Key words: Low back pain; internet intervention; self-management; primary care

STRENGHTS AND LIMITATIONS OF THIS STUDY

- This is the first pragmatic feasibility trial examining an internet intervention specifically designed for patients with LBP consulting in general practice.
- The feasibility of two methods of delivery was determined; providing the internet intervention with and without telephone physiotherapist support.
- Follow-up was relatively short at 3 months; it is unclear whether response rates would remain similar at additional follow-up points necessary for a definitive trial.

BACKGROUND

Low back pain (LBP) causes more global disability than any other condition,[1] and has a lifetime prevalence of up to 85%.[2] The economic costs of LBP have been reported at £12.3 billion per annum in the UK alone.[3] In those who consult in primary care, pain trajectories often remain stable, with patients who report persistent-mild to persistent-severe pain, often remaining in the same pain grouping at 7-year follow-up.[3] Chronic LBP, with a prevalence of 3-10%,[4] is associated with depression, anxiety, deactivation, inability to work and substantial societal costs.[2, 5]

The recently updated National Institute for Health and Care Excellence (NICE) guidelines for managing LBP continue to state the importance of self-management and advice to remain active.[6] Identifying effective means to support behavioural self-management is becoming increasingly important; a recent review questioned the effectiveness of paracetamol for spinal pain,[7, 8] and concerns continue to grow regarding the adverse effects of prescriptions for opioid-related painkillers.[9] In primary care, General Practitioners (GPs) are unlikely to have the time or the training to deliver effective self-management support, and access to NHS services such as physiotherapy are often limited, with long waiting times for patients.[10] There is a critical need for novel interventions enabling primary care practitioners to provide their LBP patients with immediate access to evidence-based, accessible self-management advice and support.

Internet interventions are automated, structured programmes delivering tailored advice over time through text and audio-visual content.[11] They differ from simple health information webpages, which in the case of LBP are abundant and often of low quality.[12] Internet interventions may offer a useful resource for primary care practitioners to draw on. Research on internet interventions for LBP is at an early stage: A recent systematic review of nine randomised controlled trials (RCTs) of internet interventions for chronic LBP [13] concluded that despite showing some promise, many of the trials were limited by small samples sizes,[14, 15] comparisons to waiting lists or no treatment controls,[16] and researchers rarely considered healthcare resource use.[13] To our knowledge, there have been no trials of internet interventions developed specifically for patients with LBP consulting in primary care. As primary care practitioners see the full spectrum of patients with LBP, ideal interventions for this context would offer effective self-management advice for those with acute, recurrent and chronic presentations, facilitating simple implementation.

'SupportBack' is an internet intervention specifically developed by our team for patients with LBP consulting in primary care using a theory-, evidence- and person-based approach.[17] Its central focus in enabling people to manage their LBP, is to support appropriate engagement in physical activity. It is also designed to contain simple advice and behaviour change support/techniques for a range of clinical presentations (e.g. acute or subacute) through effective reassurance for common concerns (such as the misconception, hurt equals harm), as well as providing elements that those with more chronic LBP may find helpful (e.g. managing low mood, fear-avoidance, challenges with work, and poor sleep). Brief additional human support often improves outcomes when added to internet interventions [18] and SupportBack has been designed to be delivered either as a stand-alone intervention, or with additional brief telephone support from a physiotherapist.

In order to determine the effectiveness of digital approaches such as SupportBack, pragmatic trials are required that examine these interventions in addition to, and compared to, usual primary care for LBP. The aim of this study was to determine the feasibility of delivering the SupportBack intervention in addition to usual care to patients with LBP consulting in general practice, with or without brief physiotherapist telephone support, compared to usual care alone. We aimed to determine the feasibility of RCT procedures alongside the acceptability, uptake and use of the interventions, as well as preliminarily exploring key clinical and economic outcomes in order to inform a future full trial.

METHOD

Design

We conducted a three-parallel arm, single centre feasibility RCT of the SupportBack internet intervention for LBP in primary care. The full details of the method and interventions can be found in the published trial protocol.[17]

Participants

Patients were included in the trial if they had current LBP (experienced pain within the last two weeks); had access to the internet; had consulted their general practice with LBP within the last 6 months; could read/understand English without assistance. Patients were excluded if they were under 18 years of age; had clinical indicators of (suspected) spinal pathology such as infection, fracture or cancer; or had taken part in

an earlier study to develop the intervention. Pregnancy was added to the exclusion criteria after the trial had begun.

Recruitment

The local Clinical Research Network (CRN) facilitated recruitment of general practices. Within practices, potentially eligible patients were identified by searching computerised lists of LBP consultations from the last 6 months. The resulting lists were screened by a practice GP who excluded patients who did not fulfil the eligibility criteria as determined from patients' notes. Practice staff sent out study packs to the remaining patients containing options for interested patients to contact the research team. Study packs were also provided to practices for opportunistic recruitment within LBP consultations. Interested patients who contacted the research team underwent a secondary telephone screen by a study manager, who asked about their current LBP and screened a list of 12 key symptoms that may indicate serious spinal pathology or systemic illness (see [17]). Patients answering yes to any symptoms were discussed with a clinician in the research team and referred back to their GP where appropriate. Those patients who remained eligible were sent a link to the study website, where they provided online consent, completed all baseline measures and were then randomised to one of the three trial arms. Recruitment opened in February 2015 and closed in September 2015. The follow-up period ended in January 2016.

Interventions

Usual care:

Those patients allocated to this arm continued to receive usual care for their LBP over the trial period. This care was unrestricted and could vary substantially; for example, patients who did not re-consult at their general practice may not have received care beyond their initial consultation, whereas others may have accessed a range of treatment including physiotherapy or pain clinics.

Internet intervention plus usual care:

Patients allocated to the internet intervention arm continued to receive unrestricted usual care for LBP. In addition, patients received access to SupportBack, a tailored multi-session internet intervention designed to support self-management of LBP, developed by our team using LifeGuide software (www.lifeguideonline.org). SupportBack has been described in more detail elsewhere.[17] In brief, the intervention focuses on self-regulatory processes including goal setting, self-monitoring and tailored feedback to support physical activity. There is also a focus on cognitive reassurance

and self-efficacy for activity in the presence of pain throughout; addressing concerns with evidence-based feedback and modelling success through patient activity stories. SupportBack was developed using the Person-Based Approach [19] incorporating systematic, in-depth, qualitative research with 22 patients and community volunteers with experience of LBP.

The intervention has six sessions, and it was recommended that patients complete one session per week for six weeks. The first session introduces the rationale for physical activity being key in the self-management of LBP and allows patients to select goals for the next week. Goals options, including gentle back exercises or walking, are automatically tailored, based on how patients report their LBP is affecting their functioning at the time. Each of the following five sessions consists of patients reviewing and amending their activity goals for the coming week with automatic feedback. From session two onwards, after the goal review, patients have access to one new module per week from the SupportBack menu. The modules on the menu focus on a broad range of LBP related topics including: mood; managing pain at work; sleep; relieving pain through medication and dealing with flare-ups. The broad aim of the intervention is to support patients to become their own expert in self-managing their LBP, thus strategies learnt (e.g. remaining active during fair-ups) could also be used to manage LBP in the future and reduce the severity of recurrences. Patients used SupportBack without support from a health professional in this arm of the trial. They received automated weekly email reminders to log in, and any technical difficulties were addressed by the study manager. Patients were able to access the SupportBack internet intervention at any time over the trial period and from wherever was most convenient.

Internet intervention plus physiotherapist telephone support plus usual care:
Patients in this arm continued to receive unrestricted usual care for LBP and had access to the SupportBack intervention as above. In addition, those in this arm received up to a total of 1 hour of physiotherapist telephone support, split into 3 calls, with approximately 30 minutes for call 1, and 15 minutes for calls 2 and 3. The calls were designed to be delivered approximately after week 1, between weeks 2-3 and after week 4. The purpose of the physiotherapists' calls was to provide support and encouragement to participants to use the SupportBack internet intervention, to address participants' concerns and provide additional reassurance. Two senior musculoskeletal physiotherapists (male and female, NHS Bands 6 and 7) provided the telephone support. They worked through a standardised checklist for each phone

call (available on request from the corresponding author), and although they were able to address individual patient concerns, they were asked not to provide additional recommendations beyond the content of the internet intervention. Their fidelity to the study protocol was evaluated by audio-recording a sample of 20 telephone consultations.

Outcomes and measures

The primary outcomes for this trial were descriptive, focusing on the feasibility of the trial design and intervention delivery, including: recruitment of general practices; recruitment of patients within the allocated timeframe of the trial; suitability of eligibility and screening criteria; withdrawals and retention at follow-up at 3 months; usage of the internet intervention and self-reported activity adherence; delivery and uptake of the telephone support along with any significant issues encountered.

The success criteria for the feasibility trial, as published in the protocol,[17] are listed below:

- *Recruiting a minimum of 60 patients with LBP, access to the internet and without indicators of serious spinal pathology from primary care within the allotted recruitment time period for the trial.*
- *Attrition at 3 months follow-up should be equal to or lower than 30% from all trial arms.*
- *By examining the recordings, the telephone support physiotherapists are able to deliver the telephone sessions in line with the protocol, covering approximately 2/3 of the checklist in each call.*
- *Patients should be able to access the intervention and complete measures, complete session 1 and set goals for future sessions.*
- *Qualitative and quantitative data should indicate that the intervention and trial procedures are acceptable to patients (acceptability referring to completion of questionnaires, retention, and appropriate use of the intervention). Qualitative data will be reported elsewhere.*

All self-reported measures were collected online using LifeGuide software at baseline. At 3 months post-randomisation, measures were primarily collected online, non-response triggered additional follow-up methods including email reminders, paper questionnaires being posted, and a telephone call from a blinded independent research assistant to collect key outcomes only. Demographic data collected included gender,

age, education, occupation, income and marital status. A range of LBP-related measures were collected: LBP-related physical disability was measured using the Roland and Morris Disability Questionnaire (RMDQ [20]), an outcome likely to be a primary outcome in a future full trial; pain duration was measured by asking about time since the last pain free month;[21] pain intensity was measured using three numerical rating scales (NRS) measuring current, average and least pain over the last two weeks as well as a mean of the 3 as a pain index;[22] number of troublesome days in pain over the last month was measured with a single item;[23] risk of persistent disability was measured using the STarT Back tool;[22] fear of movement was measured using the Tampa Scale for Kinesiophobia (TSK, [24]); catastrophising beliefs were measured using the Pain Catastrophising Scale (PCS, [25]). Self-reported physical activity was measured using the International Physical Activity Questionnaire Short Form (IPAQ-SF),[26]) and questions about numbers of weeks, and times per week people did specific activities or went walking to help their back pain were asked at 3 months follow-up. Enablement was measured using a modified patient enablement instrument (27).

Adherence to the internet intervention was examined by using LifeGuide-generated data on SupportBack sessions started and completed. Psychological process variables including patients' expectations of positive outcome were measured using a modified brief Credibility and Expectancy Questionnaire (CEQ) [28] at baseline across all arms, and the full CEQ was completed after session one in the two internet intervention arms. Exercise self-efficacy was also measured after session one in the two internet intervention arms.[29, 30] The Problematic Experiences of Therapy Scale (PETS, [31]) was used to measure difficulties with adherence to recommended exercises.

To determine the feasibility of collecting health economic measures for a cost effectiveness analysis in a future full trial, a GP notes review was conducted and health-related quality of life was measured using the EQ-5D 3L.[32] Resource use was costed using published sources of unit cost data.[33, 34] Identified resource use was costed using 2014/15 UK pound sterling.

Sample size

The target for this trial was to recruit between 60-90 patients overall, with 20-30 per arm. Guidance for sample size in feasibility trials varies with numbers ranging from 12-30+ per arm.[35, 36] A sample of not less than 60 overall allowed for the assessment of the primary feasibility outcomes including recruitment, adherence and retention.

Randomisation and blinding

Randomisation was fully automated by the internet intervention software (LifeGuide). The randomisation sequence was generated within the software and concealed from the trial team. An automated algorithm block randomised patients to the three trial arms. Patients were stratified by severity of physical disability (measured by the RMDQ ≥ 7). Patients were notified of their allocated arm automatically by the LifeGuide software. Due to the behavioural nature of the intervention, it was not possible to blind patients to interventions. The study manager allocated patients to physiotherapists and therefore was not blind to allocation. All telephone outcome data were collected by an independent blinded research assistant. The trial statistician remained blind until the analysis was finalised. More detail on randomisation can be found in the protocol. [17]

Analysis

The primary analysis for this trial focused on a description of the key feasibility outcomes including numbers of general practices recruited; patient eligibility and recruitment rates; withdrawals; response to follow-up at 3 months. Use of the internet intervention was described by reporting numbers of sessions started and completed per arm. Delivery of physiotherapist telephone support was described in terms of the number of calls successfully made and mean/modal calls per patient. Fidelity of the telephone support was examined by selecting a random sample of 30% of the verbatim transcripts of the calls and physiotherapist completed call check sheets. As detailed in the protocol,[17] the check sheets contained recommended topics to be covered in each call, acknowledging that not all topics may be appropriate. AWAG examined the transcript-check sheet pairs examining correspondence of topics covered in each case. Any major deviation was noted.

