ISRCTN14736486 https://doi.org/10.1186/ISRCTN14736486

SupportBack 2: supporting self-management of low back pain with an internet intervention

Submission date
10/09/2018

Recruitment status
No longer recruiting

Registration date
25/09/2018

Overall study status
Completed

Last Edited
24/10/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Low back pain (LBP) is one of the most common and costly problems seen in General Practitioner's (GP) surgeries. Internet interventions may provide a new and efficient way of supporting and encouraging patients to become more active in self-management of LBP.
The aim of this study is to determine if an internet intervention called 'SupportBack', provided both with and without guidance from a physiotherapist over the telephone, is effective in reducing LBP-related disability when compared to usual primary care alone.

Who can participate?
Adults with low back pain, who can speak English and have access to the internet with an active email address

What does the study involve?
Participants will be randomly allocated to one of three groups@
1. Usual care
2. Usual care + internet intervention
3. Usual care + internet intervention + telephone physiotherapist support
The internet intervention is SupportBack, which provides advice and reassurance, and encourages physical activity over a six-week period. Tailored online materials support gradual goal setting, facilitate monitoring of back-related activities and provide personalised feedback. Telephone physiotherapist support will address concerns, provide reassurance and encourage uptake and compliance with activity goals.
Participants will be followed up at six weeks, three, six and 12 months. Questionnaires will explore how LBP is affecting their daily activities, their level of pain intensity and other LBP-related issues. A GP medical records review will be performed at 12 months which will record health care service use. LBP related costs will be calculated. In-depth interviews will be conducted with up to 30 trial participants across the three groups to explore their experiences of SupportBack and the care they have received over the trial period.
As well as GPs, psychologists, physiotherapists, rheumatologists and statisticians, the team will include members of the public with experience of LBP who will provide input at all stages of the study.

What are the possible benefits and risks of participating in this study?
SupportBack is a low intensity behavioural intervention, where participants either alone or with brief support from a physiotherapist, work through LBP-related internet-based modules and set physical activity goals. Therefore, the benefit of participating is that participants may experience relief from LBP symptoms.
As participants set their own activity goals, they are unlikely to over-exert themselves. Subsequently, SupportBack is a low risk behavioural intervention. Nonetheless, participants will be made aware of indicators of serious spinal pathology, and advised to seek immediate medical attention if they should arise over the trial period.
As part of the study, participants will be asked to complete questionnaires at five time points across the 12 month study period. Those in the internet intervention groups will be expected to access SupportBack online. It is possible that some may experience the questionnaires as an inconvenience. However, participants will be informed that they can take regular breaks when completing the questionnaires, and they will be able to skip some secondary questionnaires, if they start to find completion burdensome. The Participant Information Sheet clearly explains how long the SupportBack internet intervention will take each week and participants can therefore decide if they have time to dedicate to the study prior to consent.

Where is the study run from?
Southampton Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
April 2018 to January 2022

Who is funding the study?
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) (UK)

Who is the main contact?
Frances Webley
f.webley@soton.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Frances Webley

Contact details
Southampton Clinical Trials Unit
MP131, Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
023 8120 3866
F.Webley@soton.ac.uk

Additional identifiers

Protocol serial number
39195

Study information

Scientific Title
Supporting self-management of low back pain with an internet intervention in primary care: A randomised controlled trial of clinical and cost-effectiveness

Acronym
SupportBack 2

Study objectives
To determine the clinical effectiveness of the SupportBack internet intervention on LBP-related physical disability delivered with and without telephone physiotherapist support in addition to usual care, compared to usual care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hampshire B, 17/08/2018, 18/SC/0388

Primary study design
Interventional

Study design
Interventional randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low back pain

Interventions
Following completion of consent and baseline questionnaires, the internet intervention software, LifeGuide, will randomise the participant. The randomisation sequence will be automatically generated, and a computer-generated algorithm will block randomise participants to the trial groups. Participants will be stratified by level of severity, with a score of less than four on the Roland Morris Disability Questionnaire being considered as a lower level of severity, and trial centre. As the software randomises participants, the sequencing will be concealed from the Research Team. Participants will be automatically informed of their allocated group via the internet through the intervention website. As the intervention is primarily behavioural, participants will not be blind to allocation.
Participants will be randomly allocated to one of three groups:
1. Usual care
2. Usual care + internet intervention
3. Usual care + internet intervention + telephone physiotherapist support

Usual care:
Participants allocated to this arm will continue to receive usual primary care. In the first instance, NICE recommended care for LBP consists of education and self-management advice, including advice to stay active. GPs may also prescribe medications for LBP and/or make referrals to other services that can offer other recommended treatments such as exercise programmes, manual therapy or psychological and/or pain management programmes. With regard to pharmacotherapy, recommendations are for NSAIDs or weak opioids only if NSAIDs are contraindicated, not tolerated or ineffective. Paracetamol is not recommended, neither is the routine use of opioids for LBP. Antidepressants (SSRIs or Tricyclics) are not recommended for LBP. In practice, many GPs do not adhere to guidelines for LBP, consequently, the latest NICE guidelines for LBP will be highlighted with all participating practices in a telephone call as part of the trial setup. Nonetheless, it is likely that treatment received as part of usual care will vary, and this variation will be ascertained and documented by a medical records review at 12 months and participant borne costs questionnaires at baseline, six months and 12 months. If a participant does not re-consult over the trial period they may receive no additional care beyond that which they received as part of their initial GP consultation, whereas some participants may receive ongoing care from the GP, and/or referrals for diagnostic tests or treatments from other healthcare professionals such Physiotherapists or other specialists.

