ISRCTN12146140 https://doi.org/10.1186/ISRCTN12146140

Effect of Anapana, Body scan and Metta meditation techniques on pain and disability of adult patients affected with chronic neck and shoulder region pain

Submission date
09/08/2021

Recruitment status
No longer recruiting

Registration date
20/08/2021

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
People of all ages can be affected by chronic neck and shoulder region pain, and the annual prevalence worldwide is 30-50%. This type of pain is common in the 21st century, particularly due to the extended periods of time that people sit at computer workstations. In Sri Lanka, the prevalence of work-related complaints of the neck and shoulder region among office workers is high (63.6%) and comparable to the prevalence in developed countries (30-70%). Patients in Sri Lanka prefer treatments that are low cost with fewer side effects and that are easy to comply with. Meditation is low-cost and has minimal side effects when used as a treatment for pain. Different meditation techniques can have similar but different benefits for pain relief. Previous research into the effect of meditation on pain relief for conditions such as headache, low back pain, neck pain and abdominal pain, has found that keeping the duration short (15 minutes/day) enables participants to successfully fit meditation into their daily routine.
Most studies that used a short-duration meditation programme of 15 minutes or less used only a single type of meditation technique. No studies to date have compared the effects of different types of meditation techniques on patients affected with chronic neck and shoulder region pain. Therefore, there is a necessity to find out which type of meditation is most effective in the management of chronic neck and shoulder region pain, alongside a programme that could easily fit into people's daily routines. This study aims to compare the effectiveness of an 8-week training programme of Anapanasati, Body scan and Metta meditation techniques on neck and shoulder region pain and disability, with a usual care control group and with each other at 4, 8 and 12 weeks follow-up.

Who can participate?
Adult male and female patients aged 18-65 years affected with chronic neck and shoulder region pain attending one of four clinics held on four different days of the week in a clinic in the Colombo North region of Sri Lanka

What does the study involve?
This study will be conducted in a clinic in Colombo Sri Lanka. This clinic has four rheumatology clinics held on four different days of the week. Each clinic will be randomly allocated into one of the intervention groups (Anapanasati, Metta and Body Scan) or the control group. Patients eligible to be included in the study will attend one of the clinics. Patients in the three intervention groups will take part in weekly meditation training sessions (30-45 minutes) for 8 weeks. In addition, they will be asked to practice meditation at home daily for 15 minutes/day and maintain entries in a logbook with regard to the amount of meditation done per day. Patients in all four groups will be asked to maintain entries in a logbook with regard to their level of pain (assessed three times/day) and the amount of medication taken daily and they will be assessed at the start of the study and 4, 8 and 12 weeks follow-up. The 4th and 8th week of follow-up will take place while the intervention is going on. The 12th week of assessment will take place after the intervention.

What are the possible benefits and risks of participating?
Participants will get an opportunity to learn a meditation technique that might be useful in managing their painful condition and also improve their physical, psychological and psychosocial health. Interviews will be conducted at the clinic and health guidelines related to the prevention of COVID-19 infection will be followed. This research will not involve risks beyond those normally encountered by the researcher in their life outside research.

Where is the study run from?
University of Bath (UK) and a family medicine and rheumatology clinic in Colombo (Sri Lanka)

When is the study starting and how long is it expected to run for?
May 2020 to September 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Nikki Coghill
N.Coghill@bath.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Nikki Coghill

ORCID ID
https://orcid.org/0000-0002-7000-0394

Contact details
Department of Health
Faculty of Humanities and Social Sciences
University of Bath
Building 1 West North 4.3
Bath

United Kingdom
BA2 7AY
+44 (0)1225 386623
N.Coghill@bath.ac.uk

Type(s)
Public

Contact name
Dr Aranjan Karunanayake

ORCID ID
https://orcid.org/0000-0001-9266-2332

Contact details
Department of Health
Faculty of Humanities and Social Sciences
University of Bath
Building 1 West North 4.3
Bath
United Kingdom
BA2 7AY
+94 (0)773062184
alk26@bath.ac.uk

Additional identifiers

Study information

Scientific Title
Effectiveness of Anapana, Body scan and Metta meditation techniques on chronic neck and shoulder region pain and disability in adult patients within four clinics in Sri Lanka: a cluster clinic-level parallel randomised controlled trial

Acronym
RCTONEOABMMTOCNSRP

Study objectives
There are no differences in the effects of three meditation techniques (Anapana, Body scan and Metta) with the control group and with each other on pain and disability of people affected with chronic neck and shoulder region pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/05/2021, Research Ethics Approval Committee for Health (REACH) (University of Bath, Claverton Down, Bath, BA2 7AY, UK; +44 (0)1225 384714; health-ethics@bath.ac.uk), ref: EP 20/21 037
Amendment approved 23/02/2022, Research Ethics Approval Committee for Health (REACH)

(University of Bath, Claverton Down, Bath, BA2 7AY, UK; +44 (0)1225 384714; health-ethics@bath.ac.uk), ref: EP 20/21 037

Primary study design
Interventional

Study design
Parallel cluster clinic-level randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neck and shoulder region pain due to mechanical causes such as cervical spondylosis, muscle strain, ligamental sprain and facet joint osteoarthritis

Interventions
This trial will be conducted in a clinic in Colombo Sri Lanka. This clinic has four rheumatology clinics held on four different days of the week. Each clinic will be considered as a cluster. One cluster will be the control group. The other three clusters will be the three intervention groups: Anapana, Metta and Body Scan.

Patients eligible to be included in the study will be allocated into one of the intervention arms (Anapana, Metta and Body scan) or control arm using previously generated random number groups.

