Effectiveness of Anapana, Body scan and Metta meditation techniques on chronic neck and shoulder region pain and disability in adult patients in Sri Lanka.: study protocol for a cluster clinic-level parallel randomised controlled trial

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Research Article

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Abstract

Background

Chronic neck and shoulder region pain affects many people in the world. This study aims to compare the effectiveness of an eight-week training programme on pain and disability in a patient population affected with chronic neck and shoulder region pain, using Anapana, Body Scan and Metta meditation techniques, with a usual care control group and with each other.

Methods

This parallel cluster clinic-level randomised controlled trial will be conducted with male and female patients aged 18-65 years, who are affected with chronic neck and shoulder region pain, and who attend one of four clinics held on four different days of the week in a medical centre in the Colombo North region, Sri Lanka. Clinics will be considered as clusters and randomly allocated to intervention and control arms.

Data will be collected using validated questionnaires, clinical examinations and focus groups. To compare baseline with primary (differences in changes in pain at 8 weeks) and secondary outcomes (differences in changes in pain, physical disability, range of movement and quality of life at 4 and 12 weeks), a two-way ANOVA will be used if the data is normally distributed. If the data is not normally distributed a nonparametric equivalent (Kruskal Wallis) will be used. Focus group transcriptions will be thematically analysed using the Richie and Spencer model of qualitative data analysis.

Discussion

This protocol describes how three meditation interventions will be implemented on the management of patients affected with chronic neck and shoulder region pain and compared with a usual care control-group. The effectiveness of each meditation intervention on the pain, physical and psychosocial disabilities of patients will be compared between groups. The results of this study will enable recommendations to be made for future meditation interventions for chronic neck and shoulder pain.

Trial Registration

ISRCTN12146140

Date of registration : 20/08/2021

(https://www.isrctn.com/ISRCTN12146140).

Introduction

Background and rationale {6a}

People of all ages can be affected by neck pain [1]. Most patients with neck pain are also affected with shoulder region pain [2]. Due to difficulties in demarcating neck and shoulder region pain, many prevalence studies have considered these two regions together [3]. Bad neck posture while sleeping and carrying out activities of daily living are recognised as the main risk factors for neck pain [4]. In addition to physical factors, there is an association between chronic neck pain and psychosocial factors such as cognitive distress, anxiety and depression [1].

Techniques commonly used to manage neck and shoulder region pain include medications, physiotherapy, acupuncture, physical exercises and yoga [5]. Medications used in the management of musculoskeletal painful conditions are associated with an increased risk of allergic reactions, gastritis, ischemic heart disease, type 2 diabetes, cataract, nephropathy and osteoporosis [6]. Other treatment modalities such as physiotherapy, physical exercises and yoga can be associated with adverse effects, such as pain, swelling and soft tissue injuries [5], while techniques such as spinal manipulations, acupuncture and relaxation have not been associated with significant positive effects in the management of neck pain [7]. According to Monticone and colleagues (2012), cognitive behavioural therapy has not been associated with significant positive improvements in levels of neck pain [1]. Hence, there is scope for treatment methods, such as meditation, which are safe, cheap to implement, and easily accessible.

In meditation, the person learns to take control of their emotions to become the master of their own mind [8]. There are many different types of meditation techniques. Anapana, Body scan and Metta are meditation techniques that are practiced worldwide [9].

