

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR / 2021/ 016

Scientific title of trial: Cerebral Palsy in western province, Sri Lanka: the clinical profiling and early intervention package.

Date of commencement (enrolment of first participant): 1st of July 2021

Progression: 6 months ☐ 1 year ☐ 2 years ☒ 3 years ☐

At completion ☐

1. Baseline data

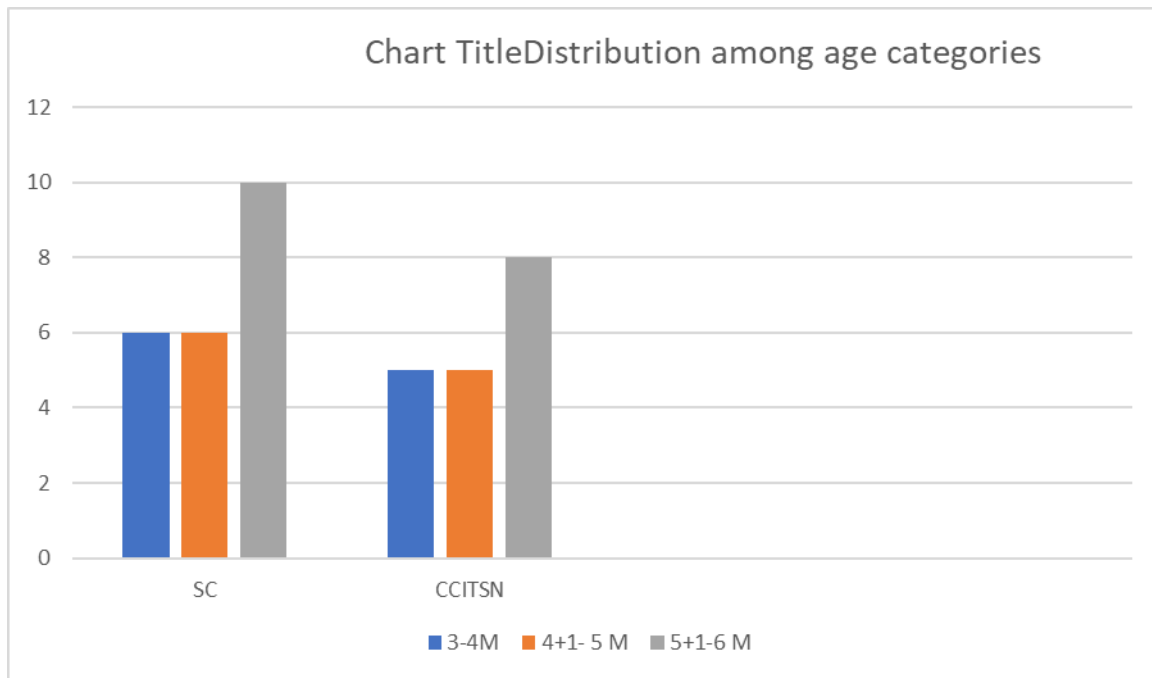
Any changes to the trial design/ methodology/ protocol after commencement: None
But due to the differences in the allocation to three groups according to the stratified randomisation (40 was recruited using 60 envelopes 20 per each age category was a methodological error).

Allocation to the two groups

Intervention	Number
SC	22
CCITSN	18

Allocation to two groups

	3-4	4+1-5	5+1-6
CCITSN	5	5	8
SC	6	6	10



we are planning to submit an amendment to the protocol to the Faculty of Graduate Studies and the Ethics Review Committee of the Faculty of Medicine, University of Kelaniya. I will share all the communications regarding this with the SLCTR when available.

Any changes to trial outcomes after commencement: None

2. Current status

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

Number assessed for eligibility: 213

Number recruited and allocated/randomized: Number recruited and randomized 40

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

Arm 1 (CCITSN): 18

Arm 2 (Standard Care): 22

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

Arm 1 (CCITSN): 1 (Reason – Child withdraw from all the services at ayati)

Arm 2(Standard Care): None

3. Trial output

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

Final sample size: Sample size 40

Summary of Interim/Final data (if available):

N/A

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).
N/A	N/A
N/A	N/A

Publications

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

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

H. Thilini Madushika



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Name and signature of Responsible Registrant/
Principal Investigator

Date: 2023/02/17