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Coping with chronic pain

Submission date
27/01/2015

Recruitment status
No longer recruiting

Registration date
20/04/2015

Overall study status
Completed

Last Edited
24/04/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The burden of chronic pain across Europe is a major challenge within health care because approximately 18% of the population currently live with moderate to severe chronic pain. This lifelong illness can result in high levels of suffering and disability. Specifically, key aspects of health and every day functioning such as sleep and mobility can be negatively impacted. Furthermore, chronic pain patients often suffer with depression and anxiety because of the difficulties in managing their ongoing pain. Individually chronic pain patients report that their pain negatively affects relationships with those close to them and on a larger socioeconomic scale chronic pain results in a large economic loss often due to loss of the ability to work. Psychological therapies have been shown to play an important role in helping patients cope with chronic illness. This has traditionally been in the form of cognitive behavioural therapy but more recently, mindfulness interventions have been explored among those with chronic illness and have been shown to have benefits for the management of illnesses, including anxiety, depression, distress and quality of life. While this research is promising, it can be difficult for chronic pain patients to participate as it generally requires patients to commit to an intensive 8 week programme (which includes weekly group meetings on top of daily individual tasks). As ability to travel and energy levels of chronic pain patients are often low, home-based interventions are likely to be more acceptable and self-management therapies are now highly promoted, supported within the National Health Service. One type of brief intervention that fits this profile is a short mindfulness-based body scan or breathing scan. These scans, which can be recorded as guided audios, are a key component of mindfulness meditation; they involve being directed to focus attention on the present moment through observing the breath, and bodily sensations, while becoming aware of, and accepting without judgment, any thoughts and feelings that arise. Whether this type of intervention is helpful has been little researched but one recent study found encouraging results with an audio recording of a 10 minute body scan with chronic pain patients. While attending a clinic visit, patients reported less distress, immediately after listening to the audio. In another study, a brief mindfulness body scan was used successfully to reduce tobacco cravings among smokers who had recently quit smoking. Together these findings provide support for investigating a brief intervention that may be helpful when used as a self-management tool for chronic pain patients. This study aims to investigate the acceptability and impact of brief mindfulness interventions (such as body scans) among those with chronic pain.

Who can participate?
Adults with chronic pain who have attended an outpatient clinic at St George's Healthcare NHS Trust (UK) and are deemed well enough by a treating clinician to participate.

What does the study involve?
Patients who consent to participate will meet with the researcher in a private room in St George' s Healthcare NHS Trust (UK) where they will be asked to complete questionnaires about their background, pain, mood, thinking and brief psychological measures before listening to a 15 min audio (i.e., either the intervention or control audio as described above). After listening to the audio, patients will complete the brief psychological measures again. Patients will then be asked to listen to the audio in their own environment as much as they like, but at least three times, in the week following their visit. At 1 week, patients in the treatment group will be asked to start using the additional two audios that will have been provided and the control group will be recommended to continue or start over with their audio recordings they have been provided with. Patients will then be followed up by telephone after the week and after one month and questionnaires will be completed at these times. A text reminder (or telephone call if the patient does not have a mobile phone) will be sent 1 day before the 1 week and 1 month telephone follow-ups. At the first visit with the researcher, patients will receive a £10 high street voucher as compensation for travel expenses and as a thank you for their time and effort. They will be allowed to keep the headphones and the audio recording if it was directly downloaded to their personal device and in the case that they did not have a device, they will be allowed to keep the MP3 player with the audio. To ensure a complete set of data and a true representation of the numbers of chronic pain patients that may be eligible, medical notes for the patients in participating clinics will be checked retrospectively for clinical diagnosis of the chronic pain.

What are the possible benefits and risks of participating?
We cannot promise the study will help patients but what is learnt may help to improve the methods for helping people cope with chronic pain. Patients are welcome to keep the recordings if they find them helpful and will be directed towards more lengthy resources freely available if they desire. There are no expected disadvantages or risks involved in taking part in this study.