Descriptive statistics were used to identify any floor or ceiling effects. Means and/or medians, standard deviations and 95% confidence intervals were reported for the measures. Exploratory quantitative analyses were conducted on patients' clinical, activity and psychological process measures. In addition to analyses reported in the protocol, linear regression models, controlling for baseline covariates (each outcome at baseline, gender, age, marital status, employment status, income, ethnicity and age left education), were used to explore between group differences in continuous outcome measures (e.g. RMDQ, numerical pain rating scale). Continuous outcomes were modelled using a linear model if they met the underlying assumptions and a non-

parametric quantile regression if not. As this was a feasibility trial the objective was not hypothesis testing, rather these analyses allowed for preliminary examination of trends in between-group comparisons. The analysis was undertaken on an intention to treat basis, analysing participants in the group to which they had been randomised, and comprised complete cases only. Proportions of patients achieving a minimal clinically important difference (MCID) was described. In this trial, a MCID was classified as a reduction of 2 points on the RMDQ compared to usual care alone.[37] Spearman correlations with 95% confidence intervals were used to explore the relationship between psychological process measures such as expectancy and exercise self-efficacy on LBP-related disability and adherence to physical activity.

Health economic analysis at this stage was descriptive. We aimed to report estimates of cost and outcomes measures and baseline and follow-up. The methods of collecting health economics data were similar to the methods that would be used in a future full RCT. NHS related costs were estimated from computer records in participating general practice. Estimates were made of the cost of making access to SupportBack and the costs of providing nurse support as per protocol. These costs were recorded over the 3-month follow-up period. Resources identified were combined with relevant unit costs [33, 34]. Outcomes for use within the economics evaluation were change in LBP-related disability (RMDQ) and the quality adjusted life year (QALY) evaluated using the EQ-5D 3L.[38]

RESULTS

Recruitment and retention

The CRN received expressions of interest to take part in the trial from 27 practices, of which 4 were initially approached and recruited, this was increased to 12 following close monitoring of initial recruitment rates. 1263 trial invitation letters were sent from the 12 participating practices to potentially eligible patients. 160 responses were received. Of these, 87 patients with LBP met the eligibility criteria after further telephone screening and were randomised over a 6-month period. This translated to a recruitment rate of 14-15 patients per month, and approximately 7 patients randomised per practice over a total of 6 months. Three patients withdrew over the course of the trial: 1 from the internet intervention plus usual care arm (no reason given), 2 from the internet intervention plus physiotherapist support arm (1. due to illness, 2. due to family bereavement). The overall follow-up rate for the key clinical outcomes was 84% (73/87)

at 3 months, and varied between arms: usual care = 93%, internet intervention plus usual care = 83%, internet intervention plus physiotherapist support = 76%. See Figure 1 for patient flow through the trial.

[INSERT FIGURE 1 ABOUT HERE]

Patient characteristics

Eighty-four participants provided baseline data. Table 1 shows participant characteristics across the three trial arms. Demographic characteristics were generally similar across the arms, with some exceptions including greater numbers of retired participants in the usual care alone arm. With regard to clinical variables at baseline, LBP-related disability (measured by the RMDQ) was similar across arms. Taken together, the RMDQ, pain numerical rating scales and STarT back scores indicate slightly higher severity in those randomised to the internet intervention plus physiotherapist support arm. Pain duration, measured as time since last pain free month, was similar across arms. Number of troublesome days in pain over the last four weeks differed substantially; from a median of 10 in the usual care alone arm to 18 in the internet intervention plus physiotherapist support arm.

Table 1. Baseline characteristics

Variable	Usual care (n=27)	Internet intervention plus usual care (n=29)	Internet intervention plus physiotherapist support (n=27)
Female	15 (55.6%)	19 (65.2%)	17 (63.0%)
Age	60.3 (16.3)	54.5 (13.7)	59.3 (10.4)
Marital Status			
- Married/partner	23 (85.2%)	19 (65.5%)	22 (81.5%)
- Single	3 (11.1%)	4 (13.8%)	2 (7.4%)
- Divorced/separated	0	5 (17.2%)	1 (3.7%)
- Widow/widower	1 (3.6%)	1 (3.6%)	2 (7.4%)
White ethnicity	27 (100%)	26 (92.9%)	27 (100%)
Age left education	17.6 (2.7)	17.3 (1.7)	17.6 (2.8)
Employment status			
- Full time	7 (25.9%)	12(41.8%)	6 (22.2%)
- Part time	2 (7.4%)	4 (13.8%)	8 (29.6%)
- Retired	13 (48.2%)	6 (20.7%)	8 (29.6%)
- Self-employed	2 (7.4%)	3 (10.3%)	4 (14.8%)
- Sickness/disability	2 (7.4%)	2 (6.9%)	1 (3.7%)
- Other	1 (3.7%)	2 (6.9%)	0
Annual income (up to £)			

- 10,000	2 (7.4%)	4 (14.3%)	3 (11.5%)
- 20,000	7 (25.9%)	6 (21.4%)	3 (11.5%)
- 40,000	9 (33.3%)	9 (32.1%)	10 (38.5%)
- > 40, 000	9 (33.3%)	9 (32.1%)	10 (38.5%)
Expectations re improvement in LBP	5.86 (1.88)	5.22 (2.06)	5.74 (2.19)
Expected percentage improvement in LBP (Item from the CEQ)	43.21% (25.53)	41.92% (21.17)	37.40% (25.50)
Median days of pain in the last 4 weeks (IQR) (Item from the CEQ)	10 (6, 25)	10 (4, 21)	18 (5, 28)
Time since you had a whole month without pain			
- Less than 3 months	5 (17.2%)	6 (21.4%)	5 (19.2%)
- 3-6 months	1 (3.5%)	2 (7.1%)	4 (15.4%)
- 7-12 months	5 (17.2%)	4 (14.3%)	6 (23.1%)
- 1-2 years	7 (24.1%)	4 (14.3%)	5 (19.2%)
- 3-5 years	4 (13.8%)	4 (14.3%)	3 (11.5%)
- 6-10 years	2 (6.9%)	4 (14.3%)	3 (11.5%)
- Over 10 years	5 (17.2%)	4 (14.3%)	0
LBP-related disability (RMDQ) mean (SD)	6.8 (4.9)	6.6 (4.6)	7.7 (4.7)
STarT Back risk group			
- Low	16 (57.1%)	19 (67.9%)	14 (51.9%)
- Medium	11 (39.3%)	6 (21.4%)	12 (44.4%)
- High	1 (3.8%)	3 (10.7%)	1 (3.7%)

Adherence outcomes

Table 2 shows the percentages of participants starting and completing sessions of the SupportBack internet intervention. Both the percentages starting and completing sessions tended to be higher in the internet intervention plus telephone support arm. For all sessions, those starting a session tended to complete it, with the exception of the internet intervention plus usual care arm in session 1. Overall, 11.1% (3/27) of those in the internet intervention plus telephone support arm and 29.6% (8/27) of patients in the internet intervention plus usual care arm partially completed session 1 and did not return to the internet intervention over the duration of the trial.

At follow-up, participants were also asked about activities they engaged with to help their LBP (walking or back exercises). All participants provided this data, serving as an indication of self-reported activity adherence in the internet intervention arms, and providing data about levels of activity in the usual care alone arm. The responses are tabulated in Table 3. Most participants regardless of arm allocation reported spending

9-12 weeks going for walks or doing back exercises and did so regularly (4+ days per week).

Table 2. Percentages starting (Start) and completing (Com.) internet intervention sessions (S)

	Start S1	Com. S1	Start S2	Com. S2	Start S3	Com. S3	Start S4	Com. S4	Start S5	Com. S5	Start S6	Com. S6
Int. interven*	89%	54%	61%	57%	54%	50%	46%	43%	36%	36%	32%	32%
Int. interven+ support**	82%	70%	85%	70%	82%	78%	59%	56%	48%	48%	41%	41%

* Internet intervention plus usual care
** Internet intervention plus physiotherapist support

Table 3. Tabulation of self-reported LBP-related activities

	Usual care alone (n=14)	**Internet intervention plus usual care (n=16)**	**Internet intervention plus telephone support (n=19)**
How many weeks spent doing back exercises or going for walks?			
• Never started	2 (14.3%)	0	0
• 1 week	0	0	0
• 1-2 weeks	0	1 (6.3%)	1 (5.3%)
• 3-5 weeks	3 (21.4%)	6 (37.5%)	4 (21.1%)
• 6-8 weeks	1 (7.1%)	2 (12.5%)	5 (26.3%)
• 9-12 weeks	8 (57.1%)	7 (43.7%)	9 (47.4%)
How many times a week did you do back exercises or go for walks?			
• Never started	2 (14.3%)	0	0
• 1 day	1 (7.1%)	2 (12.5%)	1 (5.3%)
• 2-3 days	2 (14.3%)	5 (31.3%)	2 (10.5%)
• 4-5 days	5 (35.7%)	4 (25.0%)	7 (36.8%)

• Every day	4 (28.6%)	5 (31.3%)	9 (47.4%)

Note. Numbers are lower as these variables were not part of minimum data collection over the telephone at 3 months follow-up with telephone follow-up

Physiotherapist telephone support

Support telephone calls were made to 25/29 (86%) participants who were randomised to this arm. For those that did not receive calls, 3 participants were uncontactable despite multiple call attempts made by the physiotherapists (2 of 3 continued to use the internet intervention alone), and 1 participant was not allocated a physiotherapist due to an administrative error. This was discovered at the end of the trial through the qualitative interview with this participant. This individual continued to use the internet intervention alone.

For the 25 patients receiving physiotherapist support calls, the mean number of calls made was 2.4 (*SD* = 1.03, mode = 3). Mean call durations were 17.3 minutes (*SD* = 8.5) for call 1, and 11.5 (*SD* = 6.2) and 11.9 (*SD* = 6.2) minutes for calls 2 and 3 respectively. From the 65 connected calls made, a random sample of 20 calls (30%) were selected to examine fidelity using verbatim transcripts of the calls and physiotherapist completed call check sheets. At least two thirds of the recommended topics were covered in 19 of the calls checked (95%).

Clinical outcomes/measures

Mean physical disability measured by RMDQ score, was 6.9 *(SD* = 5.5) across the trial arms at baseline. From the 84 participants who provided RMDQ data at baseline, 73 (84%) provided a response at 3 months follow-up. Of these, 27 (34.2%) were contacted by telephone or completed a paper questionnaire follow-up pack. Exploratory analysis of RMDQ scores showed, on average, participants in all three arms improved between baseline and follow-up (see Table 4). The internet intervention plus usual care arm improved by 0.6 points more than usual care alone, whilst the internet intervention plus physiotherapist support arm improved by 2.4 points, after controlling for baseline score and covariates. When those with a lower RMDQ at baseline (< 4) were excluded, the results remained similar with participants allocated to the internet intervention plus usual care improving by 0.4, and those allocated to internet intervention plus physiotherapist support improving by 2.0 more than usual care alone on the RMDQ. The proportions achieving this MCID were higher in the

internet intervention plus physiotherapist support arm (13/22, 59.1%), than the internet intervention plus usual care (8/26, 31.0%) and usual care alone (10/25, 40.0%) arms.

Table 4. Clinical and physical activity measures at baseline and follow-up

	Baseline Mean (SD)	3 months follow-up Mean (SD)	Difference (95% CI) at follow-up controlling for baseline	Difference (95% CI) at follow-up controlling for baseline and other covariates
LBP related disability (RMDQ) (n=73)				
Usual care alone	6.8 (4.9)	6.3 (5.1)		
Internet intervention plus usual care	6.6 (4.6)	5.8 (4.5)	-0.71 (-2.77, 1.35)	-0.64 (-3.10, 1.83)
Internet intervention plus physiotherapist support	7.7 (4.7)	5.1 (5.1)	-1.34 (-3.49, 0.81)	-2.38 (-5.00, 0.25)
LBP related disability (RMDQ) - Excluding those with a score below 4 (n=51)				
Usual care alone	8.5 (4.3)	7.3 (5.4)		
Internet intervention plus usual care	9.0 (3.9)	7.4 (4.9)	-.03 (-2.73, 2.82)	-0.41 (-3.08, 3.11)
Internet intervention plus physiotherapist support	9.5 (3.6)	6.4 (5.4)	-0.80 (-3.64, 1.99)	-2.02 (-4.98, 0.94)
Pain intensity (NRS) – Index average (n=72)				
Usual care alone	3.76 (2.27)	3.63 (2.09)		
Internet intervention plus usual care	3.88 (1.97)	3.18 (2.24)	-0.76 (-1.60, 0.07)	-0.49 (-1.47, 0.49)
Internet intervention plus physiotherapist support	4.19 (2.18)	3.08 (2.02)	-0.66 (-1.53, 0.21)	-0.76 (-1.78, 0.25)
Pain intensity (NRS) 1 – current (n=72)				
Usual care alone	3.57 (3.06)	3.96 (2.45)		
Internet intervention plus usual care	4.00 (2.61)	3.60 (2.48)	-0.85 (-1.86, 0.16)	-0.63 (-1.82, 0.56)
Internet	4.52 (2.57)	3.10 (2.32)	-1.35 (-2.40, -	-1.02 (-2.25,

