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A novel mobile app assistant for weight control

Submission date
10/11/2022

Recruitment status
No longer recruiting

Registration date
11/11/2022

Overall study status
Completed

Last Edited
27/04/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Obesity has become a public health issue worldwide. This pilot study aims to investigate the effect of a mobile app to assist weight management.

Who can participate?
Adults aged 30-60 years old who are overweight

What does the study involve?
Participants are randomly allocated to the control-first group or the intervention-first group. In period 1 (up to day 30), the control-first group continues with their regular life and the intervention-first group undergoes the app intervention; in period 2 (up to day 60), the groups cross over. The app provides a digital program to help users identify unhealthy eating behaviours and make positive behavioural changes. Body composition and psychological /behavioural questionnaires will be collected at the start of the study and at the end of period 1 (day 30), and at the end of period 2 (day 60).

What are the possible benefits and risks of participating?
Participants could improve their own eating behaviours and live healthier lifestyles. There are no potential risks.

Where is the study run from?
Kaohsiung University Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
January 2021 to August 2021

Who is funding the study?
Ministry of Science and Technology (Taiwan)

Who is the main contact?
Dr Jia-In Lee, u9400039@gmail.com

Contact information

Type(s)
Principal Investigator

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Dr Jia-In Lee

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
C012022

Study information

Scientific Title
Effect of a novel telehealth device for dietary cognitive behavioral intervention in overweight or obesity care

Acronym
CogniAI

Study objectives
This pilot study was aimed to investigate the effect of telehealth assisted intervention on weight reduction, mood status, and eating behavior change under a smartphone application (app) with novel 3D food picture recognition and incorporated with cognitive behavioral training programs.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 13/04/2021, the Institutional Review Board at Kaohsiung Medical University Hospital (No. 100, Tzyou 1st Road Kaohsiung 807, Taiwan; +886 (0)7 3121101 ext 6646; irb-training@kmuh.org.tw), ref: KMUHIRB-E[I]-20210067

Study design
Single-center randomized cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Community

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Management of body weight in patients with overweight or obesity

Interventions
Adults aged 30-60 years old with overweight will be recruited and randomly assigned (1:1) to the control-first group or the intervention-first group according to their order of entry into the study. In period 1 (up to day 30), the control-first group continues with their regular life and the intervention-first group undergoes the app intervention; in period 2 (up to day 60), the groups cross over. The app provides a digital program to help users identify unhealthy eating behaviors and make positive behavioral changes. Body composition and psychological/behavioral questionnaires will be collected at baseline, end of period 1 (day 30), and end of period 2 (day 60).

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Body composition is measured using InBody 770 (InBodyUSA, Cerritos, CA) at baseline, end of period 1(day 30), and end of period 2 (day 60)

Secondary outcome measures
1. Eating behaviors measured using the Dietary Behavior Questionnaire (DBQ) and Mindful Eating Behavior Scale (MEBS) at baseline, end of period 1 (day 30), and end of period 2 (day 60)
2. Mood measured using the five-item Brief Symptom Rating Scale (BSRS-5) and Chinese version

of the Beck Depression Inventory II at baseline, end of period 1 (day 30), and end of period 2 (day 60)
3. Quality of life measured via the WHO Quality-of-Life scale (WHOQOL-BREF)- Taiwan version at baseline, end of period 1 (day 30), and end of period 2 (day 60)
4. Physical activity measured using the Taiwan version of the International Physical Activity Questionnaire Short Form (IPAQ-SF) at baseline, end of period 1 (day 30), and end of period 2 (day 60)
5. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline, end of period 1 (day 30), and end of period 2 (day 60)

Overall study start date
14/01/2021

Completion date
26/08/2021

Eligibility

Key inclusion criteria
1. Adults aged between 30 and 60 years
2. Body mass index (BMI) ≥25 kg/m²

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
Major neuropsychiatric comorbidities, for example, schizophrenia, major depressive disorders, stroke, epilepsy, and Parkinson’s disease

Date of first enrolment
02/06/2021

Date of final enrolment
07/06/2021

Locations

Countries of recruitment

Taiwan

Study participating centre
Kaohsiung Medical University Hospital
No.100 , Tzyou 1st Road Kaohsiung 807
Kaohsiung
Taiwan
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Sponsor information

Organisation
Kaohsiung Medical University Chung-Ho Memorial Hospital

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No. 100 , Tzyou 1st Road Kaohsiung 807
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Sponsor type
Hospital/treatment centre

Website
http://www.kmuh.org.tw/

ROR
https://ror.org/02xmkec90

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology, Taiwan

Alternative Name(s)
Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The main data supporting the findings of this study are available within the paper and its supplementary information files. Extra data are available from the corresponding author upon request: Dr Jia-In Lee (1050644@kmuh.org.tw).
The type of data that will be shared: all the raw data.
Timing for availability: after being published.
Whether consent from participants was required and obtained.
Comments on data anonymization: all personal data are de-identification and replaced with study ID.
Any ethical or legal restrictions: requested data are only used for research.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/04/2023	27/04/2023	Yes	No