Patients in the three intervention arms will take part in weekly meditation training sessions (30-45 minutes) for 8 weeks. In addition, they will be asked to practice meditation at home daily for 15 minutes/day and maintain entries in a logbook with regard to the amount of meditation done per day.

The control group will not receive any intervention. They will receive only the usual care treatment which includes medication and physiotherapy.

Patients in all four groups will be asked to maintain entries in a logbook with regard to their level of pain (assessed three times/day) and the amount of medication taken daily and they will be assessed at baseline and 4, 8 and 12 weeks follow-up.

The 4th and 8th weeks of follow up will take place while the intervention is going on. The 12th week of assessment will take place after the intervention.

Data will be collected using validated questionnaires, clinical examinations and focus groups. A numerical pain rating scale will be used to assess the level of pain. Oswestry neck disability questionnaire, disability of shoulder arm and hand questionnaire (DASH), and clinical assessment of neck and shoulder joint movements will be used to assess the level of physical disability of patients. Clinical assessments will be conducted by a trained physiotherapist. Health-related quality of life will be assessed using the short-form SF-36 Questionnaire.

To understand how the patients feel about how regular practice of meditation has affected their level of pain and quality of life and to understand the acceptability and feasibility of the different types of meditation training and practice for the participants focus groups will be carried out after 8 weeks of the intervention.

Patient's demographic data, details of pain, treatment taken, inclusion and exclusion criteria will be assessed by the primary researcher using a structured interviewer-administered questionnaire.

Intervention Type
Behavioural

Primary outcome(s)
Pain in the neck and shoulder region assessed using the numerical pain rating scale at 8 weeks follow up

Key secondary outcome(s)
1. Pain in the neck and shoulder region assessed using the numerical pain rating scale at 4 and 12 weeks follow up
2. The range of movement in the neck and shoulder region, assessed clinically by measuring the active and passive movements of the neck and shoulder joint using a goniometer at 4, 8 and 12 weeks follow-up
3. Physical and social disability with regard to activities of daily living, occupation and social activities (with family, friends, neighbours and/or groups) assessed using validated questionnaires (Neck Disability Index, Disability of Shoulder Arm and Hand and the SF-36 Short Form) at 4, 8 and 12 weeks follow-up
4. How patients in the three intervention groups feel about the effects of meditation on pain, physical and social disability with regard to activities of daily living, occupation and social activities (with family, friends, neighbours and/or groups) and the acceptability and feasibility of the different types of meditation training and practice for the participants will be assessed using semi-structured interviews/focus groups at 8 weeks follow-up

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. Patients in the age range 18-65 years and affected with chronic (>12 weeks) neck and shoulder region pain attending the four clinics managed by the same physician and physiotherapist
2. Patients affected with mechanical causes such as degenerative changes of the spine, muscle strain, ligament sprain, and facet joint osteoarthritis
3. Patients who can understand and communicate in Sinhala

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
96

Key exclusion criteria
1. Patients affected with infections, inflammatory arthropathies, malignancies, Alzheimer's disease, psychiatric conditions, severe depression and anxiety
2. Patients who take part in yoga and other meditation programmes
3. Patients who are below the age of 18 years and above the age of 65 years

Date of first enrolment
01/03/2022

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
Sri Lanka

Study participating centre
Family Medicine and Rheumatology Clinic
No 3, Walter Gunasekera Mawatha, Nawala
Colombo
Sri Lanka
00500

Sponsor information

Organisation
University of Bath

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All personally identifiable data will be destroyed at the end of the analysis with the exception of the informed consent forms which will be stored for an additional 5 years after the study ends, in case there is any query or complaint from a participant. The researchers plan to store all anonymized data that may be used for future publications in the University of Bath Research Data Archive. The data will be kept there for at least 10 years.
Prior to conducting the study, written permission from the clinic administrators and clinicians in charge of the patients will be obtained. To gauge potential participant interest in the trial, when a patient presents to the clinic with chronic neck and shoulder region pain, the clinic nurse will provide each patient with a participant information sheet and contact details of the researcher. Patients who are happy to take part in the trial will be directed to the researcher to discuss more details about the study. The researcher, after answering all the patient's questions and if the patient is happy to take part in the study, will provide the patient with a consent form. Patients will be recruited to the study only after they have provided written informed consent. The signed copies of the consent forms will be kept securely and separately from the research data in a locked filing cabinet. The participants will also be given a copy of their consent form (signed) to take away with them. In the information sheet, participants will be made aware that they can drop out of the research study at any time without having to give a reason for doing so. However, they will not be able to withdraw the data, if they drop out after 2 weeks of taking part in the study, since by that time the data will be anonymised. This will be made clear in the participant information sheet and the consent form.
During the meditation practice and or clinical assessments, participants will not be subjected to any physical or psychological discomfort over and beyond that experienced within a clinical situation, during usual care. If participants experience any discomfort in answering questions, they can stop at any time and if they need any psychological support they will be referred to a relevant specialist. Information about this will be included in the information sheet. Participants will not be photographed or video-taped. However, the focus groups will be audio-taped with an audio recorder to aid transcription. These recordings will be encrypted. Participants will be made aware and will need to provide informed consent to be recorded.
The participants will be allocated a reference number at the beginning of the study. The identifiable data (names, addresses, contact details) and the main data will be encrypted and identifiable data will be stored separately from the main data (i.e., in a different folder) on a secure drive at the University of Bath. This drive is only accessible by the researcher and their

supervisory team. A locked filing cabinet will be used to store non-digital data. The keys will be accessible only by the researcher and their supervisory team. Once the results are published, the participants will be informed about where the results are published.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/11/2022	17/11/2022	Yes	No