Available research suggests how meditation can be useful for managing painful conditions [10]. A randomised controlled trial (RCT) conducted by Colgen and colleagues (2019) reported that meditation training can improve an individual's ability to observe and experience internal reactions to a stressor as they arise, with acceptance, and equanimity [10]. In turn, this impartial receptiveness can reduce emotional reactivity to the stressor [10]. A clinical trial conducted to investigate the effect of meditation on 48 patients, aged 30–45 years, suffering from lower back pain, demonstrated that meditation is useful in reducing pain and enhancing physical and mental quality of life, compared to usual care [9]. In this study, patients practiced three different meditation techniques for 90 minutes a day, for eight weeks. However, because the intervention group practiced three different meditation techniques, it was not possible to differentiate the effect of the individual meditation techniques on pain relief and quality of life. Asking patients to practice three different meditation techniques in order to manage their pain might be overly burdensome outside of a research environment. Being able to make recommendations for one technique in isolation is more likely to be adhered to by patients, as a treatment for their pain management. Similarly, a home-based RCT with 89 patients with chronic neck pain demonstrated that Jyoti meditation significantly reduced pain at rest as measured by numerical pain rating scale compared to a physical exercise programme [11]. Jyoti meditation involves practicing a combination of four types of meditation techniques, such as concentration on breath, sound, the flame of a candle and loving kindness [11]. Since Jyoti meditation involves practicing a variety of techniques in combination, it is difficult to assess the effectiveness of one type of meditation on pain reduction. In a systematic review of

the effectiveness of meditation interventions for the treatment of chronic pain, Magoline (2016) stated that they were unable to identify any head-to-head trials comparing different meditation interventions with regard to pain and quality of life [12].

To date, studies that have investigated the effectiveness of meditation on pain relief and disability have been conducted in countries outside of Sri Lanka. Included interventions have mostly involved lengthy meditation times that may not be feasible for working adults, ranging from 20 minutes/day [13] to 120 minutes/day [9]. To date, studies that have involved meditation sessions of a shorter duration i.e., < 15minutes, have not shown significant benefits with regard to physical, psychological and social disabilities [14]. However, a descriptive analytical study conducted by Kabat-Zinn et al. (1985) involving 90 patients with a variety of conditions (low back pain, headache, migraine, facial pain, abdominal pain and neck and shoulder pain) demonstrated that practicing meditation for 15 minutes/day for 10-weeks was associated with significant reductions in pain, negative body image, mood disturbances and pain-related drug utilisation [15]. In this study, 33% patients were affected with low back pain and 27% patients were affected with headaches. Since the patients falling into other disease conditions such as neck pain, shoulder pain, facial pain and abdominal pain were small in number, the clinical effect of meditation on those conditions cannot accurately be determined.

Patients have expressed the importance of having a meditation programme that is brief, useful for everyday living, and can be easily incorporated into their daily routine [16]. Sri Lanka is a developing country and many patients in Sri Lanka prefer traditional treatment methods that are low in cost and have minimal or no adverse effects [17]. Therefore, meditation might be a suitable treatment method to fulfill this need. 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 justified scope to find out which type of meditation is more effective in the management of chronic neck and shoulder region pain, alongside a programme that could easily fit into patients' daily routines. Thus, the present study intends to compare the effectiveness of three different mindfulness meditation techniques (Anapana, Metta and Body scan) practiced over a short duration (15 minutes), with each other and a usual care group, for patients affected with chronic neck and shoulder region pain.

Objectives {7}

[SPIRIT guidance: Specific objectives or hypotheses.]

- To compare the effectiveness of three different meditation techniques:
- Anapana
- Body scan
- Metta

with a usual care control group and with each other, at four, eight, and twelve weeks follow-up on patients' perceived neck and shoulder region pain, range of movement at the neck and shoulder, and changes in

physical and social disability relating to activities of daily living, occupation and social activities with family and friends.

- Explore how patients in each intervention group feel about the effectiveness of meditation for their chronic neck and shoulder region pain.

Trial design {8}

This is a parallel cluster clinic-level randomised controlled trial. The following flow chart (Fig. 1) provides an outline of the stages of the trial. This study will be conducted in-line with the CONSORT statement [18] (Fig. 1).

Methods: Participants, Interventions And Outcomes

Study setting {9}

The study will be conducted in a rheumatology and family medicine clinic in Colombo, Sri Lanka.

Eligibility criteria {10}

Study inclusion and exclusion criteria are described in Table 1.

Table 1
Inclusion and Exclusion criteria.