Usual care + Internet intervention:
Participants allocated to this arm will continue to receive usual primary care. In addition, they will receive access to SupportBack. SupportBack is an interactive multi-session internet intervention that provides participants with accessible information, tools and support to enable them to effectively manage their LBP. Internet provision allows the material to be accessed, and the suggested activities to be carried out wherever is most convenient for the participants. The intervention was developed using the open source LifeGuide software (www.lifeguideonline.org). The core of the intervention is focused on self-regulatory processes including graded goal setting, self-monitoring, and tailored feedback to encourage physical activity/exercise increases or maintenance. The intervention also provides educational advice regarding pain and LBP-related topics. Throughout, the included educational information has a focus on motivating behaviour change through techniques such as reassuring participants about likely consequences of movement and physical activity; helping participants interpret mild pain; modelling managing pain through physical activity using patient stories; reinforcing positive behaviour (using automated feedback); and providing simple instructions/ demonstrations regarding how to perform various back-specific exercises/physical activity behaviours. By combining the above features with in-depth feedback from patients with LBP in development, SupportBack is designed to be a highly accessible intervention supporting changes in self-efficacy and physical activity in order to improve LBP-related physical function.

The SupportBack internet intervention comprises six sessions delivered over a period of up to six weeks. Participants are encouraged to access one session per week, to allow them to engage between sessions with the activity goals they have set themselves. Participants are sent automated emails each week as a reminder to login to their next session. Specifically, in the first session participants are provided with information on how SupportBack will work, including the key rationale underlying the intervention; that keeping active is of primary importance when managing LBP. Likely concerns/potential barriers regarding this primary message are also addressed. The intervention then suggests two forms of physical activity participants can be supported with each week; walking or simple back-specific exercises. Participants select one and set goals for the coming week. The recommendations provided are tailored, based on the extent participants report their LBP is obstructing their ability to engage with activities in their day-to-day lives.

From session two onwards, the intervention follows the same format. Participants review their goals from the previous week and are provided with automated tailored feedback and encouragement. They then have the opportunity to amend their goals, increase difficulty or switch to different physical activities. From session two, after a participant's goal review they can choose to explore one of six modules containing information and advice on a LBP-related topic (see Table 2 for details). Exploration of these information modules becomes part of each broader 'session'. Although participants are advised to work through a session per week, they can view a new session every three days if they wish. If engaged with as recommended, the intervention would take six weeks to complete. After the six weeks of structured sessions, participants will still have access to activity information and LBP-related modules as a static website. The intervention is fully automated and adherence is encouraged through weekly reminder emails containing links back to the intervention.

Usual care + internet intervention + telephone physiotherapist support:
Participants allocated to this arm will continue to receive usual primary care. The SupportBack internet intervention will also be offered to participants with the addition of up to one hour of telephone support from an NHS Physiotherapist, over the same period of six weeks. The supporting Physiotherapists will be drawn from those who assess and manage patients with LBP in NHS services linked to participating GP practices. In Southampton, musculoskeletal Physiotherapists will come from Solent NHS Trust whereas in Keele they will be NIHR CRN Research Musculoskeletal Physiotherapists from the West Midlands CRN. Physiotherapists will receive participant contact details via an nhs.net email account or Dropoff, a UoS secure file transfer system.

Although support will vary with participant need, it will not exceed one hour in total (but could be less) and consists of one up to 30-minute phone call followed by two up to 15-minute phone follow-ups over six weeks. The purpose of the Physiotherapist telephone contact is to provide support and encouragement for use of the internet intervention and to address participants' concerns in relation to the internet-based content. The Physiotherapists are asked to closely adhere to a standardised content checklist for each phone call. Whilst they are able to address individual participant concerns, they are asked to avoid additional individualised participant assessment and treatment recommendations beyond the internet intervention content and adherence to this protocol will be assessed. Paper based notes made during the telephone Physiotherapist support will be stored securely at SCTU.

Call one (up to 30 minutes) is planned to take place between weeks one and two after randomisation. In this call, the Physiotherapist explores and addresses the participant's understanding and attitudes (e.g. belief that activity can be helpful for LBP); engagement with the internet intervention (e.g. enquiring how the participant has got on with their goals); and anticipates barriers (by asking what problems they anticipate in participating in the SupportBack programme). Calls two and three (up to 15 minutes) are planned to take place between weeks two and three, and between weeks four and five. In these telephone calls the Physiotherapist discusses general adherence to the internet content and internet sessions; provides positive reinforcement for adherence behaviour to both the internet intervention and physical activity goals; discusses barriers to adherence and how these might be addressed; encourages commitment to goals for the following week; and addresses any remaining concerns.

