Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registr	ation number: SLCTR	2/2017/032				
Scientific title of trial: Randomized control trial: preschool-based training and support programs to reduce intimate partner violence (IPV) by address alcohol and drug misuse in young families in Sri Lanka						
Date of commencement (enrolment of first participant): January 2018						
Progression:	6 months □	1 year □	2 years □	3 years □		
	At completion x					
1. Baseline	data					
Any changes to the trial design/ methodology/ protocol after commencement: No						
Any changes to trial outcomes after commencement: No						
2. Current status						
Recruitment status: recruitment completed Number assessed for eligibility:						
Number recruited and allocated/randomized: Schools were the experimental units. We had 34 schools (17 intervention, 17 control) in the program with an expected 20 families per preschool for a total of 680 potential participants.						
Number allocated/randomized to each intervention/arm (please edit as relevant):						
Arm 1: 17 schools (intervention), female carers of 433 children						

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

Arm 2: 17 schools (control), female carers of 486 children

Arm 1: 17 schools (intervention), 291 female carer's completed pre-

(Male carers were not included in follow up in both groups due to low recruitment at

intervention/baseline survey; 233 female carers completed post-intervention survey.

Arm 2: 17 schools (control), 326 female carers completed preintervention/baseline survey; 250 female carers completed post-intervention survey

3. Trial output

baseline)

Date of trial completion ("last patient, last visit"): December 2018

Final sample size: N = 31 schools, 483 female carers

Summary of Interim/Final data (if available):

Preliminary Results:

Data currently being entered and cleaned for analysis.

Abstract presentations of results at scientific meetings Note: please include a URL link or scanned copy of the abstract

Not applicable

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)
Protocol for a cluster-randomised controlled trial evaluating the impact of a preschool-based capacity building intervention on intimate partner violence and substance misuse in Sri Lanka.	Lokuge K, Wallace P, Subasinghe K, Thurber K, De Silva T, Clarke N, Waas D, Liyanage N, Attygalle U, Carron-Arthur B, Rodrigo K, Banks E, D'Este C, Rajapakse T. BMC Public Health. 2018 May 2;18(1):572
	PubMed URL: https://www.ncbi.nlm.nih.gov/pubmed/29716553

.....

Name and signature of Responsible Registrant/ Principal Investigator

Date: 19th February 2019

Kamate holye