intervention plus physiotherapist support			0.29)	0.21)
Pain intensity (NRS) – least pain last 2 weeks (n=72)				
Usual care alone	3.18 (2.52)	2.81 (2.08)		
Internet intervention plus usual care	3.14 (2.09)	2.3 2.3094	-0.72 (-1.60, 0.16)	-0.59 (-1.46, 0.29)
Internet intervention plus physiotherapist support	2.89 (2.68)	2.29 (2.12)	-0.04 (-0.97, 0.89)	0.19 (-0.71, 1.08)
Pain intensity (NRS) – average last 2 weeks (n=72)				
Usual care alone	4.57 (2.03)	4.08 (2.13)		
Internet intervention plus usual care	4.50 (2.06)	3.64 (2.51)	-0.51 (-1.56; 0.54)	-0.39 (-1.54, 0.76)
Internet intervention plus physiotherapist support	5.15 (2.11)	3.43 (1.69)	-0.86 (-1.96, 0.25)	-0.82 (-2.07, 0.44)
Fear avoidance (TSK) (n=59)				
Usual care alone	37.75 (6.22)	35.04 (6.40)		
Internet intervention plus usual care	37.51 (7.44)	36.06 (8.12)	0.66 (-2.52, 3.84)	0.14 (-3.02, 3.29)
Internet intervention plus physiotherapist support	35.52 (6.83)	34.32 (7.47)	0.86 (-2.30, 4.02)	-0.56 (-3.65, 2.53)
Negative orientation towards pain (PCS) (n=57)				
Usual care alone	13.71 (12.79)	14.00 (11.36)		
Internet intervention plus usual care	13.53 (10.00)	12.83 (8.96)	-1.49 (-6.37, 3.40)	-3.48 (-9.70, 2.74)
Internet intervention plus physiotherapist support	13.59 (9.38)	18.63 (8.47)	4.16 (-0.58, 8.90)	3.74 (-1.78, 9.27)
Modified Enablement Scale (n=58)				
Usual care alone	26.50 (8.37)	27.86 (10.53)		

Internet intervention plus usual care	25.14 (8.48)	25.35 (9.66)	-1.98 (-8.51, 4.55)	-1.34 (-8.69, 6.01)
Internet intervention plus physiotherapist support	26.12 (7.84)	28.26 (9.31)	0.12 (-6.19, 6.43)	-0.27 (-6.63, 6.08)
Days in pain				
Usual care alone	10 (6, 25)	6 (2,20)		
Internet intervention plus usual care	10 (4,21)	4 (0,15)	-0.69 (-9.20, 7.87)	-1.60 (-10.36, 7.16)
Internet intervention plus physiotherapist support	18 (5, 28)	10 (3,20)	0.33 (-8.71, 9.38)	1.14 (-8.62, 10.90)
Physical activity (IPAQ)	**Median (Q1, Q3)**	**Median (Q1, Q3)**		
Usual care alone	3139.5 (466.1, 5385)	2277.5 (912, 6105)		
Internet intervention plus usual care	1178.5 (480, 4131)	1130.5 (693, 2826)	-64.92 (-2796.15, 2666.32)	331.82 (-2360.85, 3024.50)
Internet intervention plus physiotherapist support	3168 (396, 7413)	990 (396, 3226.5)	-668.04 (-3347.32, 2011.25)	-408.04 (-2757.56, 1941.50)

Note. RMDQ: Roland Morris Disability Scale. NRS: Numerical Rating Scale. TSK: Tampa Scale for Kinesiophobia. PCS: Pain catastrophizing scale. IPAQ: International Physical Activity Questionnaire.

Additional pain-related measures are also shown in Table 4. There were small reductions in pain intensity (NRS) in all arms from baseline to 3 months, although greater change occurred in the internet intervention plus physiotherapist support arm in comparison with internet intervention plus usual care arm and usual care alone. There were small reductions in fear avoidance beliefs across all arms. With regard to pain catastrophising, there were small increases in the usual care alone arm and unexpectedly, in the internet intervention plus physiotherapist support arm (13.6 to 18.6). At 3 months, those in the internet intervention plus physiotherapist support arm reported 8 less days in pain, internet intervention plus usual care arm reported 6 less days in pain and those in usual care alone reported 2 less days in pain over the last 4 weeks. Finally, patient enablement showed small increases across all three arms.

The STarT Back tool [22] was used at baseline and 3 months follow-up to describe the proportions of participants at low, medium, or high risk of persistent disability (see

Table 5). There was an increase in the proportion of patients classed at low risk in both the internet intervention plus usual care (60% to 70%) and the internet intervention plus physiotherapist support arms (33% to 74%). The proportion of patients classified at high risk reduced to zero in the internet intervention plus physiotherapist support arm. There was little change in the risk proportions in the usual care alone arm from baseline to 3 months follow-up.

Table 5. Number of patients (%) in STarT Back subgroups at baseline and follow-up for all trial arms.

Arm	**Baseline**			**Follow up**		
	Low risk	Medium risk	High risk	Low risk	Medium risk	High risk
Usual care alone	15 (51.7%)	11 (37.9%)	3 (10.3%)	11 (47.8%)	10 (43.5%)	2 (8.7%)
Internet intervention plus usual care	17 (60.7%)	8 (28.6%)	3 (10.7%)	12 (70.6%)	3 (17.7%)	2 (11.8%)
Internet intervention plus physiotherapist support	9 (33.3%)	15 (55.6%)	3 (11.1%)	14 (73.7%)	5 (11.8%)	0

Physical activity

The IPAQ-SF data were converted to MET/mins per week and compared using medians, as the distribution of energy expenditure is known to be non-normal in many populations. The median at baseline for the sample was 2343 (IQR= 480, 5544). It is important to note that the American Heart Association recommends 450-750 MET/per week or approximately, moderate exercise for 30 minutes per day, 5 days a week.[39] A baseline median of 2343 is unexpected, and brings into question the reliability of this self-report measure of physical activity.

Process variables for the full trial

Thirty seven patients in the internet intervention arms completed the Credibility and Expectancy Questionnaire (CEQ) and the exercise self-efficacy questionnaire (ESE) (66%). The association between the CEQ score and the RMDQ score at follow up (*r*= -0.19, 95%CI -0.50 to 0.15), was in the expected direction, as was the association between ESE and number of weeks spent engaging in back-related exercise reported

at 3 months (r =0.28, 95% CI -0.08, 0.58). The Problematic Experiences of Therapy Scale (PETS) was completed by 67% [18] of patients in the internet intervention plus usual care and 70% [19] of the internet intervention plus physiotherapist support arm. The PETS is used to explore the relationship between its scores and quantitative adherence (both to the internet intervention and recommended exercises) data in large samples. As the numbers are small our main focus is on completion rates, which suggest the PETS is suitable for inclusion in a full trial.

Health economic outcomes

The hosting cost of providing access to SupportBack was assumed to be £12.50 per person, this based on predicted costs of server provision and website maintenance. Physiotherapist support was estimated at £38 per person. This gives a total intervention cost of £12.50 and £50.50 in the internet intervention plus usual care and internet intervention plus physiotherapist support arm respectively. The total mean cost for all 79 participants was £270, of which £107 (43%) was related to back pain; indicating that use of NHS services were an important cost for this group of patients (see Table 6). Our sample showed 66% of total NHS costs and 78% of back pain related costs occurred in secondary care. Due to delays related to referring and attending secondary care appointments it is likely that costs would occur after the 3-month period used in this study.

Two outcomes measures would be used in the economic evaluations alongside any future full trial; change in LBP-related disability (RMDQ) and the quality adjusted life year (QALY) evaluated using the EQ-5D 3L.[38] However, because of the variability in costs any estimates of cost-per point change in these measures would be subject to considerable uncertainty and so are not reported here. The EQ-5D was found to be strongly negatively correlated with RMDQ at both baseline and follow-up, with respective Pearson correlations of -0.594 and -0.560 (ps<0.01). This provides some support for the use of the EQ-5D in a future full trial of SupportBack for LBP. For QALYs there were only 57 cases with baseline and follow-up data for the EQ-5D and 54 that also had cost data. This was lower than response rate for RMDQ and other clinical measures. The EQ-5D was one of the last questionnaires participants completed, additionally, it was not part of the minimum data-set collected by telephone at 3 months.

Table 6. NHS costs (£, Mean (SD)) derived from computer records at participating general practices at 3 months follow-up

	Usual care alone (N=26)	Internet intervention plus usual care (N=28)	Internet intervention plus physiotherapist support (N=25)	All (excluding intervention costs) (N=79)
Intervention costs	0	12.5	50.5	
All NHS costs				
Primary Care costs*	96 (142)	85 (114)	108 (136)	96 (130)
Secondary Care - A&E	-	14 (42)	11 (53)	8 (39)
Secondary Care - O/P	116 (279)	48 (83)	87 (106)	83 (178)
Secondary Care - inpatient	59 (299)	129 (564)	101 (391)	97 (432)
Secondary Care Total	175 (490)	191 (586)	198 (483)	188 (517)
Total Costs	**271 (492)**	**289 (650)**	**357 (553)**	**284 (564)**
Back pain Costs Only				
Primary Care costs – back pain only	15 (40)	30 (73)	35 (75)	26 (64)
Secondary Care - A&E	-	-	11 (53)	3 (30)
Secondary Care - O/P	76 (251)	25 (62)	32 (69)	44 (153)
Secondary Care - inpatient	26 (132)	24 (129)	101 (391)	49 (244)
Secondary Care Total	102 (325)	50 (158)	143 (482)	96 (340)
Total Costs – Back pain only	**116 (327)**	**92 (178)**	**228 (535)**	**123 (367)**

* Primary care costs refer to GP consultations (at the surgery/home/phone.); practice nurse consultations (at the surgery/home/phone); use of other person in surgery (mainly phlebotomist); any other primary care related costs (walk in centre or phlebotomist); and costs of back pain relevant prescribing.

Harms

Six hospital admissions were reported: 2 (internet intervention plus physiotherapist support arm), 2 (internet intervention plus usual care), 2 (usual care alone). One case of suspected cauda equine syndrome was detected towards the end of the trial in the physiotherapist support arm (immediate clinical treatment was received, L5/S1 discectomy performed), and 5 admissions were identified from patient general practice medical record reviews: 1 for a facet joint injection, 1 for a haemoarthrosis, 1 for lumbar screening and injection, 1 for an epidural steroid injection, and 1 unrelated serious adverse event. We think it is very unlikely that the gentle activity advice offered by the internet intervention would lead to any of the above, but it is not possible to rule out; all Serious Adverse Reactions were reported to the trials' Research Ethics Committee.

DISCUSSION

We believe this is the first trial of an internet intervention specifically designed for patients with LBP consulting in general practice. Overall, the trial design was found to be feasible and the success criteria [17] were met; the target number of patients were recruited within the trial timeframe; the majority of patients were exposed to core active internet intervention content; the telephone support physiotherapists adhered to the protocol, and acceptable levels of retention were achieved for the key clinical outcomes at 3 months follow-up. Caution is required when interpreting the exploratory analysis of clinical outcomes as, due to the feasibility aims of this trial, it was not powered to determine effectiveness. The reduction of 2.4 points on the RMDQ for the internet intervention plus physiotherapist support arm compared to usual care alone at 3 months follow-up, provides an indication of the potential importance of remote, brief healthcare professional support for primary care patients with LBP. Reductions in LBP-related disability compared to usual care alone were smaller when the internet intervention was delivered without support.

The trial design had a number of strengths. The internet intervention was provided in addition to and compared with unrestricted usual care. This pragmatic design will enable evaluation of the incremental value of the interventions in addition to the existing full range of LBP healthcare available. Use of outcomes recommended as core outcome domains for LBP [40] will enable comparison with other non-digital interventions; previous studies of internet interventions for LBP have used a heterogeneous range of outcome measures.[13] To our knowledge this is the first trial to integrate brief physiotherapist telephone support with an internet intervention specifically designed for LBP patients. Physiotherapists are ideally placed to support LBP interventions with a central focus on physical activity, and this trial demonstrates the feasibility of a guided digital approach for the management of a prevalent musculoskeletal condition in primary care.

We identified some limitations to be addressed in the full trial: Encouraging physical activity was a core focus of SupportBack. The high median MET minutes of physical activity reported by patients at baseline on the IPAQ-SF appears to reflect a substantial overestimation, severely limiting the scales potential for detecting change in physical activity over the course of the trial. Despite the IPAQ-SF remaining the most widely used self-report measure of physical activity,[41] overestimation is frequently

reported.[42] Objective measures such as accelerometers can be intrusive, costly when needed in large numbers, and there are still questions over accuracy.[43] Consequently, for the full trial it may be best to provide additional support for accurate reporting on the IPAQ-SF at baseline (e.g. through providing worked examples). Our sample had a lower mean RMDQ score than other trials for LBP in primary care,[44] with approximately 30% reporting an RMDQ score of ≥4 at baseline. This may be a function of the 6 month recruitment window from patients' LBP consultation, our broad inclusion criteria (experience of LBP in the last two weeks) and the low intensity nature of the interventions on offer. For the full trial we will amend our recruitment strategy to recruit patients closer to their consultation at participating practices. We will also amend our recruitment procedure aiming at improving efficiency, working to ensure more of those invited are screened and more of those screened are eligible. Follow-up rates differed between the 3 arms, with the lowest rates in the internet intervention plus telephone support arm. In the main trial follow-up rates will be closely monitored to ensure they remain above 80% across all 3 arms. Finally, the randomisation was unbalanced on some demographic and clinical variables. This was likely a function of the small numbers in each arm, and would be expected to balance out with the numbers required (approx. 200+ per arm) for a full trial. Nevertheless, differences at baseline should be considered when interpreting the exploratory findings with variables including troublesome days in pain and risk of persistent disability.

