Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2019/014

Scientific title of trial: Evaluation of "GO BABY GO" child development programme among vulnerable groups in Sri Lanka - A pragmatic cluster randomised trial

Date of commencement (enrolment of first participant): 2019-05-13

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: Yes

There were amendments that were made due to the pandemic. SLCTR approval was obtained prior to implementing these changes to protocol.

- *The end measurements will be carried out via telephone interviews due to restrictions as a result of COVID19. The following end line measures will be carried out Caregiver reported early childhood development Instrument (CREDI) to measure child age-appropriate development for language, cognitive, social-emotional and motor development.*

The following end line measures will be NOT carried out due to the prevailing situation in the country:

- *Bayley-III, screening of child development in four domains (language, cognitive, social-emotional and motor), will be applied to a nested sample of children from control and intervention sites, by trained psychometricians or paediatricians.*

- *Child anthropometric measurements – height/length and weight at baseline and endline (after 6 months) to derive anthropometric indices (weight-for-age, weight-height and height-for-age) using instruments (Seca brand), with the support of trained data collectors; WHO Anthro software will be used to compute standard z-scores of weight for age, height for age and weight for height versus WHO 2007 reference population*

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: 694

Number recruited and allocated/randomized: 694

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

Arm 1: 383 (Intervention group)

Arm 2: 311 (Control group)

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

Arm 1: 383- 323= 60 (Intervention group)

Arm 2:311 – 223= 88 (Control group)

3. Trial output

- At endline, the percentage of children who fulfilled minimum dietary diversity criteria was higher in the intervention group (98.1%) as compared to the control group (93.7%) (7.201, p=0.007). This is a marked improvement from the baseline as at baseline a higher proportion of children in the intervention group (41.9%) had not met the minimum dietary diversity compared to the children in the control group (29.3%). At endline, the percentage of children having MDD was significantly higher in the intervention group.
- There was no significant difference in the proportion of children with minimum meal frequency (MMF) between intervention and control group either at baseline (0.082, p=0.774) or at endline (0.847, p=0.357). Within each group, the proportion of children who had minimum meal frequency at endline (control 55%, intervention 58.9%) had decreased from baseline (control 71.1%, intervention 72.2%).
- The number of children having fever, cough and diarrhoea within the past week of the interview as reported by their caregivers who reported was higher at endline compared to baseline in both intervention and control groups.
- Compared to the control group, a higher proportion of caregivers in the intervention group read to their children at baseline and at endline. In both the intervention and control groups, a greater percentage of caregivers read to their children at endline compared to baseline.
- Compared to the control group, a higher percentage of caregivers in the intervention group engaged in storytelling at endline (p=0.058). Compared to the control group, a higher percentage of caregivers in the intervention group who did not engage in storytelling to children at baseline had started the activity at endline.
- There was no difference in the status of caregivers singing to children, taking the child for a walk between baseline and endline in either the intervention or the control groups.
- At endline, (N=541), maternal well-being scores were significantly higher in the intervention group (51.61) than in the control group (49.21) (p=0.001). In both control and intervention groups, there was a significant reduction in mental wellbeing scores from baseline to endline (-12.89 in control group and -9.29 in the intervention group); the difference in the reduction of maternal mental wellbeing scores between control and intervention groups was significant (p=0.003). This indicates that the caregivers in intervention group are more resilient.

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).**
	Not applicable at the moment

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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)**
In progress	Not applicable at the moment

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Name and signature of Responsible Registrant/
Principal Investigator

Date: 9.8.2021