Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2017/005

Scientific title of trial: A study to evaluate the effectiveness of Smart Glucose Manager, a mobile application in the management of diabetes mellitus.

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: None

Any changes to trial outcomes after commencement: None

2. Current status

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

Number assessed for eligibility: 300

Number recruited and allocated/randomized: 67

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

Arm 1 (Control): n=32

Arm 2 (Intervention): n=35

Losses/exclusions after allocation/randomization (please edit as relevant):
Arm 1 (Control): n= 7

Arm 2 (Intervention): n= 8

3. Trial output

Date of trial completion ("last patient, last visit"): 2017.03.

Final sample size: 52

Summary of Interim/Final data (if available):

The mean age of the study participants was 52±11 years. The improvement of mean HbA1c from baseline to 3-months follow-up, the intervention (baseline: 9.7% ± 1.3, follow-up: 8.2% ±1.0, p =0.001) and control (baseline: 9.5%±1.6, follow-up: 8.2%±0.6, p=0.008) arms were not significantly different (p=0.98). However, a significant improvement in HbA1c was observed in the intervention arm from 3-months (8.3%±0.6) to 6-months (7.3%±0.6), (p=0.005) compared with the control arm (8.2% at 3-months) (7.9%±0.6 at 6-months), (p=0.16). Improvement of mean HbA1c was shown in both arms 3-months after the baseline clinic visit, but after 6-months, only the intervention arm continued to show statistically significant improvement of HbA1c (p=0.01).

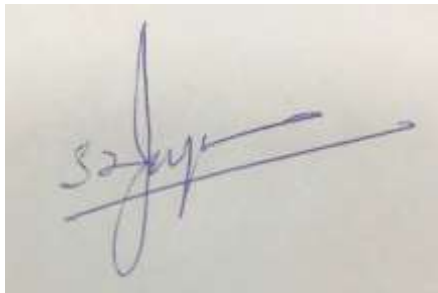Abstract presentations of results at scientific meetings
Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
The effect of the smart glucose manager (SGM) on glycosylated hemoglobin (HbA_1c).	Dhanishka, L[1,] Gunawardena, K.C[2]; Jackson R[2]; Jayamanne S.F[3]; Kalpani, A.G.S[3,] Muthukuda, D.T[4,] Robinett I[5] Annual Scientific and Clinical Congress of American Association of Clinical Endocrinology (Presented as a poster-presentation and abstract published in the abstract book of AACE-2018). Volume 24, Supplement 01, Page no: 47-48, April/2018
The effect of the smart glucose manager (SGM) on glycosylated hemoglobin (HbA_1c).	Dhanishka L[,] Gunawardena, K.C; Jackson R; Jayamanne S.F; Kalpani, A.G.S[,] Muthukuda, D.T[,] Robinett I 131st Anniversary International Congress of the Sri Lanka Medical Association-2018 (Presented as an oral presentation and the abstract published in the abstract book of SLMA 2018) Volume 63, Supplement 1, Page no: 17-18 , July/2018

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)
The Influence of the Smart Glucose Manager Mobile Application on Diabetes Management	Kasun C. Gunawardena[1], Renee Jackson, BSc[1], Iva Robinett, RN, CDE[2], Lahiru Dhaniska, B Eng[3], Shaluka Jayamanne, MBBS, MD, MRCP, FCCP[4], Sumedha Kalpani, B Pharm[4], and Dimuthu Muthukuda, MBBS, MD, MRCP[5] Journal of Diabetes Science and Technology 1–7,2018 Diabetes Technology Society, sagepub.com/journals-permissions, DOI: 10.1177/1932296818804522 journals.sagepub.com/home/dst

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Name and signature of Responsible Registrant/
Principal Investigator

Date: 03/02/2019