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Mindfulness meditation for chronic pelvic pain management

Submission date
27/06/2016

Recruitment status
No longer recruiting

Registration date
28/06/2016

Overall study status
Completed

Last Edited
16/03/2020

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Chronic pelvic pain (CPP) in women is where pain is felt in the pelvic region (the area below the belly button and between the hips) for at least 6 months. It is a relatively common condition, affecting around one million women in the UK every year, which is often painful and disabling, putting a great deal of strain on women's lives and the NHS. The exact cause of CPP can vary, making it very difficult to treat. Mindfulness is a psychological treatment that works by teaching people to accept the sensations and emotions in the present moment. This can help people to accept their pain, allowing them to focus on daily activities and improve their quality of life. This type of treatment often takes place in eight-week face-to-face courses, however recently, smartphone applications have been used to deliver this type of treatment. The aim of this study is to investigate the effectiveness of a mindfulness-based smartphone app in the treatment of CPP in women, in order to find out whether a large-scale study is possible.

Who can participate?
Adult women with CPP who have access to a smartphone.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group receive access a smartphone app delivering mindfulness instructions for 60 days. Those in the second group receive access to a smartphone app delivering muscle relaxation instructions for 60 days, in addition to usual care. Those in the third group receive usual care alone for 60 days. At the end of the study, the amount of participants that have been recruited and the amount of those who actively took part are recorded. In addition, participants who received the mindfulness app complete a questionnaire at 60 days about how user friendly the app is, and all participants complete a range of questionnaires at the start of the study, and then after 60 days, 3 months and 6 months, to measure their mental wellbeing, quality of life and acceptance of pain.

What are the possible benefits and risks of participating?
There are not expected to be any direct benefits or risks for participants taking part in this study.

Where is the study run from?
1. Royal London Hospital (UK)
2. Whipps Cross Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2015 to August 2017

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

Who is the main contact?
1. Miss Sian Newton (public)
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2. Miss Elizabeth Ball (scientific)
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Study website
http://www.blizard.qmul.ac.uk/research-project/1368-memphis2.html

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02721108

Secondary identifying numbers
20814

Study information

Scientific Title
Mindfulness meditation using a smart-phone application for women with chronic pelvic pain (MEMPHIS)

Acronym
MEMPHIS

Study objectives
The overall aim is to assess the feasibility of implementing a trial using psychological approaches delivered by a mobile phone app for patients with chronic pelvic pain (CPP).

The primary objectives are:
1. To provide feasibility data for a large multicentre RCT aimed at rigorously testing psychological approaches in CPP
2. To determine whether this app can be seamlessly integrated into clinical practice, especially CPP pathways

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Camden and Kings Cross Research Ethics Committee, 01/02/2016, ref: 15/LO/1967

Study design

Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: General gynaecology; UKCRC code/ Disease: Other/ Symptoms and signs involving the digestive system and abdomen

Interventions
Following provision of informed consent, patients will be randomised to one of three groups. Randomisation will be performed using a centralised internet service.

Group A - “Intervention”: Participants receive access to a smartphone app delivering mindfulness instructions for 60 days.
Group B - “Active control”: Participants receive access to a smartphone app delivering muscle relaxation instructions for 60 days, in addition to usual care.
Group C - Treatment as usual: Participants receive usual care

Clinical outcome data will be collected at 60 days, 3 months and 6 months post randomisation. App usability data will be collected at 60 days for the intervention and active control groups.

Intervention Type
Other

Primary outcome measure
1. Recruitment rate is measured at the end of follow up
2. Adherence rate is measured using data provided by Headspace during the intervention (first 60 days)
3. Usability of the app measured using a questionnaire at 60 days post randomisation

Secondary outcome measures
Secondary outcome measures as of 02/12/2016:
1. Quality of life-Physical Functioning subscale measured by the RAND Short form (36) Health Survey (SF-36) at baseline, 60 days, 3 months, and 6 months post-randomisation
2. Quality of life-Social Functioning subscale measured by the RAND Short form (36) Health Survey (SF-36) at baseline, 60 days, 3 months, and 6 months post-randomisation
3. Quality of life-Pain subscale measured by the RAND Short form (36) Health Survey (SF-36) at

baseline, 60 days, 3 months, and 6 months post-randomisation
4. Quality of life-General Health subscale measured by the RAND Short form (36) Health Survey (SF-36) at baseline, 60 days, 3 months, and 6 months post-randomisation
5. Depression is measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 60 days, 3 months, and 6 months post-randomisation
6. Anxiety is measured using the Hospital Anxiety and Depression Scale (HADS) at v60 days, 3 months, and 6 months post-randomisation
7. Pain Acceptance is measured using the Chronic Pain Acceptance Questionnaire (CPAQ-8) at baseline, 60 days, 3 months, and 6 months post-randomisation
8. Sexual health outcomes are measured using the Sexual Health Outcomes in Women Questionnaire (SHOW-Q) at baseline, 60 days, 3 months, and 6 months post-randomisation

Original secondary outcome measures:
1. Quality of life is measured using the Short form (36) Health Survey (SF-36) at baseline, 60 days, 3 months, and 6 months post-randomisation
2. Depression is measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 60 days, 3 months, and 6 months post-randomisation
3. Anxiety is measured using the Hospital Anxiety and Depression Scale (HADS) at v60 days, 3 months, and 6 months post-randomisation
4. Pain Acceptance is measured using the Chronic Pain Acceptance Questionnaire (CPAQ-8) at baseline, 60 days, 3 months, and 6 months post-randomisation
5. Sexual health outcomes are measured using the Sexual Health Outcomes in Women Questionnaire (SHOW-Q) at baseline, 60 days, 3 months, and 6 months post-randomisation

Overall study start date
01/11/2015

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Women with organic and non-organic chronic pelvic pain lasting for six months or more
3. Capable of understanding the information provided, with use of an interpreter if required and being able to understand simple English as is used in the app
4. Give written informed consent
5. Access to a personal computer or smartphone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Total final enrolment
90

Key exclusion criteria
1. Males
2. Absence of diagnosis of organic and non-organic chronic pelvic pain (CPP)
3. Diagnosis of organic and non-organic chronic pelvic pain (CPP) lasting for less than 3 months
4. Aged under 18 years
5. No access to a Personal computer or smart phone
6. Unable to speak / understand English

Added 28/10/2016:
7. Current users of the Headspace app content available to the public

Date of first enrolment
13/05/2016

Date of final enrolment
20/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1BB

Study participating centre
Whips Cross Hospital
Whipps Cross Road
Leytonstone
London
United Kingdom
E11 1NR

Sponsor information

Organisation
Barts Health NHS Trust

Sponsor details
The Royal London Hospital
Whitechapel Road
London
England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00b31g692

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 high-impact peer reviewed journal.

Intention to publish date
31/10/2019

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?
Protocol article	protocol	15/01/2018		Yes	No
Results article	results	12/03/2020	16/03/2020	Yes	No
Results article	user experience results	12/03/2020	16/03/2020	Yes	No
HRA research summary			26/07/2023	No	No