Inclusion criteria	Exclusion criteria
• Patients affected with chronic (> 12 weeks) neck and shoulder region pain attending the four clinics managed by the same physician and physiotherapist.	Patients affected with infections, inflammatory arthropathies, malignancies, Alzheimer's disease, psychiatric conditions, severe depression and anxiety will be excluded.
• Patients affected with mechanical causes such as degenerative changes of the spine, muscle strain, ligament sprain.	Patients who take part in yoga and other meditation programmes.
• Patients who can understand and communicate in Sinhala.	Patients who are below the age of 18 years and above the age of 65 years.

Who will take informed consent? {26a}

The corresponding author will collect written informed consent from the participants after explaining the details of the study to them.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not relevant

Interventions

Explanation for the choice of comparators {6b}

Not relevant

Intervention description {11a}

This study consists of three intervention groups and a control group. Each intervention group will be practicing a different meditation technique for eight weeks in addition to usual care. The control group will follow only usual care. The three different types of meditation techniques are:

- Anapana (concentration on breathing)
- Body scan (concentration on bodily sensations without reacting to them)

- Metta (concentration on loving kindness) [19].

In Anapana meditation, the attention is on ‘the breath’ and it focuses on ignoring any distractions that might break the chain of awareness on ‘the breath’. It helps to keep away thoughts of cravings, aversions, fantasies and illusions [8].

In Body scan meditation the meditator observes bodily sensations in a systematic manner from head to feet and from feet to head; by not reacting to them it helps the meditator to realise the impermanent nature of these sensations and consequently, this will help the meditator to get rid of thoughts of cravings and aversions [8].

Practicing Metta type of meditation helps to remove thoughts of anger and hatred from the mind and introduce thoughts of patience, friendship and love [20].

The meditation techniques will be taught to the patients by a meditation trainer who has more than ten years of experience in teaching meditation. Meditation techniques will be taught on a weekly basis for eight weeks. Each session will include five patients and last for 30–45 minutes [9]. In between weekly training sessions, patients in the intervention groups will be requested to practice the meditation technique that was taught to them, for fifteen minutes each day. They will be advised to only practice the meditation technique that was taught to them and not to practice any other technique. Participants will be requested and instructed in keeping a logbook record of their daily meditation practice. They will be requested to log the duration of each practice session. Additionally, using a numerical pain rating scale [21], they will be requested to log the pain intensity ratings from the previous 24-hours corresponding to:

- current pain when they wake up in the morning
- least pain
- worst pain

Participants will also be requested to log the type, dose and amount of medication taken each day.

Criteria for discontinuing or modifying allocated interventions {11b}

Participants will not be subjected to any pain or harmful interventions. Therefore, we do not feel that there will be a necessity to modify the allocated intervention.

Strategies to improve adherence to interventions {11c}

Daily short message services (SMS) will be sent to participants reminding them to practice their allocated meditation and to complete their log book. Weekly face-to-face meditation training sessions with the meditation trainer will also be used to address any concerns or difficulties experienced by participants.

Relevant concomitant care permitted or prohibited during the trial {11d}

Participants in the intervention groups will be asked not to take part in any meditation or yoga programmes other than their allocated meditation intervention. Participants in the usual care group will also be requested not to take part in any meditation programmes or yoga during the eight-week intervention period of the trial. Additionally, participants will be advised not to engage in treatment for their neck and shoulder region pain, other than from the physician or therapist in the registered clinic as part of the trial.

Provisions for post-trial care {30}

No harmful procedures will be conducted during the trial. Therefore, it is unlikely that the participants will need post trial care. If by chance the participants need any care they will be referred to the appropriate specialist.

Outcomes {12}

Primary and secondary outcomes are stated in Table 2.

Table 2
Primary and Secondary Outcomes

Primary Outcome	Secondary Outcomes
Compare the three intervention groups with usual care group and with each other with regard to differences in changes in pain in the neck and shoulder region at eight weeks follow-up.	(i) Compare the three intervention groups with usual care group and with each other with regard to differences in changes in pain in the neck and shoulder region at four and twelve weeks follow-up.
	(ii) Compare the three intervention groups with usual care group and with each other with regard to differences in changes in the pain free range of movement in the neck and shoulder region at four, eight and twelve week follow-up.
	(iii) Compare the three intervention groups with usual care group and with each other with regard to differences in changes in quality of life with regard to activities of daily living, occupation and social activities with family and friends at four, eight, and twelve weeks follow-up.
	(iv) To determine 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 and friends at eight weeks follow-up.