Where is the study run from?
St George's, University of London (UK)

When is the study starting and how long is it expected to run for?
September 2014 to December 2015

Who is funding the study?
St George's, University of London (UK)

Who is the main contact?
Ms Ana Howarth

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of a brief mindfulness intervention for coping with chronic pain: a randomised controlled feasibility study

Study objectives
1. To assess the immediate effects of a brief mindfulness-based intervention on patients with chronic pain
2. To assess the feasibility of conducting a definitive randomised controlled trial to determine effectiveness and cost-effectiveness of a brief self-help mindfulness intervention for improving mindfulness and quality of life in people with chronic pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London - Camden and Islington, 24/11/2014, ref: 14/LO/1912

Study design
Randomised controlled feasibility study

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic pain

Interventions
1. The treatment group will be given an audio recording of a 15 minute body scan on an MP3 player (with earphones) or will be offered the option of having the audio downloaded directly to a device such as a smart phone or iPad of their choice. The audio recording will direct the listener to focus on breathing and other sensations. The body scan encourages the listener to become aware of and accept all thoughts and feelings, both positive and negative, without trying to alter them in any way while focusing on different areas of the body. The body scan that will be given to the treatment group is an extended version of a 10 minute body scan that we have used in a qualitative study, investigating the acceptability of the intervention to patients. This body scan audio is based on a transcript from Breathworks (UK), which is an established mindfulness meditation organisation that specialises in supporting chronic pain sufferers. Feedback regarding length (i.e., a longer version is preferable so as to make it less rushed) and narrator style have been implemented so as to make it easier to follow. The treatment group will also be given an audio with a breathing meditation and a moving meditation, but use will not be recommended until after 1 week. These audios will also be based on transcripts from Breathworks.
2. The control group will be given an audio recording of four 15 minute readings on an MP3 player (with earphones) or will be offered the option of having the audio downloaded directly to a device such as a smart phone or iPad of their choice. The readings will be from the text of "The English Village: History and Traditions", which is a non-fiction book considered to be neutral in nature. The readings, which will be recorded with the same narrator as the intervention audio, will be presented in consecutive 15 minute sections starting with the beginning of the book for the first session in the clinic. Non-fiction material, similar in style and content, has been used in a previous study of the acute effects of mindfulness in people with chronic pain, where it has been found to be an acceptable intervention.

An instruction sheet will be given to both groups on how to silence mobile phones and any electronics and to sit quietly and to listen to the audio. In response to patient feedback, the treatment group's instruction sheet will include frequently asked questions regarding the intervention.

Intervention Type
Behavioural

Primary outcome measure

1. Eligibility, recruitment and retention rates
2. Depression, anxiety, mindfulness and quality of life
3. Patients' adherence to the treatment regimen, experiences of the intervention and its acceptability and usefulness
Experience of the intervention, acceptability and usefulness will be assessed at 1 week and 1 month.

4. Resources used in provision of the intervention, including cost of the MP3 players, telephone calls and text messages and staff time involved. This will be assessed at the end of recruitment.

Secondary outcome measures
Immediate effects of a brief mindfulness-based intervention on patients with chronic pain

1. Background and pain related questionnaire: at baseline
2. Pain self-efficacy item: at baseline and at one month
3. Mood questionnaire (HADS): at baseline and at one month
4. Mindfulness questionnaire (CAMS-R): at baseline, one week and at one month
5. Pain specific questionnaire (BPI): at baseline
6. Pain catastrophizing questionnaire (PCS): at baseline and at one month
7. HRQoL questionnaire (EQ-5D-5L): at baseline and at one month
8. Brief psychological measures (two times, before and then after intervention): at baseline and during week
9. Experience of audio items: at one week
10. Previous experience: at one week
11. Self-monitoring Table: during week and during month

HADS (Hospital Anxiety and Depression Scale), CAMS-R (Cognitive and Affective Mindfulness Scale Revised), BPI (Brief Pain Inventory), PCS (Pain Catastrophizing Scale), EQ-5D-5L (EuroQuol - 5 Dimensions - 5 Levels)

Overall study start date
01/09/2014

Completion date
28/03/2017

Eligibility

Key inclusion criteria
1. Chronic pain (i.e., patients who live with a diagnosis of chronic pain or those who have had pain for > 3 months past the time healing would have been thought to have occurred)
2. Age at least 18 years old
3. Considered well enough to participate by the clinician
4. Able to speak and read English due to the nature of the intervention
5. Able to hear the audio recordings or have their own equipment to enable them to do so because it is beyond the scope of a student study to provide specialist equipment

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90 (45 patients in each arm)

Total final enrolment
147

Key exclusion criteria
1. Considered too unwell to participate by the clinician
2. Unable to speak or read English
3. Age < 18 years old

Date of first enrolment
19/01/2015

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's Healthcare NHS Trust
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
St George's Joint Research & Enterprise Office (UK)

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Sponsor type
University/education

ROR
https://ror.org/020kx6615

Funder(s)

Funder type
University/education

Funder Name
St. George's, University of London

Alternative Name(s)
St. George's

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Reporting and dissemination of the results will be through peer-reviewed scientific journals, conference presentations and a student thesis.

Intention to publish date
31/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/06/2016		Yes	No
Results article	results	01/12/2019		Yes	No
HRA research summary			28/06/2023	No	No