Health economic evaluations of digital health interventions can be complex. A recent paper has discussed these complexities inherent in costing digital health interventions, such as SupportBack, highlighting the importance of considering ongoing costs and benefits of digital interventions.[45] For costing future implementation it would be important to identify any hosting costs as well as documenting any additional development costs needed and whether any of these would be ongoing (to keep the intervention up to date). We would also propose sensitivity analysis to allow for different assumptions as to the number of people who will use the intervention as this affects the estimate of unit cost. As this was a small-scale feasibility trial, there was considerable uncertainty caused by a small number of high cost items such as inpatient stays. As well as substantially increasing participants, in the full trial the EQ-5D will be collected after the RMDQ and included in the minimum data-set phone calls, and follow-up will occur at regular intervals over a 12-month period. Finally, potential future benefit should be considered and assessed where possible beyond the perspective of the trial timeframe; since LBP tends to be recurrent coping strategies learned from SupportBack might help prevent or manage back pain recurrence.

To conclude, digital approaches with and without healthcare professional support have the potential to offer an accessible means of effectively supporting behavioural self-management. We have shown that the SupportBack intervention is acceptable to patients with LBP presenting to primary care, and demonstrated the feasibility of a future definitive randomised controlled trial aimed at determining its clinical and cost effectiveness.

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Ethics approval: NHS Research Committee, REC Reference: 13/SC/020

Contributors: LY, AWAG and PL conceived the idea for the study. AWAG, LY, PL, LR, NEF, EMH and JCH designed the trial and secured funding. RS and AWAG developed the internet intervention with LY and LR, with further input from NEF, JCH, EMH, PL and LL. LY, AG, LR, JCH, NEF, developed the physiotherapy telephone support package. RS managed the trial on a day-to-day basis with oversight from AG, PL, LR, LY and input from NEF, JCH, EMH and LL. BS, DT, WM planned and carried out the statistical and health economic analysis. AWAG drafted the manuscript with input from all authors, AWAG is the guarantor for the data.

Data sharing statement: The datasets generated during the current study are available from the corresponding author on reasonable request.

REFERENCES

1. Hoy D, March L, Brooks P et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis. 2014;73:968-974.
2. Andersson GB. Epidemiological features of chronic low-back pain. Lancet. 1999;354:581-585.
3. Maniadakis N, Gray A. The economic burden of back pain in the UK. Pain. 2000;84:95-103.
4. Freburger JK, Holmes GM, Agans RP et al. The rising prevalence of chronic low back pain. Arch Intern Med. 2009;169:251-258.
5. Gore M, Sadosky A, Stacey BR, Tai KS, Leslie D. The burden of chronic low back pain: clinical comorbidities, treatment patterns, and health care costs in usual care settings. Spine (Phila Pa 1976). 2012;37:E668-77.
6. Excellence NIFHAC. Low back pain: Early management of persistent non-specific low back pain. Clinical Guideline 134. London: Nice; 2009
7. Machado GC, Maher CG, Ferreira PH et al. Efficacy and safety of paracetamol for spinal pain and osteoarthritis: systematic review and meta-analysis of randomised placebo controlled trials. BMJ. 2015;350:h1225.
8. Mallen C, Hay E. Managing back pain and osteoarthritis without paracetamol. BMJ. 2015;350:h1352.
9. Crofford LJ. Adverse effects of chronic opioid therapy for chronic musculoskeletal pain. Nat Rev Rheumatol. 2010;6:191-197.
10. Salisbury C, Foster NE, Hopper C et al. A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of 'PhysioDirect' telephone assessment and advice services for physiotherapy. Health Technol Assess. 2013;17:1-157, v.
11. Current Issues and Future Directions for Research Into Digital Behavior Change Interventions. [editorial]. Am J Prev Med 2016;51(5):814.
12. Butler L, Foster NE. Back pain online: a cross-sectional survey of the quality of web-based information on low back pain. Spine (Phila Pa 1976). 2003;28:395-401.
13. Garg S, Garg D, Turin TC, Chowdhury MF. Web-Based Interventions for Chronic Back Pain: A Systematic Review. J Med Internet Res. 2016;18:e139.
14. Buhrman M, Faltenhag S, Strom L, Andersson G. Controlled trial of Internet-based treatment with telephone support for chronic back pain. Pain. 2004;111:368-377.
15. Buhrman M, Nilsson-Ihrfeldt E, Jannert M, Strom L, Andersson G. Guided internet-based cognitive behavioural treatment for chronic back pain reduces pain catastrophizing: a randomized controlled trial. J Rehabil Med. 2011;43:500-505.

16. Carpenter KM, Stoner SA, Mundt JM, Stoelb B. An online self-help CBT intervention for chronic lower back pain. Clin J Pain. 2012;28:14-22.

17. Geraghty AWA, Stanford R, Little P et al. Using an internet intervention to support self-management of low back pain in primary care: protocol for a randomised controlled feasibility trial (SupportBack). BMJ Open. 2015;5:e009524.

18. Andersson G, Cuijpers P. Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. Cogn Behav Ther. 2009;38:196-205.

19. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behavior change interventions. J Med Internet Res. 2015;17:e30.

20. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. Spine (Phila Pa 1976). 2000;25:3115-3124.

21. Dunn KM, Croft PR. The importance of symptom duration in determining prognosis. Pain. 2006;121:126-132.

22. Hill JC, Dunn KM, Lewis M et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. Arthritis Rheum. 2008;59:632-641.

23. Little P, Lewith G, Webley F et al. Randomised controlled trial of Alexander technique lessons, exercise, and massage (ATEAM) for chronic and recurrent back pain. BMJ. 2008;337:a884.

24. Goubert L, Crombez G, Van Damme S, Vlaeyen JW, Bijttebier P, Roelofs J. Confirmatory factor analysis of the Tampa Scale for Kinesiophobia: invariant two-factor model across low back pain patients and fibromyalgia patients. Clin J Pain. 2004;20:103-110.

25. Sullivan M, Bishop SR, Pivik J. The pain catastrophizing scale: User manual. 2009

26. Craig CL, Marshall AL, Sjostrom M et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc. 2003;35:1381-1395.

27. Howie JG, Heaney DJ, Maxwell M, Walker JJ. A comparison of a Patient Enablement Instrument (PEI) against two established satisfaction scales as an outcome measure of primary care consultations. Fam Pract. 1998;15:165-171.

28. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. J Behav Ther Exp Psychiatry. 2000;31:73-86.

29. Resnick B, Palmer MH, Jenkins LS, Spellbring AM. Path analysis of efficacy expectations and exercise behaviour in older adults. J Adv Nurs. 2000;31:1309-1315.

30. Tijou I, Yardley L, Sedikides C, Bizo L. Understanding adherence to physiotherapy: findings from an experimental simulation and an observational clinical study. Psychol Health. 2010;25:231-247.
31. Kirby S, Donovan-Hall M, Yardley L. Measuring barriers to adherence: validation of the problematic experiences of therapy scale. Disabil Rehabil. 2014
32. Brooks R, Rabin R, De Charro F. The measurement and valuation of health status using EQ-5D: a European perspective: evidence from the EuroQol BIO MED research programme. Berlin: Springer Science & Business Media; 2003
33. Curtis L, Burns A. Unit costs of health and social care 2015. 2015
34. Department of Health. NHS Reference costs 2014-15. 2014. Retrieved from https://www.gov.uk/government/publications/nhs-reference-costs-2014-to-2015
35. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics. 2005;4:287-291.
36. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. J Clin Epidemiol. 2012;65:301-308.
37. Stratford PW, Binkley JM, Riddle DL, Guyatt GH. Sensitivity to change of the Roland-Morris Back Pain Questionnaire: part 1. Phys Ther. 1998;78:1186-1196.
38. Brooks R. EuroQol: the current state of play. Health Policy. 1996;37:53-72.
39. Haskell WL, Lee IM, Pate RR et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. Med Sci Sports Exerc. 2007;39:1423-1434.
40. Chiarotto A, Deyo RA, Terwee CB et al. Core outcome domains for clinical trials in non-specific low back pain. Eur Spine J. 2015;24:1127-1142.
41. Lee PH, Macfarlane DJ, Lam TH, Stewart SM. Validity of the International Physical Activity Questionnaire Short Form (IPAQ-SF): a systematic review. Int J Behav Nutr Phys Act. 2011;8:115.
42. Hallal PC, Gomez LF, Parra DC et al. Lessons learned after 10 years of IPAQ use in Brazil and Colombia. J Phys Act Health. 2010;7 Suppl 2:S259-64.
43. Napolitano MA, Borradaile KE, Lewis BA et al. Accelerometer use in a physical activity intervention trial. Contemporary Clinical Trials. 2010;31:514-523.
44. Hill JC, Whitehurst DG, Lewis M et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet. 2011;378:1560-1571.
45. McNamee P, Murray E, Kelly MP et al. Designing and Undertaking a Health Economics Study of Digital Health Interventions. Am J Prev Med. 2016;51:852-860.

Figure legends

Figure 1. SupportBack patient flow diagram

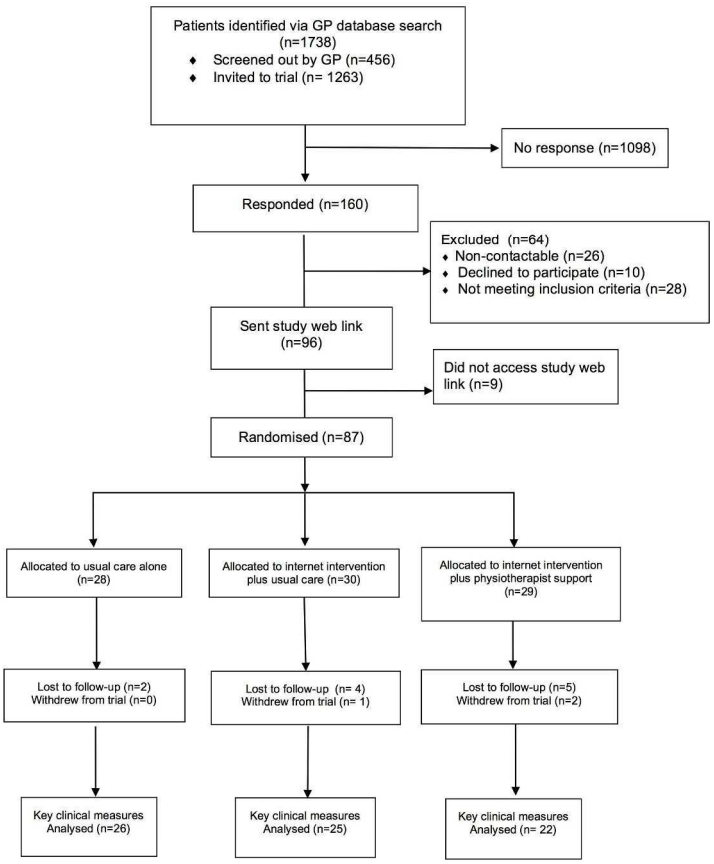

Figure 1. SupportBack patient flow diagram

209x297mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	8
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	8
Sample size	7a	Rationale for numbers in the pilot trial	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	10

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	10
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	See Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	See Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the pilot trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12-13
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	11-20
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	11-20
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	11-20
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	21
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	22
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	22-23
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	22-23
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	22-23
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2
Protocol	24	Where the pilot trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24
	26	Ethical approval or approval by research review committee, confirmed with reference number	24

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*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Using an internet intervention to support self-management of low back pain in primary care: Findings from a randomised controlled feasibility trial (SupportBack)

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Using an internet intervention to support self-management of low back pain in primary care: Findings from a randomised controlled feasibility trial (SupportBack)

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ABSTRACT

Objective: To determine the feasibility of a randomised controlled trial of an internet intervention for low back pain (LBP) using 3 arms: 1) usual care, 2) usual care plus an internet intervention or 3) usual care plus an internet intervention with additional physiotherapist telephone support.

Design and setting: A three-armed randomised controlled feasibility trial conducted in 12 general practices in England.

Participants: Primary care patients aged over 18, with current LBP, access to the internet, and without indicators of serious spinal pathology or systemic illness.

Interventions: The 'SupportBack' internet intervention delivers a 6-week, tailored programme, focused on graded goal setting, self-monitoring, and provision of tailored feedback to encourage physical activity. Additional physiotherapist telephone support consisted of three brief telephone calls over a 4-week period, to address any concerns and provide reassurance.

Outcomes: The primary outcomes were the feasibility of the trial design including recruitment, adherence and retention at follow-up. Secondary descriptive and exploratory analyses were conducted on clinical outcomes including LBP-related disability at 3 months follow-up.

