

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2022/001**

Scientific title of trial: **Family- centred, early intervention package for infants at high risk for Neuro- Development Disabilities to promote language development during early infancy; a randomized controlled trial**

Date of commencement (enrolment of first participant):07.01.2022

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**

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- **Recruitment completed, Follow-up completed**

Number assessed for eligibility:**90**

Number recruited and allocated/randomized:**84**

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

Arm 1:**42**

Arm 2:**42**

Losses/exclusions after allocation/randomization (please edit as relevant): **Losses at the point of final evaluation**

Arm 1:**5**

Arm 2:**6**

3. Trial output

Date of trial completion ("last patient, last visit"): **18th of August 2022**

Final sample size: **73**

Summary of Interim/Final data (if available):

Final data analysis continuing

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

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)



.....L.D.Y.S.K Weerasinghe.....

Name and signature of Responsible Registrant/
Principal Investigator

Date: 31.08.2022