

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2023/001

Scientific title of trial: Open-Label, Randomized Controlled Trial to Investigate Outcome of a Pain Coping Skills Psychological Intervention in Relieving Pain and Psychological Distress in Sinhala-conversant Patients with Chronic Knee Osteoarthritis

Date of commencement (enrolment of first participant): 17 January 2023

Progression: 6 months 1 year 2 years 3 years
At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement:

As per the RCT protocol, the intervention group was divided into three distinct subgroups. The first session of the trial commenced on May 4, 2023. However, due to heavy rain and influenza fever, 12 participants were unable to attend the first two sessions. These participants promptly communicated their unavailability to the principal investigator.

To ensure fair participation, the research team decided to introduce a fourth group for the participants who missed the initial two sessions. This fourth group will operate separately from the existing groups mentioned in the protocol. To ensure consistency, the fourth group will follow the same intervention and data collection protocol as the original three groups. The scientific integrity and statistical analysis of the study will not be affected by this amendment.

2. Current status

Recruitment status: pending/ recruiting/ **recruitment completed**: follow up continuing/ recruitment complete: follow up complete/ recruitment suspended / recruitment terminated

Number assessed for eligibility: 149

Number recruited and allocated/randomized: 74

Number allocated/randomized to each intervention/arm (please edit as relevant):

Intervention group - 37
Control group - 37

Losses/exclusions after allocation/randomization (please edit as relevant): N/A

3. Trial output

Date of trial completion ("last patient, last visit"):

Final sample size:

Summary of Interim/Final data (if available):

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Abstract presentations of results at scientific meetings

Note: please include a URL link or scanned copy of the abstract

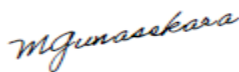
Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).

Publications

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Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)

Medhavi Gunasekara



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Name and signature of Responsible Registrant/
Principal Investigator

Date: 12/06/2023