Results: Primary outcomes: 87 patients with LBP were recruited (target 60-90) over 6 months, and there were 3 withdrawals. Adherence to the intervention was higher in the physiotherapist-supported arm, compared to the stand-alone internet intervention. Trial physiotherapists adhered to the support protocol. Overall follow-up rate on key clinical outcomes at three months follow-up was 84%.

Conclusions: This study demonstrated the feasibility of a future definitive randomised controlled trial to determine the clinical and cost effectiveness of the SupportBack intervention in primary care patients with LBP.

Trial registration: ISRCTN 31034004

Key words: Low back pain; internet intervention; self-management; primary care

STRENGHTS AND LIMITATIONS OF THIS STUDY

- This is the first pragmatic feasibility trial examining an internet intervention specifically designed for patients with LBP consulting in general practice.
- The feasibility of two methods of delivery was determined; providing the internet intervention with and without telephone physiotherapist support.
- Follow-up was relatively short at 3 months; it is unclear whether response rates would remain similar at additional follow-up points necessary for a definitive trial.

BACKGROUND

Low back pain (LBP) causes more global disability than any other condition,[1] and has a lifetime prevalence of up to 85%.[2] The economic costs of LBP have been reported at £12.3 billion per annum in the UK alone.[3] In those who consult in primary care, pain trajectories often remain stable, with patients who report persistent-mild to persistent-severe pain, often remaining in the same pain grouping at 7-year follow-up.[3] Chronic LBP, with a prevalence of 3-10%,[4] is associated with depression, anxiety, deactivation, inability to work and substantial societal costs.[2, 5]

The recently updated National Institute for Health and Care Excellence (NICE) guidelines for managing LBP continue to state the importance of self-management and advice to remain active.[6] Identifying effective means to support behavioural self-management is becoming increasingly important; a recent review questioned the effectiveness of paracetamol for spinal pain,[7, 8] and concerns continue to grow regarding the adverse effects of prescriptions for opioid-related painkillers.[9] In primary care, General Practitioners (GPs) are unlikely to have the time or the training to deliver effective self-management support, and access to NHS services such as physiotherapy are often limited, with long waiting times for patients.[10] There is a critical need for novel interventions enabling primary care practitioners to provide their LBP patients with immediate access to evidence-based, accessible self-management advice and support.

Internet interventions are automated, structured programmes delivering tailored advice over time through text and audio-visual content.[11] They differ from simple health information webpages, which in the case of LBP are abundant and often of low quality.[12] Internet interventions may offer a useful resource for primary care practitioners to draw on. Research on internet interventions for LBP is at an early stage: A recent systematic review of nine randomised controlled trials (RCTs) of internet interventions for chronic LBP [13] concluded that despite showing some promise, many of the trials were limited by small samples sizes,[14, 15] comparisons to waiting lists or no treatment controls,[16] and researchers rarely considered healthcare resource use.[13] To our knowledge, there have been no trials of internet interventions developed specifically for patients with LBP consulting in primary care. As primary care practitioners see the full spectrum of patients with LBP, ideal interventions for this context would offer effective self-management advice for those with acute, recurrent and chronic presentations, facilitating simple implementation.

'SupportBack' is an internet intervention specifically developed by our team for patients with LBP consulting in primary care using a theory-, evidence- and person-based approach.[17] Its central focus in enabling people to manage their LBP, is to support appropriate engagement in physical activity. It is also designed to contain simple advice and behaviour change support/techniques for a range of clinical presentations (e.g. acute or subacute) through effective reassurance for common concerns (such as the misconception, hurt equals harm), as well as providing elements that those with more chronic LBP may find helpful (e.g. managing low mood, fear-avoidance, challenges with work, and poor sleep). Brief additional human support often improves outcomes when added to internet interventions [18] and SupportBack has been designed to be delivered either as a stand-alone intervention, or with additional brief telephone support from a physiotherapist.

In order to determine the effectiveness of digital approaches such as SupportBack, pragmatic trials are required that examine these interventions in addition to, and compared to, usual primary care for LBP. The aim of this study was to determine the feasibility of delivering the SupportBack intervention in addition to usual care to patients with LBP consulting in general practice, with or without brief physiotherapist telephone support, compared to usual care alone. We aimed to determine the feasibility of RCT procedures alongside the acceptability, uptake and use of the interventions, as well as preliminarily exploring key clinical and economic outcomes in order to inform a future full trial.

METHOD

Design

We conducted a three-parallel arm, single centre feasibility RCT of the SupportBack internet intervention for LBP in primary care. The full details of the method and interventions can be found in the published trial protocol.[17]

Participants

Patients were included in the trial if they had current LBP (experienced pain within the last two weeks); had access to the internet; had consulted their general practice with LBP within the last 6 months; could read/understand English without assistance. Patients were excluded if they were under 18 years of age; had clinical indicators of (suspected) spinal pathology such as infection, fracture or cancer; or had taken part in

an earlier study to develop the intervention. Pregnancy was added to the exclusion criteria after the trial had begun.

Recruitment

The local Clinical Research Network (CRN) facilitated recruitment of general practices. Within practices, potentially eligible patients were identified by searching computerised lists of LBP consultations from the last 6 months. The resulting lists were screened by a practice GP who excluded patients who did not fulfil the eligibility criteria as determined from patients' notes. Practice staff sent out study packs to the remaining patients containing options for interested patients to contact the research team. Study packs were also provided to practices for opportunistic recruitment within LBP consultations. Interested patients who contacted the research team underwent a secondary telephone screen by a study manager, who asked about their current LBP and screened a list of 12 key symptoms that may indicate serious spinal pathology or systemic illness (see [17]). Patients answering yes to any symptoms were discussed with a clinician in the research team and referred back to their GP where appropriate. Those patients who remained eligible were sent a link to the study website, where they provided online consent, completed all baseline measures and were then randomised to one of the three trial arms. Recruitment opened in February 2015 and closed in September 2015. The follow-up period ended in January 2016.

Interventions

Usual care:

Those patients allocated to this arm continued to receive usual care for their LBP over the trial period. This care was unrestricted and could vary substantially; for example, patients who did not re-consult at their general practice may not have received care beyond their initial consultation, whereas others may have accessed a range of treatment including physiotherapy or pain clinics.

Internet intervention plus usual care:

Patients allocated to the internet intervention arm continued to receive unrestricted usual care for LBP. In addition, patients received access to SupportBack, a tailored multi-session internet intervention designed to support self-management of LBP, developed by our team using LifeGuide software (www.lifeguideonline.org). SupportBack has been described in more detail elsewhere.[17] In brief, the intervention focuses on self-regulatory processes including goal setting, self-monitoring and tailored feedback to support physical activity. There is also a focus on cognitive reassurance

and self-efficacy for activity in the presence of pain throughout; addressing concerns with evidence-based feedback and modelling success through patient activity stories. SupportBack was developed using the Person-Based Approach [19] incorporating systematic, in-depth, qualitative research with 22 patients and community volunteers with experience of LBP.

The intervention has six sessions, and it was recommended that patients complete one session per week for six weeks. The first session introduces the rationale for physical activity being key in the self-management of LBP and allows patients to select goals for the next week. Goals options, including gentle back exercises or walking, are automatically tailored, based on how patients report their LBP is affecting their functioning at the time. Each of the following five sessions consists of patients reviewing and amending their activity goals for the coming week with automatic feedback. From session two onwards, after the goal review, patients have access to one new module per week from the SupportBack menu. The modules on the menu focus on a broad range of LBP related topics including: mood; managing pain at work; sleep; relieving pain through medication and dealing with flare-ups. The broad aim of the intervention is to support patients to become their own expert in self-managing their LBP, thus strategies learnt (e.g. remaining active during fair-ups) could also be used to manage LBP in the future and reduce the severity of recurrences. Patients used SupportBack without support from a health professional in this arm of the trial. They received automated weekly email reminders to log in, and any technical difficulties were addressed by the study manager. Patients were able to access the SupportBack internet intervention at any time over the trial period and from wherever was most convenient.

Internet intervention plus physiotherapist telephone support plus usual care:
Patients in this arm continued to receive unrestricted usual care for LBP and had access to the SupportBack intervention as above. In addition, those in this arm received up to a total of 1 hour of physiotherapist telephone support, split into 3 calls, with approximately 30 minutes for call 1, and 15 minutes for calls 2 and 3. The calls were designed to be delivered approximately after week 1, between weeks 2-3 and after week 4. The purpose of the physiotherapists' calls was to provide support and encouragement to participants to use the SupportBack internet intervention, to address participants' concerns and provide additional reassurance. Two senior musculoskeletal physiotherapists (male and female, NHS Bands 6 and 7) provided the telephone support. They worked through a standardised checklist for each phone

call (available on request from the corresponding author), and although they were able to address individual patient concerns, they were asked not to provide additional recommendations beyond the content of the internet intervention. Their fidelity to the study protocol was evaluated by audio-recording a sample of 20 telephone consultations.

Outcomes and measures

The primary outcomes for this trial were descriptive, focusing on the feasibility of the trial design and intervention delivery, including: recruitment of general practices; recruitment of patients within the allocated timeframe of the trial; suitability of eligibility and screening criteria; withdrawals and retention at follow-up at 3 months; usage of the internet intervention and self-reported activity adherence; delivery and uptake of the telephone support along with any significant issues encountered.

The success criteria for the feasibility trial, as published in the protocol,[17] are listed below:

- *Recruiting a minimum of 60 patients with LBP, access to the internet and without indicators of serious spinal pathology from primary care within the allotted recruitment time period for the trial.*
- *Attrition at 3 months follow-up should be equal to or lower than 30% from all trial arms.*
- *By examining the recordings, the telephone support physiotherapists are able to deliver the telephone sessions in line with the protocol, covering approximately 2/3 of the checklist in each call.*
- *Patients should be able to access the intervention and complete measures, complete session 1 and set goals for future sessions.*
- *Qualitative and quantitative data should indicate that the intervention and trial procedures are acceptable to patients (acceptability referring to completion of questionnaires, retention, and appropriate use of the intervention). Qualitative data will be reported elsewhere.*

All self-reported measures were collected online using LifeGuide software at baseline. At 3 months post-randomisation, measures were primarily collected online, non-response triggered additional follow-up methods including email reminders, paper questionnaires being posted, and a telephone call from a blinded independent research assistant to collect key outcomes only. Demographic data collected included gender,

age, education, occupation, income and marital status. A range of LBP-related measures were collected: LBP-related physical disability was measured using the Roland and Morris Disability Questionnaire (RMDQ [20]), an outcome likely to be a primary outcome in a future full trial; pain duration was measured by asking about time since the last pain free month;[21] pain intensity was measured using three numerical rating scales (NRS) measuring current, average and least pain over the last two weeks as well as a mean of the 3 as a pain index;[22] number of troublesome days in pain over the last month was measured with a single item;[23] risk of persistent disability was measured using the STarT Back tool;[22] fear of movement was measured using the Tampa Scale for Kinesiophobia (TSK, [24]); catastrophising beliefs were measured using the Pain Catastrophising Scale (PCS, [25]). Self-reported physical activity was measured using the International Physical Activity Questionnaire Short Form (IPAQ-SF),[26]) and questions about numbers of weeks, and times per week people did specific activities or went walking to help their back pain were asked at 3 months follow-up. Enablement was measured using a modified patient enablement instrument .[27]

Adherence to the internet intervention was examined by using LifeGuide-generated data on SupportBack sessions started and completed. Psychological process variables including patients' expectations of positive outcome were measured using a modified brief Credibility and Expectancy Questionnaire (CEQ) [28] at baseline across all arms, and the full CEQ was completed after session one in the two internet intervention arms. Exercise self-efficacy was also measured after session one in the two internet intervention arms.[29, 30] The Problematic Experiences of Therapy Scale (PETS, [31]) was used to measure difficulties with adherence to recommended exercises.

To determine the feasibility of collecting health economic measures for a cost effectiveness analysis in a future full trial, a GP notes review was conducted and health-related quality of life was measured using the EQ-5D 3L.[32] Resource use was costed using published sources of unit cost data.[33, 34] Identified resource use was costed using 2014/15 UK pound sterling.

Sample size

The target for this trial was to recruit between 60-90 patients overall, with 20-30 per arm. Guidance for sample size in feasibility trials varies with numbers ranging from 12-30+ per arm.[35, 36] A sample of not less than 60 overall allowed for the assessment of the primary feasibility outcomes including recruitment, adherence and retention.

Randomisation and blinding

Randomisation was fully automated by the internet intervention software (LifeGuide). The randomisation sequence was generated within the software and concealed from the trial team. An automated algorithm block randomised patients to the three trial arms. Patients were stratified by severity of physical disability (measured by the RMDQ ≥ 7). Patients were notified of their allocated arm automatically by the LifeGuide software. Due to the behavioural nature of the intervention, it was not possible to blind patients to interventions. The study manager allocated patients to physiotherapists and therefore was not blind to allocation. All telephone outcome data were collected by an independent blinded research assistant. The trial statistician remained blind until the analysis was finalised. More detail on randomisation can be found in the protocol.[17]

Analysis

The primary analysis for this trial focused on a description of the key feasibility outcomes including numbers of general practices recruited; patient eligibility and recruitment rates; withdrawals; response to follow-up at 3 months. Use of the internet intervention was described by reporting numbers of sessions started and completed per arm. Delivery of physiotherapist telephone support was described in terms of the number of calls successfully made and mean/modal calls per patient. Fidelity of the telephone support was examined by selecting a random sample of 30% of the verbatim transcripts of the calls and physiotherapist completed call check sheets. As detailed in the protocol,[17] the check sheets contained recommended topics to be covered in each call, acknowledging that not all topics may be appropriate. AWAG examined the transcript-check sheet pairs examining correspondence of topics covered in each case. Any major deviation was noted.

