

## Progress Report: Sri Lanka Clinical Trials Registry

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SLCTR registration number: SLCTR/2019/023

Scientific title of trial: Voice disorders and the effectiveness of a behavioural change intervention to improve functional voice disorders among primary school teachers in the Colombo District

Date of commencement (enrolment of first participant): 10.07.2019

Progression: 6 months  1 year  2 years  3 years

At completion X

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### 1. Baseline data

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

Modifications to the delivery of the package intervention had to be done, as some of the teachers consenting to participate were unable to attend the package intervention programme conducted at NHSL. The intervention programme was video recorded and it was viewed by such teachers, in their schools under the guidance of the PI/ a teacher already trained at the programme at NHSL. These teachers were then followed up together with the others who participated at the programme, in the same manner. Please note that this modification only involved the teachers in the intervention arm.

Any changes to trial outcomes after commencement: No

### 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: 230

Number recruited and allocated/randomized: 215

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

Arm 1: 106

Arm 2: 109

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

Arm 1: 13 + 3 (did not hand over the completed forms)

Arm 2: 25

### 3. Trial output

Date of trial completion ("last patient, last visit"): 30.03.2020

Final sample size: 174

Summary of Interim/Final data (if available):

The results showed a marked improvement in the primary and secondary outcome variables in the intervention arm.

Following adjusting for cluster effect and confounders the outcome of the intervention remained significant with an adjusted OR of 2.10 (95% CI: 1.07 – 4.10), indicating an improvement of 52.4% in voice disorders attributable to intervention in the intervention arm.

Abstract presentations of results at scientific meetings

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

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

Publications

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

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

*M.S. Herath*

Name and signature of Responsible Registrant/  
Principal Investigator

- DR. M.S. HERATH

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