

Weight-loss application: short-term study of efficacy in the setting of supervised weight-loss activities

Submission date 15/07/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/08/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In response to the current obesity epidemic, various initiatives and potential solutions have been introduced. As evident from recent national statistics, the upward trend in obesity continues. Surgical approaches remain most effective in long-term management of morbid obesity; however, the effectiveness and sustainability of short-term, non-surgical weight loss strategies is controversial. Gamification, or the application of typical elements of game playing (e.g., point systems and constructive competition within a pre-defined set of rules) to daily life activities, has been proposed as one approach to encourage sustainable results. We hypothesized that the use of smartphone-based gamification platform (SBGP) would result in sustained non-surgical weight loss at 3 months.

Who can participate?

Anyone attending a weight-loss programme at one of the SLUHN bariatric clinics, who is aged 18+ and has access to a smartphone.

What does the study involve?

The study sample consisted of two patient groups; those using Ayogo app and those who do not. The patients were followed for three months after enrollment for monthly weight check, administration of patient engagement questionnaire, and documentation of any unanticipated health care contacts like emergency visits.

What are the possible benefits and risks of participating?

Benefits: The weight loss app can benefit the participants by of increasing patient engagement in self-care and weight loss within the framework of primary care delivery network.

Risks: none

Where is the study run from?

St Luke's Weight Management Center, Allentown, PA, USA

When is the study starting and how long is it expected to run for?
January 2017 to February 2018

Who is funding the study?
St. Luke's University Health Network (SLUHN) Research and Innovation

Who is the main contact?
Dr Pampreet Kaur
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SLUHN 2016-42

Study information

Scientific Title
Prospective, randomized study of short-term weight loss outcomes using gamification-based strategy

Acronym

AYOGO

Study objectives

1. The Ayogo weight-loss app has a positive effect on weight loss when compared to patients who do not use the Ayogo weight-loss app
2. The use of Ayogo's weight-loss app results in greater patient engagement, measured by Ayogo app engagement data
3. Patients using Ayogo will have fewer unanticipated health care contacts (emergency visits) compared to patients not using Ayogo

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/07/2016, (St. Luke's University Health Network) SLUHN Institutional Review Board (IRB) (801 Ostrum Street, Bethlehem, PA 18015; +1 484-526-6742; jayne.silva@sluhn.org), ref: SLUHN 2016-42

Study design

Randomised case-control study

Primary study design

Interventional

Secondary study design

Randomized case-control study

Study setting(s)

Home

Study type(s)

Quality of life

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Obesity

Interventions

A total of 100 patients from one of the SLUHN Bariatric Clinics with an available medically supervised weight-loss program were allocated to intervention or control using alternate allocation.

The study sample consisted of two patient groups; those using Ayogo app (intervention group) and those who do not (control group). The app includes motivational tools, informative content, food/activity/weight tracking (which is known to support weight loss), a social space to engage with others in the medical weight loss program, and encouragement from St. Luke's Health Coaches to stay on track with your care plan. The HCP Dashboard allows healthcare professionals to monitor patients and encourage them on their health journeys. There are two main components where health coaches can engage with patients: community activity and

patient logs (food logs, activity logs, and weight logs).

Health Coaches spend approximately 90 minutes per week (combined time) engaging with members via the HCP Dashboard, as follows:

- 4-5 times / week: Review community activity (5 min)

Community activity can be viewed under the Community Activity tab for the relevant group.

Like or comment on posts as you wish

In unlikely case of an inappropriate post, the Health Coach can hide this post

- 2-3 times / week: Review patient logs (15-20 min)

Review patient food, weight, and activity logs. An overview of the patient logs is viewed under the Logs tab for the relevant group.

Send encouragements or nudges where appropriate

Encouragements reinforce consistent logging

Nudges indicate when patients have been neglecting logging and motivate them to resume

Encouragements and nudges can be general, or specific to food, weight, or activity logging

Encouragements and nudges can be delivered to patients within their individual member pages (accessed by clicking on their names) or on the overview screen under their names.

The patients were followed for three months after enrollment for monthly weight check, administration of patient engagement questionnaire, and documentation of any unanticipated health care contacts like emergency visits.

The control group attended the weight loss program as usual.

The data was collected in HIPPA protected REDCap web-based data collection tool and analyzed on SPSS.

The sample size was based on previously published Kaiser Permanente Bariatric population study 5%-7% reductions in body weight during the duration of the trial and two-sided testing with statistical significance of $\alpha=0.05$ and statistical power $(1-\beta)=0.80$.

Intervention Type

Behavioural

Primary outcome measure

1. Weight measured weekly from baseline to 3-months

2. Degree of individual interaction with app and app usage measured over the course of the program using:

- 2.1 Encouragements received

- 2.2 Encouragements received in first two weeks

- 2.3 Total number of swipes

- 2.4 Total active days on app

- 2.5 Social wall likes

- 2.6 Social wall answers

- 2.7 Daily Quest answers

- 2.8 Narratives page views

- 2.9 Number of weight, exercise, and diet entries

3. Patient engagement using a secondary Patient Engagement Questionnaire administered on monthly basis

Secondary outcome measures

1. Glucose control measured by Hemoglobin A1c at baseline and 3-months
2. Number of emergency and physician office visits over the 3-month period

Overall study start date

01/03/2016

Completion date

19/02/2018

Eligibility

Key inclusion criteria

1. Aged >18 years
2. Owns or has access to a smartphone
3. Proficient in English
4. Comfortable using the app
5. Attending a weight-loss programme at one of the SLUHN bariatric clinics

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

Do not meet the inclusion criteria

Date of first enrolment

16/01/2017

Date of final enrolment

13/02/2018

Locations

Countries of recruitment

United States of America

Study participating centre
St Luke's Weight Management Center
240 Cetronia Road
Suite 205 North
Allentown
United States of America
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Sponsor information

Organisation

St. Luke's University Health Network (SLUHN)

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01qc17q17>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St. Luke's University Health Network (SLUHN)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/09/2019

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		15/11/2016	16/08/2019	No	Yes