Descriptive statistics were used to identify any floor or ceiling effects. Means and/or medians, standard deviations and 95% confidence intervals were reported for the measures. Exploratory quantitative analyses were conducted on patients' clinical, activity and psychological process measures. In addition to analyses reported in the protocol, linear regression models, controlling for baseline covariates (each outcome at baseline, gender, age, marital status, employment status, income, ethnicity and age left education), were used to explore between group differences in continuous outcome measures (e.g. RMDQ, numerical pain rating scale). Continuous outcomes were modelled using a linear model if they met the underlying assumptions that the outcome

measure and the residuals were normally distributed. Where these assumptions were not met, a non-parametric quantile regression was used.[37] As this was a feasibility trial the objective was not hypothesis testing, rather these analyses allowed for preliminary examination of trends in between-group comparisons. The analysis was undertaken on an intention to treat basis, analysing participants in the group to which they had been randomised, and comprised complete cases only. Proportions of patients achieving a minimal clinically important difference (MCID) was described. In this trial, a MCID was classified as a reduction of 2 points on the RMDQ compared to usual care alone.[38] Spearman correlations with 95% confidence intervals were used to explore the relationship between psychological process measures such as expectancy and exercise self-efficacy on LBP-related disability and adherence to physical activity.

Health economic analysis at this stage was descriptive. We aimed to report estimates of cost and outcomes measures and baseline and follow-up. The methods of collecting health economics data were similar to the methods that would be used in a future full RCT. NHS related costs were estimated from computer records in participating general practice. Estimates were made of the cost of making access to SupportBack and the costs of providing nurse support as per protocol. These costs were recorded over the 3-month follow-up period. Resources identified were combined with relevant unit costs [33, 34]. Outcomes for use within the economics evaluation were change in LBP-related disability (RMDQ) and the quality adjusted life year (QALY) evaluated using the EQ-5D 3L.[39]

RESULTS

Recruitment and retention

The CRN received expressions of interest to take part in the trial from 27 practices, of which 4 were initially approached and recruited, this was increased to 12 following close monitoring of initial recruitment rates. 1263 trial invitation letters were sent from the 12 participating practices to potentially eligible patients. 160 responses were received. Of these, 87 patients with LBP met the eligibility criteria after further telephone screening and were randomised over a 6-month period. This translated to a recruitment rate of 14-15 patients per month, and approximately 7 patients randomised per practice over a total of 6 months. Three patients withdrew over the course of the trial: 1 from the internet intervention plus usual care arm (no reason given), 2 from the

internet intervention plus physiotherapist support arm (1. due to illness, 2. due to family bereavement). The overall follow-up rate for the key clinical outcomes was 84% (73/87) at 3 months, and varied between arms: usual care = 93%, internet intervention plus usual care = 83%, internet intervention plus physiotherapist support = 76%. See Figure 1 for patient flow through the trial.

[INSERT FIGURE 1 ABOUT HERE]

Patient characteristics

Eighty-four participants provided baseline data. Table 1 shows participant characteristics across the three trial arms. Demographic characteristics were generally similar across the arms, with some exceptions including greater numbers of retired participants in the usual care alone arm. With regard to clinical variables at baseline, LBP-related disability (measured by the RMDQ) was similar across arms. Taken together, the RMDQ, pain numerical rating scales and STarT back scores indicate slightly higher severity in those randomised to the internet intervention plus physiotherapist support arm. Pain duration, measured as time since last pain free month, was similar across arms. Number of troublesome days in pain over the last four weeks differed substantially; from a median of 10 in the usual care alone arm to 18 in the internet intervention plus physiotherapist support arm.

Table 1. Baseline characteristics

Variable	Usual care (n=27)	Internet intervention plus usual care (n=29)	Internet intervention plus physiotherapist support (n=27)
Female	15 (55.6%)	19 (65.2%)	17 (63.0%)
Age	60.3 (16.3)	54.5 (13.7)	59.3 (10.4)
Marital Status			
- Married/partner	23 (85.2%)	19 (65.5%)	22 (81.5%)
- Single	3 (11.1%)	4 (13.8%)	2 (7.4%)
- Divorced/separated	0	5 (17.2%)	1 (3.7%)
- Widow/widower	1 (3.6%)	1 (3.6%)	2 (7.4%)
White ethnicity	27 (100%)	26 (92.9%)	27 (100%)
Age left education	17.6 (2.7)	17.3 (1.7)	17.6 (2.8)
Employment status			
- Full time	7 (25.9%)	12(41.8%)	6 (22.2%)
- Part time	2 (7.4%)	4 (13.8%)	8 (29.6%)
- Retired	13 (48.2%)	6 (20.7%)	8 (29.6%)
- Self-employed	2 (7.4%)	3 (10.3%)	4 (14.8%)

- Sickness/disability	2 (7.4%)	2 (6.9%)	1 (3.7%)
- Other	1 (3.7%)	2 (6.9%)	0
Annual income (up to £)			
- 10,000	2 (7.4%)	4 (14.3%)	3 (11.5%)
- 20,000	7 (25.9%)	6 (21.4%)	3 (11.5%)
- 40,000	9 (33.3%)	9 (32.1%)	10 (38.5%)
- > 40, 000	9 (33.3%)	9 (32.1%)	10 (38.5%)
Expectations re improvement in LBP	5.86 (1.88)	5.22 (2.06)	5.74 (2.19)
Expected percentage improvement in LBP (Item from the CEQ)	43.21% (25.53)	41.92% (21.17)	37.40% (25.50)
Median days of pain in the last 4 weeks (IQR) (Item from the CEQ)	10 (6, 25)	10 (4, 21)	18 (5, 28)
Time since you had a whole month without pain			
- Less than 3 months	5 (17.2%)	6 (21.4%)	5 (19.2%)
- 3-6 months	1 (3.5%)	2 (7.1%)	4 (15.4%)
- 7-12 months	5 (17.2%)	4 (14.3%)	6 (23.1%)
- 1-2 years	7 (24.1%)	4 (14.3%)	5 (19.2%)
- 3-5 years	4 (13.8%)	4 (14.3%)	3 (11.5%)
- 6-10 years	2 (6.9%)	4 (14.3%)	3 (11.5%)
- Over 10 years	5 (17.2%)	4 (14.3%)	0
LBP-related disability (RMDQ) mean (SD)	6.8 (4.9)	6.6 (4.6)	7.7 (4.7)
STarT Back risk group			
- Low	16 (57.1%)	19 (67.9%)	14 (51.9%)
- Medium	11 (39.3%)	6 (21.4%)	12 (44.4%)
- High	1 (3.8%)	3 (10.7%)	1 (3.7%)

Adherence outcomes

Table 2 shows the percentages of participants starting and completing sessions of the SupportBack internet intervention. Both the percentages starting and completing sessions tended to be higher in the internet intervention plus telephone support arm. For all sessions, those starting a session tended to complete it, with the exception of the internet intervention plus usual care arm in session 1. Overall, 11.1% (3/27) of those in the internet intervention plus telephone support arm and 29.6% (8/27) of patients in the internet intervention plus usual care arm partially completed session 1 and did not return to the internet intervention over the duration of the trial.

At follow-up, participants were also asked about activities they engaged with to help their LBP (walking or back exercises). All participants provided this data, serving as an indication of self-reported activity adherence in the internet intervention arms, and

providing data about levels of activity in the usual care alone arm. The responses are tabulated in Table 3. Most participants regardless of arm allocation reported spending 9-12 weeks going for walks or doing back exercises and did so regularly (4+ days per week).

	Start S1	Com. S1	Start S2	Com. S2	Start S3	Com. S3	Start S4	Com. S4	Start S5	Com. S5	Start S6	Com. S6
Int. interven*	89%	54%	61%	57%	54%	50%	46%	43%	36%	36%	32%	32%
Int. interven+ support**	82%	70%	85%	70%	82%	78%	59%	56%	48%	48%	41%	41%

Table 2. Percentages starting (Start) and completing (Com.) internet intervention sessions (S)

* Internet intervention plus usual care
** Internet intervention plus physiotherapist support

Table 3. Tabulation of self-reported LBP-related activities

	Usual care alone (n=14)	**Internet intervention plus usual care (n=16)**	**Internet intervention plus telephone support (n=19)**
How many weeks spent doing back exercises or going for walks?			
• Never started	2 (14.3%)	0	0
• 1 week	0	0	0
• 1-2 weeks	0	1 (6.3%)	1 (5.3%)
• 3-5 weeks	3 (21.4%)	6 (37.5%)	4 (21.1%)
• 6-8 weeks	1 (7.1%)	2 (12.5%)	5 (26.3%)
• 9-12 weeks	8 (57.1%)	7 (43.7%)	9 (47.4%)
How many times a week did you do back exercises or go for walks?			
• Never started	2 (14.3%)	0	0

• 1 day	1 (7.1%)	2 (12.5%)	1 (5.3%)
• 2-3 days	2 (14.3%)	5 (31.3%)	2 (10.5%)
• 4-5 days	5 (35.7%)	4 (25.0%)	7 (36.8%)
• Every day	4 (28.6%)	5 (31.3%)	9 (47.4%)

Note. Numbers are lower as these variables were not part of minimum data collection over the telephone at 3 months follow-up with telephone follow-up

Physiotherapist telephone support

Support telephone calls were made to 25/29 (86%) participants who were randomised to this arm. For those that did not receive calls, 3 participants were uncontactable despite multiple call attempts made by the physiotherapists (2 of 3 continued to use the internet intervention alone), and 1 participant was not allocated a physiotherapist due to an administrative error. This was discovered at the end of the trial through the qualitative interview with this participant. This individual continued to use the internet intervention alone.

For the 25 patients receiving physiotherapist support calls, the mean number of calls made was 2.4 (*SD* = 1.03, mode = 3). Mean call durations were 17.3 minutes (*SD* = 8.5) for call 1, and 11.5 (*SD* = 6.2) and 11.9 (*SD* = 6.2) minutes for calls 2 and 3 respectively. From the 65 connected calls made, a random sample of 20 calls (30%) were selected to examine fidelity using verbatim transcripts of the calls and physiotherapist completed call check sheets. At least two thirds of the recommended topics were covered in 19 of the calls checked (95%).

Clinical outcomes/measures

Mean physical disability measured by RMDQ score, was 6.9 *(SD* = 5.5) across the trial arms at baseline. From the 84 participants who provided RMDQ data at baseline, 73 (84%) provided a response at 3 months follow-up. Of these, 27 (34.2%) were contacted by telephone or completed a paper questionnaire follow-up pack. Exploratory analysis of RMDQ scores showed, on average, participants in all three arms improved between baseline and follow-up (see Table 4). The internet intervention plus usual care arm improved by 0.6 points more than usual care alone, whilst the internet intervention plus physiotherapist support arm improved by 2.4 points, after controlling for baseline score and covariates. When those with a lower RMDQ at baseline (< 4) were excluded, the results remained similar with participants allocated to the internet intervention plus usual care improving by 0.4, and those allocated to internet intervention plus physiotherapist support improving by 2.0 more than usual

care alone on the RMDQ. The proportions achieving this MCID were higher in the internet intervention plus physiotherapist support arm (13/22, 59.1%), than the internet intervention plus usual care (8/26, 31.0%) and usual care alone (10/25, 40.0%) arms.

Table 4. Clinical and physical activity measures at baseline and follow-up, including linear regression analysis (Mean difference), and quantile regression analysis (Median difference).