Participant timeline {13}

The duration of the trial is twelve weeks and the supervised intervention duration is eight weeks. The participants will be assessed at baseline and four, eight and twelve weeks follow up.

Sample size {14}

Sample size was calculated using the WinPepi version 11.65 statistical software. Results from a study by Jeitler et al. (2015) with patients with chronic neck pain were used to calculate the sample size [11]. This study used a numerical pain rating scale, similar to the one proposed for the current study. After eight weeks of Jyoti meditation training, improvements in pain intensity rating in the intervention group compared to the control group were 17.8. Using this improvement value of 17.8, a power of 80%, and a ratio of 1:1, the sample size calculation for each cluster (clinic) was n = 19. Therefore, the total sample in our study will be n = 76. In an RCT conducted by Rantonen et al. (2018) involving three intervention groups and a control group the dropout rate was 26% [22]. Therefore, our total study sample size, after accounting for this rate of dropout will be n = 96; evenly spread across each group allocation, resulting in 24 participants per group.

Recruitment {15}

All patients who are not currently being treated for neck and shoulder pain in this clinic who meet the eligibility criteria and who attend the clinic on one of the intervention clinic days will be notified about the

research study by an independent person (nurse). Patients who show their willingness to participate will be provided more information about the project and their written consent will be obtained prior to recruitment.

Assignment Of Interventions: Allocation

Sequence generation {16a}

Since this is a cluster clinic-based trial, participants will be randomised according to the clinic day rather than individually.

Concealment mechanism {16b}

The person who assesses the outcomes will be blinded to the group allocation.

Implementation {16c}

Implementation will be done by the researchers. Participants will be assigned to intervention groups and the control group by a clinic nursing assistant.

Assignment Of Interventions: Blinding

Who will be blinded {17a}

Participants in one cluster will not know about the interventions that are given to participants in other clusters. The usual care givers (doctor and the physiotherapist), and the physiotherapist who will be assessing the outcomes will be blinded to the intervention allocation.

Procedure for unblinding if needed {17b}

Not applicable

Data Collection And Management

Plans for assessment and collection of outcomes {18a}

The outcomes will be assessed using validated questionnaires and physical examinations (Table 3).

Table 3
Methods of measurement of outcomes.

Outcome Measure	Method of measurement
Level of Pain	Numerical pain rating scale
Physical disability	Oswestry neck disability questionnaire [23], Disability of shoulder arm and hand questionnaire (DASH) [24], Questionnaire to assess details of pain and demographic data, and clinical assessment of active and passive movement of neck and shoulder joint [5]
Quality of Life	The SF-36 Questionnaire Short Form [25]
Feelings on pain, physical disability and psycho social disability	Focus groups

A questionnaire to assess details of presenting complaint, demographic data and details of medical and surgical history will be administered by the lead researcher. Physical and social disabilities will be assessed by a trained physiotherapist using methods listed in Table 3. Participants' perceptions of the effects of meditation on pain, physical disability and psycho-social disability will be assessed using focus groups conducted by the lead researcher. The focus groups will be audio-recorded and transcribed verbatim. The transcriptions in Sinhala will then be translated into English.

Data collection forms can be obtained on request from the lead researcher.

The neck disability questionnaire consists of 10 sections which include questions on pain intensity, personal care (washing, dressing etc.,), lifting objects, reading, headaches, concentration, work, driving, sleeping and recreation. Under each section there are five responses graded from 0–5, whereby zero indicates no disability and five indicates the highest disability [23].

DASH consists of three sections which include questions on activities performed at home, work and during recreation. First section has thirty questions. Under each question there are five responses graded from 0–5, where zero indicates no difficulty and five indicates extreme difficulty [24].