Participants will be followed up at 6 weeks, and 3, 6 and 12 months.

Intervention Type
Other

Primary outcome(s)

Back-specific physical disability, assessed using the Roland Morris Disability Questionnaire (RMDQ) at the baseline and after 6 weeks and 3, 6 and 12 months (a repeated measures design)

Key secondary outcome(s)

1. Health economics, assessed in terms of:
1.1. Health-related quality of life, assessed using the EQ-5D-5L at the baseline and after 6 weeks and 3, 6 and 12 months
1.2. Self-reported over the counter (OTC) medication use, assessed using a single item developed for this study at the baseline and after 6 and 12 months
1.3. Participant borne costs, assessed by participant-reported resource use and time off work at the baseline and after 6 and 12 months
1.4. Brief occupational items, assessed using an occupational questionnaire at the baseline and after 6 and 12 months
1.5. Health care resource use (including GP appointments, nurse appointments, referrals, hospital stays and medication between specified dates, along with data on pre-existing conditions), assessed using a GP medical records review at the 12 month follow up
2. Pain, assessed in terms of:
2.1. Number of troublesome days in pain over the last month, assessed using a single-item Days In Pain Questionnaire at the baseline and after 6 weeks and 3, 6 and 12 months
2.2. Numerical Pain Rating Scale, assessed at the baseline and after 6 weeks and 3, 6 and 12 months
2.3. Risk of persistent disability, assessed using the Keele STarT Back screening tool at the baseline and after 12 months
3. Psychological processes related to pain, assessed in terms of:
3.1. Fear of movement, assessed using the Tampa Scale for Kinesiophobia (TSK-11) at the baseline and after 12 months
3.2. Negative orientation towards pain, assessed using the Pain Catastrophizing Scale (PCS) at the baseline and after 12 months
3.3. Confidence in ability to manage pain, assessed using the Pain Self-Efficacy Questionnaire at the baseline and after 6 weeks and 12 months
3.4. Self-efficacy for managing low back pain, assessed using a single item from Keele's Musculoskeletal Health Questionnaire tool (MSK-HQ) at the baseline and after 6 weeks and 3, 6 and 12 months
3.5. How much the intervention may reduce limitation due to back pain, assessed using the Modified Expectancy Questionnaire at the baseline following session one of the SupportBack Internet Intervention (assessed in the intervention arms only)
3.6. Mental health (depression and anxiety), assessed using the Patient Health Questionnaire (PHQ-4) at the baseline and after 12 months
4. Physical activity/adherence, assessed in terms of:
4.1. Physical activity, assessed using the Godin Leisure-Time Exercise Questionnaire at the baseline and after 12 months
4.2. Back-specific physical activity, assessed using a single-item SupportBack-related physical activity assessment tool at the baseline and after 6 weeks and 3, 6 and 12 months
4.3. Self-reported adherence to back-specific exercises, assessed using 4 items developed specifically for this study at the 12 month follow-up
4.4. How easy/difficult it was to carry out the therapy, assessed using the Problematic Experiences of Therapy Scale (PETS) at the 12 month follow-up (assessed in the intervention arms only)
5. Satisfaction with back pain care, assessed using a single item developed specifically for this study after 6 weeks

6. Ability to cope as a result of healthcare received, assessed using the Patient Enablement Instrument (PEI) after 6 weeks and 12 months
7. Participant-reported use of internet resources for back pain, assessed using a single item developed for this study after 12 months

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Aged 18 and above
2. Current low back pain (have experienced pain in the last week) with or without sciatica
3. Access to the internet and an active email address
4. Ability to read/understand English without assistance
5. Ability to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
826

Key exclusion criteria
1. 'Red flag' signs and symptoms in a patient with LBP which indicate serious spinal pathology such as infection, malignancy, fracture, inflammatory back pain, progressive neurology and/or cauda equine; or suspected serious pathology
2. Have had spinal surgery in the past six months
3. Pregnancy
4. Taken part in the prior SupportBack feasibility study (ISRCTN31034004)

Date of first enrolment
01/10/2018

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
Research & Innovation Services
Highfield Campus
Southampton
United Kingdom
SO17 1BJ

Study participating centre
NIHR CRN Wessex
Unit 7 Berrywood Business Village
Tolbar Way
Hedge End
Southampton
United Kingdom
SO30 2UN

Study participating centre
NIHR CRN West Midlands
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/111/78

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/05/2024	03/06/2024	Yes	No
Results article		16/04/2025	16/04/2025	Yes	No
Protocol article	protocol	20/08/2020	24/08/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Nested qualitative process evaluation	20/10/2025	24/10/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes