ISRCTN31034004 https://doi.org/10.1186/ISRCTN31034004

Internet intervention supporting management of low back pain in primary care

Submission date
08/11/2013

Recruitment status
No longer recruiting

Registration date
08/11/2013

Overall study status
Completed

Last Edited
17/12/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 ares 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
a.w.geraghty@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Adam Geraghty

ORCID ID
https://orcid.org/0000-0001-7984-8351

Contact details
Aldermoor Close
Southampton
United Kingdom
SO16 5ST

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Not specified

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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 trail)
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
United Kingdom

England

Study participating centre

University of Southampton
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

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

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