The SF 36 questionnaire has 11 sections which include questions on vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health. Under each section the potential responses range from 1–6 with higher scores indicating less disability [25].

Plans to promote participant retention and complete follow-up {18b}

Participants in the intervention groups will be taught meditation by an experienced meditation instructor during the first eight weeks on a weekly basis. At the beginning of the study, participants will be educated

on the nature and potential purpose of meditation and, that for any potential benefits of meditation to be realised it is important that they practice their meditation on a regular basis for the required period of time. This intervention does not include any harmful or painful procedures, thus adverse events are unlikely. Participants will be regularly monitored on a weekly basis and if by any chance an adverse event does occur they will be referred to the appropriate specialist.

Data management {19} and Confidentiality {27}

Participants will be allocated a unique identification number at the beginning of the study. Participants will not be photographed or video-taped, but they will be audio recorded for focus groups. All identifiable data (names, addresses, contact details) and the main data will be encrypted and stored separately from each other in a secure folder that can only be accessed by the research team. A locked filing cabinet will be used to store non-digital data. The keys will be accessible only by the research team. Data will be protected for ten years. The results published from this study will be in the form of data for the whole group. During the study, monthly checks will be conducted by the research team comparing the hard and soft copies to identify any missing data.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable

Statistical Methods

Statistical methods for primary and secondary outcomes {20a}

If data is normally distributed, a two-way ANOVA will be used to explore any changes in the primary outcome between the intervention and usual care control groups and between groups at 8-week follow-up. Similarly, any changes in secondary outcomes between intervention and control groups and between groups will be explored at 4 and 12-week follow-up. If the data is not normally distributed, a nonparametric equivalent such as Kruskal Wallis will be used.

Multivariate linear regression will be used to explore any effect of the independent variables of age, gender, level of income, level of education, changes in the amount of medication used and the weekly, mean meditation duration on the primary outcome at 8-week follow-up and in the secondary outcomes at 4- and 12-week follow-up.

All focus groups will be audio-recorded and transcribed verbatim, and, translated to English [26]. For the qualitative data analysis, the literature recommends a scientific model be used [26]. To do this, the Richie and Spencer model will be used as it provides a sound analytical model [26]. Atlas ti will be used to manage the analysis for its usefulness in coding.

Interim analyses {21b}

Not applicable

Methods for additional analyses (e.g. subgroup analyses) {20b}

Not applicable

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

In calculating the sample size, adjustments were made to include for protocol non adherence.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

When the trial results are published, an anonymised version of the dataset will also be provided as a supplementary file. Confidential data related to the trial participants will not be provided.

Oversight And Monitoring

Composition of the coordinating centre and trial steering committee {5d}

The trial will be handled by the three researchers who will meet once every two weeks to assess how the trial is running. In addition, there will be a physician and physiotherapist involved in the routine treatment of patients. The meditating instructor will train the participants in the meditation techniques, while another therapist will assess the outcomes. Allocating patients to usual care control and intervention arms and registering patients will be carried out by a nursing assistant. Data entry will be conducted by a research assistant.

Composition of the data monitoring committee, its role and reporting structure {21a}

Data monitoring will be conducted by the three researchers on a monthly basis.

Adverse event reporting and harms {22}

The interventions does not include any harmful procedures. Therefore, adverse events are unlikely.

Frequency and plans for auditing trial conduct {23}

Not applicable

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

At present we do not feel any protocol amendments are required. However, if any important protocol amendments are done, it will be notified to the University of Bath ethics committee, ISRCTN trial registry and the participants.

Dissemination plans {31a}

We intend to publish the trial results in scientific journals and present these at scientific conferences. There are no publication restrictions.

Discussion

The prevalence of work-related complaints of neck and shoulder among office workers in Sri Lanka is high (63.6%) [27], and comparable to the prevalence in developed countries (30–70%) [28, 2]. Sri Lankan patients similar to patients in other countries prefer treatments that are low cost, with less side effects, and are easy to comply with [17].

