

Internet intervention supporting management of low back pain in primary care

Submission date 08/11/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/12/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Low back pain is one of the most common and costly problems seen by general practitioners (GP). The aim of this study is to develop and test an interactive internet intervention specifically designed for patients having low back pain consulting their GP. Financial pressures on the NHS restrict access to face-to-face physiotherapy. An internet intervention may provide a unique and efficient means for offering education and advice for the self-management of low back pain. Patient feedback is used to inform amendments to the structure and content (phase 1). The acceptability of the intervention and the feasibility of this study are then assessed (phase 2).

Who can participate?

Adult patients experiencing low back pain and who have access to the internet

What does the study involve?

Participants are randomly allocated to one of three groups. The first group receives the internet intervention with telephone physiotherapist support, the second group receives the internet intervention without support, and the third group receives usual care from their GP. All patients are followed up after 3 months. Factors including recruitment rates, the extent of patient interaction with the intervention and patient dropout are assessed. Interviews are conducted with GPs, patients completing the intervention, and physiotherapists giving the telephone support.

What are the possible benefits and risks of participating?

Using the internet allows patients immediate access to tailored information in their own homes. The multidisciplinary team of general practitioners and specialists works collaboratively with patients to develop and amend existing high quality educational materials, making them suitable for delivery in an interactive internet format. There are no risks associated with participation in the study.

Where is the study run from?

The study is run from various GP surgeries around Hampshire and Wiltshire areas of the UK.

When is the study starting and how long is it expected to run for?
January 2015 to December 2015

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Adam Geraghty
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14614

Study information

Scientific Title
Internet intervention supporting management of low back pain in primary care: a feasibility study

Acronym
SupportBack

Study objectives
This study will examine the feasibility of the trial design and acceptability of the internet intervention for management of low back pain in primary care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South Central - Southampton A, 25/06/2013, ref: 13/SC/0202

Study design

Randomised; Interventional; Design type: Not specified

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

Patients will consent to the study online prior to completing the baseline information and questionnaires. They will then be randomised to three groups automatically, using internet-based software:

1. Internet intervention with telephone physiotherapist support: SupportBack is an online intervention providing advice and support in getting active for people with low back pain. Provides tailored activity programme and self management advice
2. Internet intervention with no telephone physiotherapist support
3. Usual care from the GP

Follow up will take place at 3 months.

Intervention Type

Behavioural

Primary outcome measure

Recruitment rate; Timepoint(s): Baseline & 3 months

Secondary outcome measures

1. Back pain care related resource use (i.e. no of GP visits) collected by simple questions; Timepoint(s): 3 months
2. Quality of life, measured with EuroQol EQ-5D; Timepoint(s): Baseline & 3 months
3. Objective measures of use of internet intervention; Timepoint(s): Baseline & 3 months

4. Patient experience & perceived usefulness of intervention, measured by qualitative interview /quantitative scale; Timepoint(s): Baseline & 3 months
5. Patient experience/perceived usefulness of phone support, measured by qualitative interview /quantitative scale; Timepoint(s): 3 months
6. Problematic Experiences of Therapy Scale (PETS); Timepoint(s): 3 months
7. Roland Morris Disability Questionnaire (RMDQ); Timepoint(s): Baseline & 3 months
8. Time off work via simple questions; Timepoint(s): Baseline & 3 months
9. Visual Analogue Scale for measuring pain as a process measure across the study; Timepoint(s): Baseline & 3 months

Overall study start date

13/01/2014

Completion date

01/12/2015

Eligibility

Key inclusion criteria

1. Access to the internet and an active email address
 2. Current low back pain
 3. Prior presentation in primary care with low back pain (for those invited directly from practice lists)
 4. An ability to read/understand English without assistance
- Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 70; UK Sample Size: 70

Total final enrolment

87

Key exclusion criteria

1. Patients under 18
2. Clinical indicators of potentially serious spinal disease (indicated through a 'red flag' screen. Red flags are rare in primary care, thus we expect the majority of patients with low back pain to be eligible for this trial)
3. Those patients without the internet will be ineligible for this trial and will be offered usual care

Date of first enrolment

01/01/2015

Date of final enrolment

01/07/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Southampton

Southampton

United Kingdom

SO16 5ST

Sponsor information

Organisation

University of Southampton (UK)

Sponsor details

Southampton Primary Care Academic Unit

School of Medicine

Aldermoor Close

Southampton

England

United Kingdom

SO16 5ST

Sponsor type

University/education

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/04/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Adam Geraghty (a.w.geraghty@soton.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/03/2018		Yes	No
Results article	qualitative results	01/09/2020	17/12/2019	Yes	No
HRA research summary			28/06/2023	No	No