	Baseline Mean (SD)	3 months follow-up Mean (SD)	Mean difference (95% CI) at follow-up controlling for baseline	Mean difference (95% CI) at follow-up controlling for baseline and other covariates*
LBP related disability (RMDQ) (n=73)				
Usual care alone	6.8 (4.9)	6.3 (5.1)		
Internet intervention plus usual care	6.6 (4.6)	5.8 (4.5)	-0.7 (-2.77, 1.35)	-0.6 (-3.10, 1.83)
Internet intervention plus physiotherapist support	7.7 (4.7)	5.1 (5.1)	-1.3 (-3.49, 0.81)	-2.4 (-5.00, 0.25)
LBP related disability (RMDQ) - Excluding those with a score below 4 (n=51)				
Usual care alone	8.5 (4.3)	7.3 (5.4)		
Internet intervention plus usual care	9.0 (3.9)	7.4 (4.9)	-.03 (-2.73, 2.82)	-0.4 (-3.08, 3.11)
Internet intervention plus physiotherapist support	9.5 (3.6)	6.4 (5.4)	-0.8 (-3.64, 1.99)	-2.0 (-4.98, 0.94)
Pain intensity (NRS) – Index average (n=72)				
Usual care alone	3.8 (2.3)	3.6 (2.1)		
Internet intervention plus usual care	3.9 (2.0)	3.2 (2.2)	-0.8 (-1.60, 0.07)	-0.5 (-1.47, 0.49)
Internet intervention plus physiotherapist support	4.2 (2.2)	3.1 (2.0)	-0.7 (-1.53, 0.21)	-0.8 (-1.78, 0.25)
Pain intensity (NRS) 1 – current				

(n=72)				
Usual care alone	3.6 (3.1)	4.0 (2.5)		
Internet intervention plus usual care	4.0 (2.6)	3.6 (2.5)	-0.9 (-1.86, 0.16)	-0.6 (-1.82, 0.56)
Internet intervention plus physiotherapist support	4.5 (2.6)	3.1 (2.3)	-1.4 (-2.40, -0.29)	-1.0 (-2.25, 0.21)
Pain intensity (NRS) – least pain last 2 weeks (n=72)				
Usual care alone	3.2 (2.5)	2.8 (2.1)		
Internet intervention plus usual care	3.1 (2.1)	2.3 (2.3)	-0.7 (-1.60, 0.16)	-0.6 (-1.46, 0.29)
Internet intervention plus physiotherapist support	2.9 (2.7)	2.3 (2.1)	-0.04 (-0.97, 0.89)	0.2 (-0.71, 1.08)
Pain intensity (NRS) – average last 2 weeks (n=72)				
Usual care alone	4.6 (2.0)	4.1 (2.1)		
Internet intervention plus usual care	4.5 (2.1)	3.6 (2.5)	-0.5 (-1.56; 0.54)	-0.4 (-1.54, 0.76)
Internet intervention plus physiotherapist support	5.2 (2.1)	3.4 (1.7)	-0.9 (-1.96, 0.25)	-0.8 (-2.07, 0.44)
Fear avoidance (TSK) (n=59)				
Usual care alone	37.8 (6.2)	35.0 (6.4)		
Internet intervention plus usual care	37.5 (7.4)	36.1 (8.1)	0.7 (-2.52, 3.84)	0.1 (-3.02, 3.29)
Internet intervention plus physiotherapist support	35.5 (6.8)	34.3 (7.5)	0.8 (-2.30, 4.02)	-0.6 (-3.65, 2.53)
Negative orientation towards pain (PCS) (n=57)				
Usual care alone	13.7 (12.8)	14.0 (11.4)		
Internet intervention plus usual care	13.5 (10.0)	12.8 (9.0)	-1.5 (-6.37, 3.40)	-3.5 (-9.70, 2.74)
Internet intervention plus physiotherapist	13.6 (9.4)	18.63 (8.5)	4.2 (-0.58, 8.90)	3.7 (-1.78, 9.27)

support				
Modified Enablement Scale (n=58)				
Usual care alone	26.5 (8.4)	27.9 (10.5)		
Internet intervention plus usual care	25.1 (8.5)	25.4 (9.7)	-2.0 (-8.51, 4.55)	-1.3 (-8.69, 6.01)
Internet intervention plus physiotherapist support	26.1 (7.8)	28.3 (9.3)	0.1 (-6.19, 6.43)	-0.3 (-6.63, 6.08)
Days in pain	**Median (Q1, Q3)**	**Median (Q1, Q3)**	Median difference (95% CI) at follow-up controlling for baseline	Median difference (95% CI) at follow-up controlling for baseline and other covariates*
Usual care alone	10 (6, 25)	6 (2,20)		
Internet intervention plus usual care	10 (4,21)	4 (0,15)	-0.7 (-9.20, 7.87)	-1.6 (-10.36, 7.16)
Internet intervention plus physiotherapist support	18 (5, 28)	10 (3,20)	0.3 (-8.71, 9.38)	1.1 (-8.62, 10.90)
Physical activity (IPAQ)	**Median (Q1, Q3)**	**Median (Q1, Q3)**		
Usual care alone	3139.5 (466.1, 5385)	2277.5 (912, 6105)		
Internet intervention plus usual care	1178.5 (480, 4131)	1130.5 (693, 2826)	-64.9 (-2796.15, 2666.32)	331.8 (-2360.85, 3024.50)
Internet intervention plus physiotherapist support	3168 (396, 7413)	990 (396, 3226.5)	-668.0 (-3347.32, 2011.25)	-408.0 (-2757.56, 1941.50)

Note. RMDQ: Roland Morris Disability Scale. NRS: Numerical Rating Scale. TSK: Tampa Scale for Kinesiophobia. PCS: Pain catastrophizing scale. IPAQ: International Physical Activity Questionnaire.

*covariates controlled for were age, gender, marital status, employment status, income, ethnic group and age left education.

Additional pain-related measures are also shown in Table 4. There were small reductions in pain intensity (NRS) in all arms from baseline to 3 months, although greater change occurred in the internet intervention plus physiotherapist support arm in comparison with internet intervention plus usual care arm and usual care alone. There

were small reductions in fear avoidance beliefs across all arms. With regard to pain catastrophising, there were small increases in the usual care alone arm and unexpectedly, in the internet intervention plus physiotherapist support arm (13.6 to 18.6). At 3 months, those in the internet intervention plus physiotherapist support arm reported 8 less days in pain, internet intervention plus usual care arm reported 6 less days in pain and those in usual care alone reported 2 less days in pain over the last 4 weeks. Finally, patient enablement showed small increases across all three arms.

The STarT Back tool [22] was used at baseline and 3 months follow-up to describe the proportions of participants at low, medium, or high risk of persistent disability (see Table 5). There was an increase in the proportion of patients classed at low risk in both the internet intervention plus usual care (60% to 70%) and the internet intervention plus physiotherapist support arms (33% to 74%). The proportion of patients classified at high risk reduced to zero in the internet intervention plus physiotherapist support arm. There was little change in the risk proportions in the usual care alone arm from baseline to 3 months follow-up.

Table 5. Number of patients (%) in STarT Back subgroups at baseline and follow-up for all trial arms.

Arm	**Baseline**			**Follow up**		
	Low risk	Medium risk	High risk	Low risk	Medium risk	High risk
Usual care alone	15 (51.7%)	11 (37.9%)	3 (10.3%)	11 (47.8%)	10 (43.5%)	2 (8.7%)
Internet intervention plus usual care	17 (60.7%)	8 (28.6%)	3 (10.7%)	12 (70.6%)	3 (17.7%)	2 (11.8%)
Internet intervention plus physiotherapist support	9 (33.3%)	15 (55.6%)	3 (11.1%)	14 (73.7%)	5 (11.8%)	0

Physical activity

The IPAQ-SF data were converted to MET/mins per week and compared using medians with quantile regression, as the distribution of energy expenditure is known to be non-normal in many populations. The median at baseline for the sample was 2343 (IQR= 480, 5544). It is important to note that the American Heart Association

recommends 450-750 MET/per week or approximately, moderate exercise for 30 minutes per day, 5 days a week.[40] A baseline median of 2343 is unexpected, and brings into question the reliability of this self-report measure of physical activity.

Process variables for the full trial

Thirty seven patients in the internet intervention arms completed the Credibility and Expectancy Questionnaire (CEQ) and the exercise self-efficacy questionnaire (ESE) (66%). The association between the CEQ score and the RMDQ score at follow up (*r*= -0.19, 95%CI -0.50 to 0.15), was in the expected direction, as was the association between ESE and number of weeks spent engaging in back-related exercise reported at 3 months (r =0.28, 95% CI -0.08, 0.58). The Problematic Experiences of Therapy Scale (PETS) was completed by 67% [18] of patients in the internet intervention plus usual care and 70% [19] of the internet intervention plus physiotherapist support arm. The PETS is used to explore the relationship between its scores and quantitative adherence (both to the internet intervention and recommended exercises) data in large samples. As the numbers are small our main focus is on completion rates, which suggest the PETS is suitable for inclusion in a full trial.

Health economic outcomes

The hosting cost of providing access to SupportBack was assumed to be £12.50 per person, this based on predicted costs of server provision and website maintenance. Physiotherapist support was estimated at £38 per person. This gives a total intervention cost of £12.50 and £50.50 in the internet intervention plus usual care and internet intervention plus physiotherapist support arm respectively. The total mean cost for all 79 participants was £270, of which £107 (43%) was related to back pain; indicating that use of NHS services were an important cost for this group of patients (see Table 6). Our sample showed 66% of total NHS costs and 78% of back pain related costs occurred in secondary care. Due to delays related to referring and attending secondary care appointments it is likely that costs would occur after the 3-month period used in this study.

Two outcomes measures would be used in the economic evaluations alongside any future full trial; change in LBP-related disability (RMDQ) and the quality adjusted life year (QALY) evaluated using the EQ-5D 3L.[39] However, because of the variability in costs any estimates of cost-per point change in these measures would be subject to considerable uncertainty and so are not reported here. The EQ-5D was found to be strongly negatively correlated with RMDQ at both baseline and follow-up, with

respective Pearson correlations of -0.594 and -0.560 (ps<0.01). This provides some support for the use of the EQ-5D in a future full trial of SupportBack for LBP. For QALYs there were only 57 cases with baseline and follow-up data for the EQ-5D and 54 that also had cost data. This was lower than response rate for RMDQ and other clinical measures. The EQ-5D was one of the last questionnaires participants completed, additionally, it was not part of the minimum data-set collected by telephone at 3 months.

Table 6. NHS costs (£, Mean (SD)) derived from computer records at participating general practices at 3 months follow-up

	Usual care alone (N=26)	Internet intervention plus usual care (N=28)	Internet intervention plus physiotherapist support (N=25)	All (excluding intervention costs) (N=79)
Intervention costs	0	12.5	50.5	
All NHS costs				
Primary Care costs*	96 (142)	85 (114)	108 (136)	96 (130)
Secondary Care - A&E	-	14 (42)	11 (53)	8 (39)
Secondary Care - O/P	116 (279)	48 (83)	87 (106)	83 (178)
Secondary Care - inpatient	59 (299)	129 (564)	101 (391)	97 (432)
Secondary Care Total	175 (490)	191 (586)	198 (483)	188 (517)
Total Costs	**271 (492)**	**289 (650)**	**357 (553)**	**284 (564)**
Back pain Costs Only				
Primary Care costs – back pain only	15 (40)	30 (73)	35 (75)	26 (64)
Secondary Care - A&E	-	-	11 (53)	3 (30)
Secondary Care - O/P	76 (251)	25 (62)	32 (69)	44 (153)
Secondary Care - inpatient	26 (132)	24 (129)	101 (391)	49 (244)
Secondary Care Total	102 (325)	50 (158)	143 (482)	96 (340)
Total Costs – Back pain only	**116 (327)**	**92 (178)**	**228 (535)**	**123 (367)**

* Primary care costs refer to GP consultations (at the surgery/home/phone.); practice nurse consultations (at the surgery/home/phone); use of other person in surgery (mainly phlebotomist); any other primary care related costs (walk in centre or phlebotomist); and costs of back pain relevant prescribing.

Harms

Six hospital admissions were reported: 2 (internet intervention plus physiotherapist support arm), 2 (internet intervention plus usual care), 2 (usual care alone). One case of suspected cauda equine syndrome was detected towards the end of the trial in the physiotherapist support arm (immediate clinical treatment was received, L5/S1 discectomy performed), and 5 admissions were identified from patient general practice medical record reviews: 1 for a facet joint injection, 1 for a haemoarthrosis, 1 for lumbar screening and injection, 1 for an epidural steroid injection, and 1 unrelated serious adverse event. We think it is very unlikely that the gentle activity advice offered by the internet intervention would lead to any of the above, but it is not possible to rule out; all Serious Adverse Reactions were reported to the trials' Research Ethics Committee.

DISCUSSION

We believe this is the first trial of an internet intervention specifically designed for patients with LBP consulting in general practice. Overall, the trial design was found to be feasible and the success criteria [17] were met; the target number of patients were recruited within the trial timeframe; the majority of patients were exposed to core active internet intervention content; the telephone support physiotherapists adhered to the protocol, and acceptable levels of retention were achieved for the key clinical outcomes at 3 months follow-up. Caution is required when interpreting the exploratory analysis of clinical outcomes as, due to the feasibility aims of this trial, it was not powered to determine effectiveness. The reduction of 2.4 points on the RMDQ for the internet intervention plus physiotherapist support arm compared to usual care alone at 3 months follow-up, provides an indication of the potential importance of remote, brief healthcare professional support for primary care patients with LBP. Reductions in LBP-related disability compared to usual care alone were smaller when the internet intervention was delivered without support.

The trial design had a number of strengths. The internet intervention was provided in addition to and compared with unrestricted usual care. This pragmatic design will enable evaluation of the incremental value of the interventions in addition to the existing full range of LBP healthcare available. Use of outcomes recommended as core outcome domains for LBP [41] will enable comparison with other non-digital interventions; previous studies of internet interventions for LBP have used a heterogeneous range of outcome measures.[13] To our knowledge this is the first trial to integrate brief physiotherapist telephone support with an internet intervention

specifically designed for LBP patients. Physiotherapists are ideally placed to support LBP interventions with a central focus on physical activity, and this trial demonstrates the feasibility of a guided digital approach for the management of a prevalent musculoskeletal condition in primary care.