Meditation has minimal or no negative side effects and the effect of meditation on easing pain and disability has not been studied in Sri Lanka. Comparing three meditation techniques with a usual care control group and with each other on pain, physical disability and psycho-social disability has not been described in previous literature. Therefore, conducting this study will contribute toward filling gaps in knowledge in this area of research. It may also evidence a treatment technique which is low-cost and less time consuming for managing patients who are affected with chronic neck and shoulder region pain in Sri Lanka.

Study limitations

In a randomised controlled trial patients are randomly allocated to intervention or control arms. Therefore, the meditation intervention the patient is randomized to receive may not be the ideal method for that patient. In this study the patients have to meditate for at least 15minutes/day at their homes, on their own. Therefore, it will, not be definitively possible to assess whether this is actually performed or to assess the quality of meditation practiced.

Study strengths

In many randomised controlled trials the interventions are compared with a control group but not with each other. In this trial the effect of three meditation interventions will be compared with a usual care control group, and with each other. This study in addition to the quantitative component has a qualitative component to assess and compare the effects of three meditation interventions on chronic neck and

shoulder region pain. Many randomised controlled trials that have been conducted to investigate the effects of meditation on pain management have only used a quantitative component to assess pain. Since meditation is a cost effective and a risk free treatment technique this treatment method may be more acceptable for people in Sri Lanka.

An additional strength of the study is that all the patents in the four groups will be treated by the same physician, physiotherapist and the meditation instructor. The study outcomes will also be assessed by the same person, who will be anonymized to group allocation.

To evaluate the effect of an intervention on usual care, a randomised controlled trial is accepted as being the most rigorous study design. The process of randomization maximizes the external validity of findings [29]. In this clinic-based trial three meditation interventions are compared with a usual care control group and with each other. To prevent patients discussing their group allocation with each other, patients are randomised to groups by clinic that act as clusters rather than within clinics; making this a cluster randomized controlled trial.

Abbreviations

Very few abbreviations are used and they are explained in the text itself. Therefore, we feel a list is not required.

Declarations

Trial status

Protocol version number is 01 and date 08.03.2022

The date of recruitment has still not begun due to the present pandemic situation in Sri Lanka. Once the recruitment begins we anticipate that it will take one year to recruit and an additional three months to complete the monitoring.

Acknowledgements

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Authors' contributions {31b}

All the authors were responsible in identifying the research question, design of the study, obtaining ethics approval and trial registration and drafting the manuscript and approving the final version

Funding {4}

This research will be funded by the personal funds of the corresponding author's salary which includes a research allowance provided by the Higher Education Ministry of Sri Lanka. The research work and results that will be generated by the research will be completely independent and not biased by the opinions of the Higher Education Ministry of Sri Lanka.

Availability of data and materials {29}

The data will be accessible only by the three authors. After the study the data will be stored in University of Bath data Achieve.

Ethics approval and consent to participate {24}

Ethical approval for the study was obtained by Research Ethics Committee of the University of Bath, United Kingdom (**REACH reference number**: EP 20/21 137). In addition permission was obtained by the medical centre management committee in Sri Lanka to conduct the study. Patients will not be subjected to any painful or harmful procedures. Prior to recruitment all potential participants will receive written information about the nature and purpose of the study and each participant will be requested to sign an informed consent form. Participants will be reassured that they can withdraw from the study at any point of time without giving any reasons and that it will not cause any effect on their treatment course. Authors are happy to provide a model consent form on request.

The hard and soft copies of the data obtained through the course of study will be anonymised and will be kept in a locked cabinet and password protected encrypted computer files. The results published from this study will be in the form of data for the whole group. After the study is completed, the data will be protected and stored for a period of ten years

Consent for publication {32}

Not applicable

Competing interests {28}

This study has no competing interests to be declared.

Authors' information

This section is optional. For the time being we prefer to keep it as it is

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Figures

Figure 1

Flow Chart to demonstrate the follow up time periods