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A mobile-based serious game for young adults with disordered eating

Submission date	Recruitment status	[X] Prospectively registered
02/02/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/02/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/02/2018	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Disordered eating describes a variety of abnormal eating behaviors that, by themselves, do not warrant a diagnosis of an eating disorder but involve common features of eating disorders such as binge eating (overeating) or restrained eating (not eating enough). Some forms of disordered eating can limit a person's ability to change their lifestyle to improve their health, such as by dieting or avoiding weight gain. Disordered eating that prevents people from losing weight can be associated with several behavioral eating patterns, such as emotional eating which is, in essence, a way of coping with stress and unpleasant emotions through eating. SIGMA (the Self-help, Integrated and Gamified Mobile-phone Application) is an treatment program delivered using mobile phones (mHealth) to target overweight young adults that are at risk for obesity not only because of their weight, but also because of disordered eating habits. The app consists of four modules, one of which is in the form of a game that uses elements of cognitive behavioural therapy (CBT - a type of therapy that helps people to change the way they think and behave) to help change behavior and thoughts towards food. The aim of this study is to find out whether SIGMA can help people to change their behaviour and eat better.

Who can participate?

Overweight Romanian-speaking young adults that own an Android operating smartphone who have problems with eating (emotional, compulsive or unstoppable eating or cravings) and are feeling depressed.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in the SIGMA program for eight weeks. This involves completing four of mHealth modules via a mobile phone app. The first module consists of education. The second module is a game which uses elements of CBT to help change behaviour and thought patterns relating to eating. The third module consists of motivational messages, relaxation tools and distraction techniques to prevent relapse in dieting, and the fourth module consists of self-monitoring and feedback. Those in the second group receive a modified version of the SIGMA app for eight weeks, which includes education but without the second module. At the start of the study and then again after eight weeks and three months, participants complete questionnaires about their eating habits and have body measurements taken.

What are the possible benefits and risks of participating?
Participants may benefit from the CBT element of the program, as this type of therapy has been shown to be very effective at treating a range of mental health problems. There are no direct risks involved with participating.

Where is the study run from?
1. Babeș-Bolyai University (Romania)
2. University of Bucharest (Romania)

When is the study starting and how long is it expected to run for?
May 2017 to November 2017

Who is funding the study?
Romanian Authority for Scientific Research: CNCS-UEFISCDI (Romania)

Who is the main contact?
Dr Ioana Podina
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Study website
http://sigma-mhealth.ro/en/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PN-II-RU-TE-2014-4-2481

Study information

Scientific Title
Rationale and study design of an evidence-based gamified mHealth intervention for weight management in young adults with disordered eating: a placebo-controlled randomized trial

Acronym
SIGMA

Study objectives
The SIGMA intervention will be significantly more effective in promoting change in maladaptive behaviors and cognitive styles, decreasing the maladaptive counterparts and increasing adaptive food-related behavioral and cognitive styles of response.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission, Babes-Bolyai University, ref: 30599/06.02.2017

Study design
Multi-center randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Irresistible food cravings, emotional eating or binge eating

Interventions
Selected participants will be randomized in the intervention and control trial arms in a 1:1 ratio. An independent researcher will handle the randomization and the random sequence will be generated using a 1:1 allocation ratio via an online available random number generator (i.e., www.randomization.com). The randomization sequence will be concealed from the staff responsible for the enrollment and assignment of the participants in the trial arms, by using the sealed opaque envelopes method.

SIGMA intervention: The SIGMA intervention is designed to accommodate four mHealth modules, as follows:

1. The psychoeducation module, where information about the purpose of the app, as well as information about physical activity and dieting is provided
2. The gamified intervention module, consisting firstly in an explicit cognitive-behavioral intervention targeting conscious cognitive and behavioral contents, such as sabotaging thoughts regarding foods and maladaptive eating habits and secondly, in an implicit attention training intervention aimed at addressing an unconscious process, the biased attention towards appetizing stimuli
3. The Crisis & Relapse prevention module, aimed at preventing relapses in dieting, and consisting of motivational messages and coping strategies, relaxation tools and distracting strategies
4. The self-monitoring, feedback, and evolution module

Attention placebo control: Participants allocated to the attention placebo control condition will have full access to a modified version of the SIGMA app, which includes all the SIGMA modules except for the gamified intervention module, thus lacking the active/distinctive ingredients of the SIGMA app.

Both interventions are scheduled to take place for 8 weeks. The follow-up evaluation will take place 3 months after treatment conclusion.

Intervention Type
Other

Primary outcome measure
1. Maladaptive cognitive styles are measured using the Eating Disorders Beliefs Questionnaire at baseline, 8 weeks and 3 months
2. Behavioral eating habits are measured using the Dutch Eating Behavior Questionnaire at baseline, 8 weeks and 3 months

Secondary outcome measures
1. Weight is measured using the SIGMA application’s embedded self-report forms at baseline, 8 weeks and 3 months
2. Body mass index (BMI) is measured using the SIGMA application’s embedded self-report forms at baseline, 8 weeks and 3 months
3. Physical activity levels are assessed by measuring the number of steps taken per day using the SIGMA application’s embedded pedometer at baseline, 8 weeks and 3 months
4. General mood is measured using the Positive and Negative Affect Schedule – Short Form at baseline, 8 weeks and 3 months

Overall study start date
01/11/2016

Completion date
30/11/2017

Eligibility

Key inclusion criteria
1. Young overweight adults (25 ≤ BMI ≤ 29)
2. Age between 18 and 35 years
3. Non-clinical eating behaviors in the range of irresistible food cravings, emotional eating or

binge eating.
4. Owning an Android compatible smartphone

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
74

Key exclusion criteria
1. Presence of any medical condition incompatible with physical/dietary recommendations (including pregnancy and type 2 diabetes)
2. Presence of an eating disorder
3. The use of appetite influencing medication and/or current enrollment in other weight-management programs
4. Current depression or any form of psychotic disorder
5. Lack of access to an Android compatible smartphone

Date of first enrolment
05/04/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Romania

Study participating centre
Babes-Bolyai University
Faculty of Psychology and Educational Sciences
No. 7 Sindicatelor Street
Cluj-Napoca
Romania
400029

Study participating centre

University of Bucharest
Faculty of Psychology and Educational Sciences
No. 90 Panduri Street
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050663

Sponsor information

Organisation
Romanian Authority for Scientific Research (CNCS-UEFISCDI)

Sponsor details
Str. Mendeleev nr. 21-25
Bucharest
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010362

Sponsor type
Research council

Website
http://www.cncs-nrc.ro/

Funder(s)

Funder type
Research council

Funder Name
Romanian Authority for Scientific Research (CNCS-UEFISCDI)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal with an intent to publish around one year after the overall trial end date.

Intention to publish date
30/11/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are/will be available upon request from ioana.podina@fpse.unibuc.ro

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/12/2017		Yes	No