

## Progress Report: Sri Lanka Clinical Trials Registry

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SLCTR registration number: SLCTR/2023/023

Scientific title of trial: Effectiveness of a behavior change intervention package on health literacy of behavioural risk factors of non-communicable diseases among health care assistants of government hospitals in Colombo district: Cluster randomized controlled trial

Date of commencement (enrolment of first participant): 15<sup>th</sup> December 2023

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

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### 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

Number assessed for eligibility:240

Number recruited and allocated/randomized:240

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

Arm 1: 120

Arm 2: 120

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

Arm 1: 0

Arm 2: 0

### 3. Trial output

Date of trial completion ("last patient, last visit"): 16<sup>th</sup> June 2024

Final sample size:240

Summary of Interim/Final data (if available):

The intervention group showed significant increments in HL scores in unadjusted ( $p<0.001$ ), cluster level ( $p=0.005$ ) and GEE ( $OR=7.801, 95\%CI: 7.378-8.224, p<0.001$ ) analyses and HL level in unadjusted ( $p=0.003$ ), cluster level ( $p=0.011$ ) and GEE analyses ( $OR=3.8, 95\% CI: 1.585- 9.113, p=0.003$ ). Age  $<35$  years was a significant positive predictor of HL score and educated only up to O/Ls was a significant negative predictor of HL level. The GEE analysis revealed significant improvement in behaviour change related to diet, physical activity, avoiding smokeless tobacco, and non-exposure to secondhand smoking except avoiding smoking tobacco and alcohol intake. Overall, the BCIP effectively improved HL and reduced behavioral risk factors for NCDs, supporting potential broader implementation.

Abstract presentations of results at scientific meetings

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

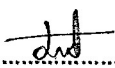
| <b>Title of Abstract</b>                                                                                                                                                                                                                                 | <b>Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).</b>                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effectiveness of a behaviour change intervention on health literacy for behavioural risk factors of non-communicable diseases among health care assistants of government hospitals in Colombo district, Sri Lanka: a cluster-randomized controlled trial | Mashood I., Samaranayake D., Kumarapeli V.<br><br>Journal of College of Community Physicians of Sri Lanka, Vol 31, ISSN 2579 - 1451, OP45, Pg: 46, <a href="https://doi.org/10.4038/jccpsl.v31i5.8864">https://doi.org/10.4038/jccpsl.v31i5.8864</a><br><br>Presented at Global Public Health Summit -2025 and 30 <sup>th</sup> Annual Academic sessions of the College of Community Physicians of Sri Lanka on 15 <sup>th</sup> July 2025 |

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>                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effectiveness of a behaviour change intervention on health literacy for behavioural risk factors of noncommunicable diseases among health care assistants of government hospitals in Colombo District: a cluster randomized controlled trial | Mashood I., Samaranayake D. & Kumarapeli V. Effectiveness of a behaviour change intervention on health literacy for behavioural risk factors of noncommunicable diseases among health care assistants of government hospitals in Colombo District: a cluster randomized controlled trial. <i>BMC Public Health</i> (2026). <a href="https://doi.org/10.1186/s12889-025-26110-9">https://doi.org/10.1186/s12889-025-26110-9</a> |

Date: 07/01/2026

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