

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2016/004**

Scientific title of trial: The influence of three months of physical exercises and verbal stimulation on functional efficiency and the ways elderly people spend their free time under institutional care – a randomized controlled study.

Date of commencement (enrolment of first participant): 2016.03.01

Progression: At completion

1. Baseline data

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

1. During the study, the GDS 30-point version was changed to the 15-point version (Inclusion criterium GDS < 11).
2. Primary outcomes: Short Physical Performance Battery
Secondary outcomes: Physical Activity Scale for Elderly, Grip strength (JAMAR+), Timed Up-and-Go Test, 10-Metre-Walk Test, Back Scratch, Chair Sit and Reach, Berg Balance Scale
3. All tools were evaluated at baseline (before commencement of the intervention), immediately post-intervention (12th week), and 12 weeks after the completion of the intervention (24th week).

Any changes to trial outcomes after commencement: -

4. Current status

Recruitment status: pending/ recruiting/ recruitment complete: follow up continuing/ recruitment complete: follow up complete/ recruitment suspended / recruitment terminated

Number assessed for eligibility: 792

Number recruited and allocated/randomized: 204

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

Arm 1: 51

Arm 2: 51

Arm 3: 51

Arm 4: 51

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

Arm 1: 38

Arm 2: 41

Arm 3: 42

Arm 4: 41

5. Trial output

Date of trial completion ("last patient, last visit"): 2019-08-01

Final sample size: 162

Summary of Interim/Final data (if available):

Our study showed that a functional exercise program combined with verbal stimulation is effective in improving physical fitness and raising the level of free time physical activity.

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).

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)
Effects of Physical Exercises and Verbal Stimulation on the Functional Efficiency and Use of Free Time in an Older Population under Institutional Care: A Randomized Controlled Trial	Wiśniowska-Szurlej A., Ćwirlej-Sozańska A., Wołoszyn N., Sozański B, Wilmowska-Pietruszyńska A.: Effects of physical exercises and verbal stimulation on functional efficiency and use of free time in an older population under institutional care: A randomized controlled trial. Journal of Clinicam Medicine 2020;9(2):447. https://doi.org/10.3390/jcm9020477

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Name and signature of Responsible Registrant/
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Date: *12.02.2020*