

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number:

Scientific title of trial: "A randomized control study of audio versus visual distraction to reduce patient discomfort during colonoscopy"

Date of commencement (enrolment of first participant):

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

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: As the sample size we calculated was approximate, during the course of the study our trial satatistician recommended an interim analysis after recruiting 200 individuals to make an informed decision as to whether the trial should continue recruiting beyond the planned sample size of 228. As the results of this interim analysis unequivocal benefit of audio distraction over video distraction or sedation alone with regard to primary outcome, it was decided to terminate the trial at this stage

Any changes to trial outcomes after commencement: no

2. Current status

Recruitment status: pending/ recruiting/ recruitment complete/ recruitment suspended / recruitment terminated

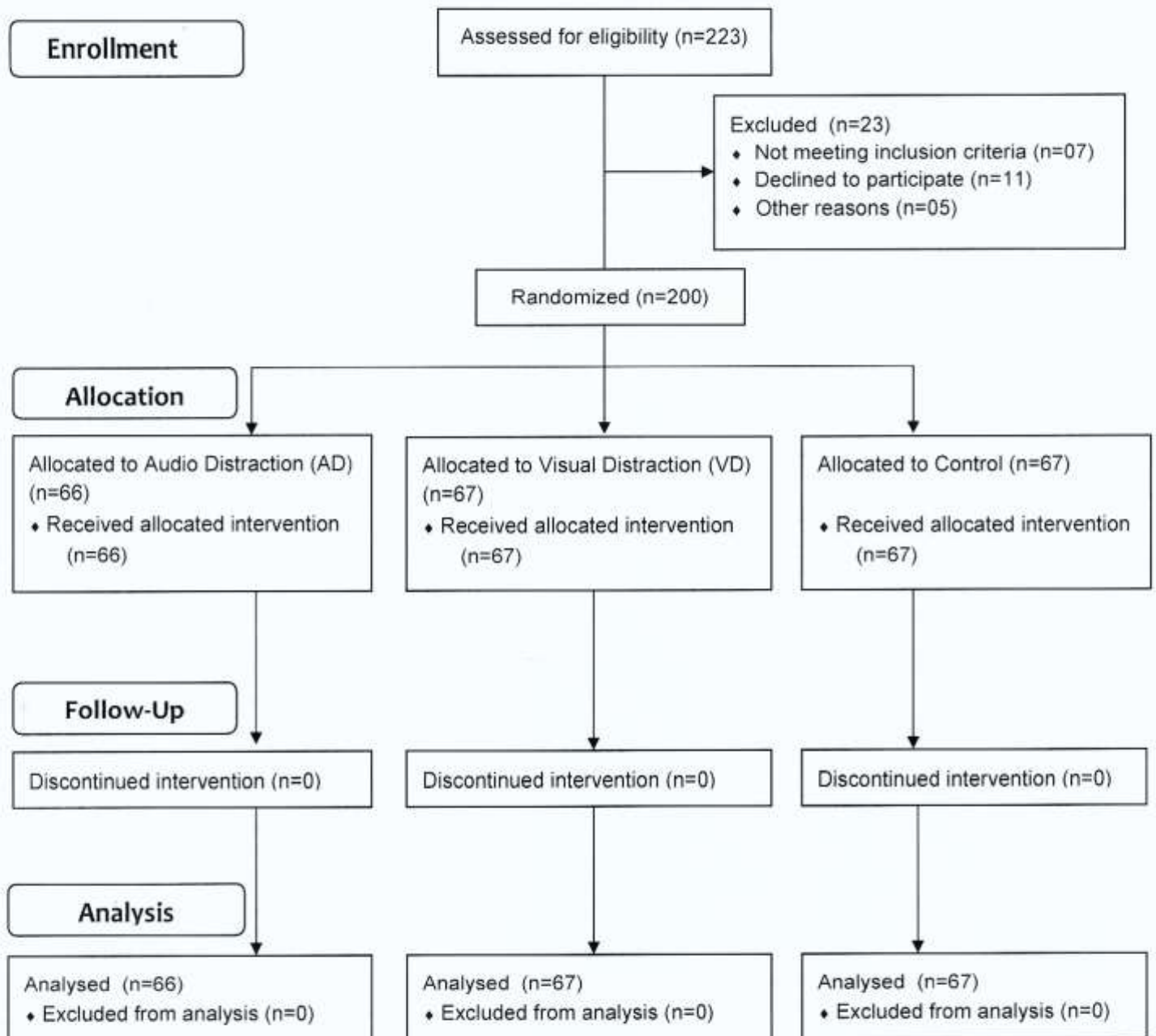
Number assessed for eligibility: view consort diagram

Number recruited and randomized: view consort diagram

Number allocated to each intervention/arm: view consort diagram

Losses/exclusions after randomization: view consort diagram

CONSORT flow chart of study



3. Trial output

Summary of Interim/Final data (if available): view table

Outcomes

Outcome	Group			P value
	Audio (AD)	Visual (VD)	Control	
Pain score	^b 3 (2 – 4)	^a 4 (2 – 6)	^{ab} 5 (3 – 8)	<0.001
No of top ups	1 (0 – 2)	2 (1 – 2)	2 (0 – 3)	0.059
Total dose of Pethidine	10 (5 – 15)	10 (10 – 15)	15 (5 – 20)	0.075
Total dose of midazolam	1.5 (1.0 -2.0)	1.5 (1.5 – 2.0)	2 (1.0 – 2.5)	0.087
Willing to repeat	^a 3 (3 – 3)	3 (3 – 3)	^a 3 (2 – 3)	0.024
Level of cooperation	^b 9 (8 – 10)	^a 9 (6 – 10)	^{ab} 8 (4 – 9)	<0.001

Median (Interquartile range)

P values based on Kruskal Wallis test

a – Indicates significant pairwise difference between groups at 0.05 level

b - Indicates significant pairwise difference between groups at 0.01 level

Presentations of results at scientific meetings: AGA 2015

SLMA 2015

(Please attach a scanned copy or link to abstract)

https://scholar.google.com/citations?view_op=view_citation&hl=en&user=QTmUa8EAAA-AJ&cstart=20&citation_for_view=QTmUa8EAAA-AJ:-f6ydRqryjwC

Publications:

(Please attach a scanned copy or link to paper)

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Name and signature of Responsible Registrant/

Date:

26/4/16