We identified some limitations to be addressed in the full trial: Encouraging physical activity was a core focus of SupportBack. The high median MET minutes of physical activity reported by patients at baseline on the IPAQ-SF appears to reflect a substantial overestimation, severely limiting the scales potential for detecting change in physical activity over the course of the trial. Despite the IPAQ-SF remaining the most widely used self-report measure of physical activity,[42] overestimation is frequently reported.[43] Objective measures such as accelerometers can be intrusive, costly when needed in large numbers, and there are still questions over accuracy.[44] Consequently, for the full trial it may be best to provide additional support for accurate reporting on the IPAQ-SF at baseline (e.g. through providing worked examples). Our sample had a lower mean RMDQ score than other trials for LBP in primary care,[45] with approximately 30% reporting an RMDQ score of ≥4 at baseline. This may be a function of the 6 month recruitment window from patients' LBP consultation, our broad inclusion criteria (experience of LBP in the last two weeks) and the low intensity nature of the interventions on offer. For the full trial we will amend our recruitment strategy to recruit patients closer to their consultation at participating practices. We will also amend our recruitment procedure aiming at improving efficiency, working to ensure more of those invited are screened and more of those screened are eligible. Follow-up rates differed between the 3 arms, with the lowest rates in the internet intervention plus telephone support arm. In the main trial follow-up rates will be closely monitored to ensure they remain above 80% across all 3 arms. Finally, the randomisation was unbalanced on some demographic and clinical variables. This was likely a function of the small numbers in each arm, and would be expected to balance out with the numbers required (approx. 200+ per arm) for a full trial. Nevertheless, differences at baseline should be considered when interpreting the exploratory findings with variables including troublesome days in pain and risk of persistent disability.

Health economic evaluations of digital health interventions can be complex. A recent paper has discussed these complexities inherent in costing digital health interventions, such as SupportBack, highlighting the importance of considering ongoing costs and benefits of digital interventions.[46] For costing future implementation it would be important to identify any hosting costs as well as documenting any additional

development costs needed and whether any of these would be ongoing (to keep the intervention up to date). We would also propose sensitivity analysis to allow for different assumptions as to the number of people who will use the intervention as this affects the estimate of unit cost. As this was a small-scale feasibility trial, there was considerable uncertainty caused by a small number of high cost items such as inpatient stays. As well as substantially increasing participants, in the full trial the EQ-5D will be collected after the RMDQ and included in the minimum data-set phone calls, and follow-up will occur at regular intervals over a 12-month period. Finally, potential future benefit should be considered and assessed where possible beyond the perspective of the trial timeframe; since LBP tends to be recurrent coping strategies learned from SupportBack might help prevent or manage back pain recurrence.

To conclude, digital approaches with and without healthcare professional support have the potential to offer an accessible means of effectively supporting behavioural self-management. We have shown that the SupportBack intervention is acceptable to patients with LBP presenting to primary care, and demonstrated the feasibility of a future definitive randomised controlled trial aimed at determining its clinical and cost effectiveness.

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Competing interests: None declared.

Ethics approval: NHS Research Committee, REC Reference: 13/SC/020

Contributors: LY, AWAG and PL conceived the idea for the study. AWAG, LY, PL, LR, NEF, EMH and JCH designed the trial and secured funding. RS and AWAG developed the internet intervention with LY and LR, with further input from NEF, JCH, EMH, PL and LL. LY, AG, LR, JCH, NEF, developed the physiotherapy telephone support package. RS managed the trial on a day-to-day basis with oversight from AG, PL, LR,

LY and input from NEF, JCH, EMH and LL. BS, DT, WM planned and carried out the statistical and health economic analysis. AWAG drafted the manuscript with input from all authors, AWAG is the guarantor for the data.

Data sharing statement: The datasets generated during the current study are available from the corresponding author on reasonable request.

REFERENCES

1. Hoy D, March L, Brooks P et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis. 2014;73:968-974.
2. Andersson GB. Epidemiological features of chronic low-back pain. Lancet. 1999;354:581-585.
3. Maniadakis N, Gray A. The economic burden of back pain in the UK. Pain. 2000;84:95-103.
4. Freburger JK, Holmes GM, Agans RP et al. The rising prevalence of chronic low back pain. Arch Intern Med. 2009;169:251-258.
5. Gore M, Sadosky A, Stacey BR, Tai KS, Leslie D. The burden of chronic low back pain: clinical comorbidities, treatment patterns, and health care costs in usual care settings. Spine (Phila Pa 1976). 2012;37:E668-77.
6. Excellence NIFHAC. Low back pain: Early management of persistent non-specific low back pain. Clinical Guideline 134. London: Nice; 2009
7. Machado GC, Maher CG, Ferreira PH et al. Efficacy and safety of paracetamol for spinal pain and osteoarthritis: systematic review and meta-analysis of randomised placebo controlled trials. BMJ. 2015;350:h1225.
8. Mallen C, Hay E. Managing back pain and osteoarthritis without paracetamol. BMJ. 2015;350:h1352.
9. Crofford LJ. Adverse effects of chronic opioid therapy for chronic musculoskeletal pain. Nat Rev Rheumatol. 2010;6:191-197.
10. Salisbury C, Foster NE, Hopper C et al. A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of 'PhysioDirect' telephone assessment and advice services for physiotherapy. Health Technol Assess. 2013;17:1-157, v.
11. Current Issues and Future Directions for Research Into Digital Behavior Change Interventions. [editorial]. Am J Prev Med 2016;51(5):814.
12. Butler L, Foster NE. Back pain online: a cross-sectional survey of the quality of web-based information on low back pain. Spine (Phila Pa 1976). 2003;28:395-401.
13. Garg S, Garg D, Turin TC, Chowdhury MF. Web-Based Interventions for Chronic Back Pain: A Systematic Review. J Med Internet Res. 2016;18:e139.
14. Buhrman M, Faltenhag S, Strom L, Andersson G. Controlled trial of Internet-based treatment with telephone support for chronic back pain. Pain. 2004;111:368-377.
15. Buhrman M, Nilsson-Ihrfeldt E, Jannert M, Strom L, Andersson G. Guided internet-based cognitive behavioural treatment for chronic back pain reduces pain catastrophizing: a randomized controlled trial. J Rehabil Med. 2011;43:500-505.

16. Carpenter KM, Stoner SA, Mundt JM, Stoelb B. An online self-help CBT intervention for chronic lower back pain. Clin J Pain. 2012;28:14-22.
17. Geraghty AWA, Stanford R, Little P et al. Using an internet intervention to support self-management of low back pain in primary care: protocol for a randomised controlled feasibility trial (SupportBack). BMJ Open. 2015;5:e009524.
18. Andersson G, Cuijpers P. Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. Cogn Behav Ther. 2009;38:196-205.
19. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behavior change interventions. J Med Internet Res. 2015;17:e30.
20. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. Spine (Phila Pa 1976). 2000;25:3115-3124.
21. Dunn KM, Croft PR. The importance of symptom duration in determining prognosis. Pain. 2006;121:126-132.
22. Hill JC, Dunn KM, Lewis M et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. Arthritis Rheum. 2008;59:632-641.
23. Little P, Lewith G, Webley F et al. Randomised controlled trial of Alexander technique lessons, exercise, and massage (ATEAM) for chronic and recurrent back pain. BMJ. 2008;337:a884.
24. Goubert L, Crombez G, Van Damme S, Vlaeyen JW, Bijttebier P, Roelofs J. Confirmatory factor analysis of the Tampa Scale for Kinesiophobia: invariant two-factor model across low back pain patients and fibromyalgia patients. Clin J Pain. 2004;20:103-110.
25. Sullivan M, Bishop SR, Pivik J. The pain catastrophizing scale: User manual. 2009
26. Craig CL, Marshall AL, Sjostrom M et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc. 2003;35:1381-1395.
27. Howie JG, Heaney DJ, Maxwell M, Walker JJ. A comparison of a Patient Enablement Instrument (PEI) against two established satisfaction scales as an outcome measure of primary care consultations. Fam Pract. 1998;15:165-171.
28. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. J Behav Ther Exp Psychiatry. 2000;31:73-86.
29. Resnick B, Palmer MH, Jenkins LS, Spellbring AM. Path analysis of efficacy expectations and exercise behaviour in older adults. J Adv Nurs. 2000;31:1309-1315.

30. Tijou I, Yardley L, Sedikides C, Bizo L. Understanding adherence to physiotherapy: findings from an experimental simulation and an observational clinical study. Psychol Health. 2010;25:231-247.

31. Kirby S, Donovan-Hall M, Yardley L. Measuring barriers to adherence: validation of the problematic experiences of therapy scale. Disabil Rehabil. 2014

32. Brooks R, Rabin R, De Charro F. The measurement and valuation of health status using EQ-5D: a European perspective: evidence from the EuroQol BIO MED research programme. Berlin: Springer Science & Business Media; 2003

33. Curtis L, Burns A. Unit costs of health and social care 2015. 2015

34. Department of Health. NHS Reference costs 2014-15. 2014. Retrieved from https://www.gov.uk/government/publications/nhs-reference-costs-2014-to-2015

35. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics. 2005;4:287-291.

36. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. J Clin Epidemiol. 2012;65:301-308.

37. Hao L, Naiman DQ. Quantile regression. London: Sage Publications Inc; 2007

38. Stratford PW, Binkley JM, Riddle DL, Guyatt GH. Sensitivity to change of the Roland-Morris Back Pain Questionnaire: part 1. Phys Ther. 1998;78:1186-1196.

39. Brooks R. EuroQol: the current state of play. Health Policy. 1996;37:53-72.

40. Haskell WL, Lee IM, Pate RR et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. Med Sci Sports Exerc. 2007;39:1423-1434.

41. Chiarotto A, Deyo RA, Terwee CB et al. Core outcome domains for clinical trials in non-specific low back pain. Eur Spine J. 2015;24:1127-1142.

42. Lee PH, Macfarlane DJ, Lam TH, Stewart SM. Validity of the International Physical Activity Questionnaire Short Form (IPAQ-SF): a systematic review. Int J Behav Nutr Phys Act. 2011;8:115.

43. Hallal PC, Gomez LF, Parra DC et al. Lessons learned after 10 years of IPAQ use in Brazil and Colombia. J Phys Act Health. 2010;7 Suppl 2:S259-64.

44. Napolitano MA, Borradaile KE, Lewis BA et al. Accelerometer use in a physical activity intervention trial. Contemporary Clinical Trials. 2010;31:514-523.

45. Hill JC, Whitehurst DG, Lewis M et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet. 2011;378:1560-1571.

46. McNamee P, Murray E, Kelly MP et al. Designing and Undertaking a Health Economics Study of Digital Health Interventions. Am J Prev Med. 2016;51:852-860.

Figure legends

Figure 1. SupportBack patient flow diagram

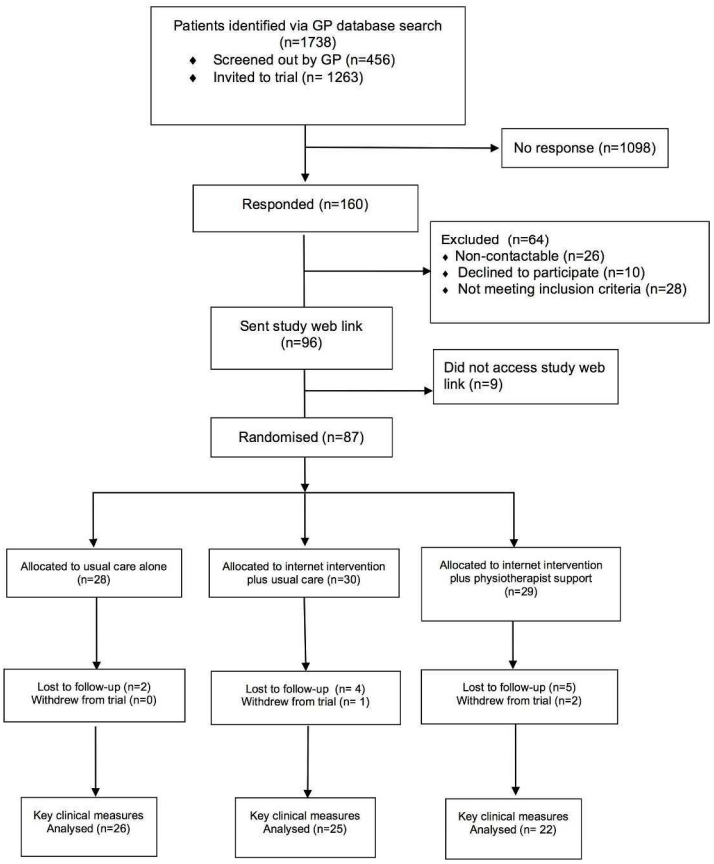

Figure 1. SupportBack patient flow diagram

209x297mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	8
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	8
Sample size	7a	Rationale for numbers in the pilot trial	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	10

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	10
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	See Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	See Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the pilot trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12-13
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	11-20
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	11-20
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	11-20
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	21
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	22
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	22-23
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	22-23
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	22-23
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2
Protocol	24	Where the pilot trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24
	26	Ethical approval or approval by research review committee, confirmed with reference number	24

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.