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Efficacy of a mindfulness-based intervention for spinal cord injured outpatients with chronic neuropathic pain

Submission date
17/10/2014

Recruitment status
No longer recruiting

Registration date
02/12/2014

Overall study status
Completed

Last Edited
14/02/2018

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:
Millions of people suffer from chronic pain. Living with chronic pain causes the sufferer both physical and mental strain and they can often feel frustrated, angry and/or depressed. Pain killing medications may help ease the physical discomfort but can cause unpleasant side effects. Recently, mindfulness-based techniques have been attracting interest, having been shown to reduce symptoms and help people cope better with their condition. Further research into this area is therefore important. Mindfulness differs from cognitive-behavioural approaches, in that it does not aim to change or alter thoughts or the ways that a patient responds to pain. Mindfulness encourages active acceptance of the experience as it is, by observing pain in a non-analytical way and without judgement. Web-based mindfulness interventions (programmes) are growing in use, and may be ideal for use with those with spinal cord injuries (SCI) who may find getting to face-to-face meetings difficult due to mobility issues. No previous work has explored whether mindfulness can help people with SCI. Here, we want to test a web-based mindfulness intervention for people with SCI and chronic pain, alongside their partners or primary care-givers, in order to assess the effects of the intervention on their quality of life, experience of pain, and social relationships and understanding.

Who can participate?
Outpatients from the National Spinal Injuries Centre, Stoke Mandeville Hospital (UK) database who are suffering with chronic neuropathic pain. They must be at least 18 years of age.

What does the study involve?
Participants (SCI patients and their partners) are randomly allocated into one of two groups. Those in group 1 (control group) are asked to complete questionnaires regarding quality of life, depression, anxiety, pain-related outcomes, and social relationship measures, at the start of the trial, then at four weeks, eight weeks, and 20 weeks into the trial. Those in group 2 (mindfulness group) are registered onto an eight-week online mindfulness course, and must have internet access for the full eight weeks. The course involves doing mindfulness exercises for ten minutes twice a day. Like the participants in the control group, they complete questionnaires regarding quality of life,

depression, anxiety, pain-related outcomes, and social relationship measures, at the start of the trial, then at four weeks, eight weeks, and 20 weeks into the trial. The data is analysed using statistics, and will contribute to the literature base surrounding mindfulness. If positive results of the intervention are found, participants may continue to be involved in the research in order to explore the data further.

What are the possible benefits and risks to taking part in this study?
There will be no risk of physical harm to participants. It is possible, however, that engaging in mindfulness may cause some distress. The mindfulness course will ask participants to engage with their body and acknowledge any feelings that may or may not be present. It may be possible that distress may occur at the beginning of this course, as participants become accustomed to mindfulness, particularly for those who have had difficult times managing their pain. However, as they engage with their body more, the benefits are likely to far outweigh the risks. Participants will be allowed to pause or stop mindfulness exercises should they need to. Weekly motivational emails will be sent to the group, and participants will be welcome to contact the researchers and the company providing the online course, should they desire. They may also withdraw from the study and have their data destroyed should they so wish. Data will be stored in a password-protected computer database on the psychology department server at The University of Buckingham. Only those directly involved in the research will have access to this information.

Where is the study run from?
The study has been set up by The University of Buckingham, in collaboration with the National Spinal Injuries Centre, Stoke Mandeville Hospital, Aylesbury (UK).

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

Who is funding the study?
PhD scholarship from the University of Buckingham (UK).

Who is the main contact?
Jasmine Hearn, Principal Investigator, jasmine.hearn@buckingham.ac.uk
Katherine Finlay, Chief Investigator, katherine.finlay@buckingham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title
Efficacy of a mindfulness-based intervention for spinal cord injured outpatients with chronic neuropathic pain: a randomised controlled trial

Acronym
N/A

Study objectives
Engaging in mindfulness will improve quality of life of those living with SCI and chronic neuropathic pain, including depression, anxiety, pain catastrophising, and social relationships.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 04/02/2015, ref: 14/SC/1424

Study design
Single-centre trial using a between-subjects design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Spinal Cord Injury: Chronic Pain; Neuropathic Pain; Mindfulness

Interventions
For this research, all SCI patients who have been discharged from Stoke Mandeville Hospital within the last 20 years will be contacted. Of those who respond reporting chronic pain, 24 SCI participants and 24 partners or primary caregivers will be recruited. They will be randomised into one of the two groups, and then asked to sign a consent form after reading the participant information sheet. Those in the mindfulness group will then be contacted by email with links and login details for the online course. Data will be collected via questionnaires online, with data analysed using SPSS.

Intervention Type

Phase
Not Applicable

Primary outcome(s)
1. Quality of life
2. Depression
3. Anxiety

Outcome measures will be assessed using online questionnaires, and will be measured at baseline, four weeks, eight weeks (or upon completion of the online course), and 20 weeks (or three months post-completion of the course).

Key secondary outcome(s))
1. Pain-related outcomes (catastrophising, pain intensity)
2. Social relationship measures.

Completion date
28/08/2015

Eligibility

Key inclusion criteria
1. Participants with a spinal cord injury must be one year post-discharge from a spinal unit.
2. Each SCI participant must have a partner or primary caregiver willing to also take part.
3. All participants both male and female must be over 18 years of age and sufferers of chronic pain for three months or longer. There is no upper age limit.
4. Sufficient understanding of English must be held by all participants.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Participants will not be recruited if they hold any cognitive impairment or mental illness.
2. Participants with articulation difficulties and an insufficient understanding of English will be excluded from this study.
3. Any respondents with any other long term health condition that may affect the experience of pain, or be the cause of chronic pain (as opposed to the spinal injury) will be excluded.

Date of first enrolment
05/01/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Psychology Department
Buckingham
United Kingdom
MK18 1EG

Sponsor information

Organisation
The University of Buckingham

ROR
https://ror.org/03kd28f18

Funder(s)

Funder type
University/education

Funder Name
The University of Buckingham (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes