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An app based ecological momentary intervention tool to enhance the treatment of obesity in young adolescents to maintain weight loss and improve wellbeing

Submission date
24/08/2021

Recruitment status
No longer recruiting

Registration date
14/10/2021

Overall study status
Completed

Last Edited
14/10/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The worldwide prevalence of pediatric overweight and obesity has risen sharply over the last 35 years. This 'obesity epidemic' is alarming because overweight is associated with numerous negative consequences, both in the short and in the long term. Evidence shows that the odds of spontaneous remission of pediatric overweight are low, making focusing on treatment of great importance. Currently, multidisciplinary interventions of several weeks that combine a dietary approach, exercise, behavioral and cognitive therapy techniques remain the standard. However, the effectiveness on the long term of these intervention programs remains low, including substantial relapse rates. When considering initiatives to ameliorate treatment and after care, we should consider recent findings that plead for more personalized interventions. Overweight is a heterogeneous disease, with multicausal origins. A way to approach this multicausal origin, is by using a network approach. Here, the causes of overweight are seen as complex networks of variables (biological, psychological and social factors) that interact with each other directly, within a certain environment and culture. A way to map and respond to these networks is by introducing an Ecological Momentary Intervention APP.
The aim of the current study is to test whether an network-informed eHealth intervention, based on an Ecological Momentary Intervention APP as blended care, with additional eHealth Cognitive Behavioral Therapy Modules, on top of care as usual, will result in BMI reduction, improvement of quality of life, wellbeing and eating behavior.

Who can participate?
Youngsters aged 10-16 years old who are involved in an obesity treatment program (care as usual).

What does the study involve?
Participants are randomly allocated to receive either care as usual or the app-based Ecological Momentary Intervention and CBT-based intervention on top of care as usual. The app-based intervention lasts 4 weeks and consists of 7 modules. The participants are tested before and

after the training and at 2 and 6 months follow-ups to measure quality of life, well-being, perception of health and eating behavior.

What are the possible benefits and risks of participating?
It is expected that the quality of life, the wellbeing, the perception of health and the eating behavior of the children in the experimental group will improve more as they have a personal 'coach' that help them 24hours/day. Adding an additional value to the current childhood obesity treatments is the purpose of this study. If the app-based intervention is found to be effective, the next step is to implement it in all treatment programs for this target group.
There are no risks of participating in the study.

Where is the study run from?
Belgium: Zeepreventorium
France: SSR Nutrition Obesité UGECAM Tza Nou & CMI Romagnat

When is the study starting and how long is it expected to run for?
August 2021 to August 2022

Who is funding the study?
EU Horizon 2020, EIT Digital & EIT Health (Germany)

Who is the main contact?
Maurane Desmet, Maurane.Desmet@Ugent.be

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
211172

Study information

Scientific Title
Improving weight loss and wellbeing in adolescents with obesity via an Ecological Momentary - and CBT app-based intervention.

Study objectives
We expect that adding an Ecological Momentary CBT-based intervention to the care as usual results in:
1. BMI reduction (5-10%)
2. Improvement of quality of life (10-20%)
3. Improvement of wellbeing (10-20%)
4. Improvement of perception of health (10-20%)
5. Improvement of eating behavior (10-20%)
6. Satisfaction with Think Slim Junior APP
7. Intention to continue using Think Slim Junior APP compared to care as usual only (CAU-only).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Childhood obesity

Interventions

Current interventions as of 14/10/2021:
The Think Slim Junior APP consists of two parts: (1) an app-based Ecological Momentary Intervention and (2) an app-based Cognitive Behavioral Therapy (CBT)-based intervention as blended care, as a personal coach on top of care as usual

(1) Ecological Momentary Assessment intervention (EMI) is a framework that combines real-time assessment (Ecological Momentary Assessment) with feedback. The app-based EMI provides feedback, based on algorithms, relying on a network-approach. It maps individual networks of variables (sleep quality, illness, emotions, craving, social circumstances, activity, location, eating behavior) via registrations in the APP and, on this basis, the EMI estimates when the adolescents are likely to overeat ('risky' moments) and intervenes at such moments via individualized feedback.

(2) The CBT-based intervention consists of 7 modules (eHealth, via the APP) with visualized exercises (to open at least twice a week) (automatic online reminders and compliments) on:
• psycho-education (1),
• motivational parts (internal and external reinforcers) (2),
• goalsetting + contracting (3),
• self observation and problem solving (4),
• self instructions and self efficacy, identifying negative thinking (5),
• emotion regulation and seeking support (6),
• combatting external eating via stimulus control (7),

(3) The CAU (care as usual) consists of:
• Psycho-education on food and physical activity
• Sessions on diet/healthy eating and healthy food habits
• Physical activity (4h a day)
• Parental involvement
• Protocols about psychological aspects: problem solving, social competencies and self-worth
• Individual sessions with a psychologist (every 2 weeks)

Participants are randomly allocated to receive either care as usual (control group) or the app-based Ecological Momentary Intervention and CBT-based intervention on top of care as usual (experimental group). Randomization is stratified on age and gender via sealed envelope.

The app-based intervention lasts 4 weeks and consists of 7 modules. The participants are tested before and after the training and at 2 and 6 months follow-up to measure quality of life, well-being, perception of health and eating behavior.

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The app-based intervention lasts 4 weeks and consists of 7 modules. The participants are tested before and after the training and at 3 months follow-up to measure quality of life, well-being, perception of health and eating behavior.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Smartphone app

Primary outcome measure
Current primary outcome measure as of 14/10/2021:
BMI (kg/m²) as measured by:
1. Weight, measured at baseline, post (1 month), and follow-up (2 months and 6 months)
2. Height, measured at baseline, 1, 2, and 6 months

Previous primary outcome measure:
BMI (kg/m²) as measured by:
1. Weight, measured at baseline, post, and follow-up (3 months and 6 months)
2. Height, measured at baseline, post and follow-up (3 months and 6 months)

Secondary outcome measures
Current secondary outcome measures as of 14/10/2021:
Measured at baseline and posttest (1 month) unless noted otherwise:
1. Quality of life (Kidscreen) (10 items) (also measured at 2 and 6 months follow-up)

2. Wellbeing (Child Depression Inventory, CDI) (27 items) (also measured at 2 and 6 months follow-up)
3. Wellbeing: global self-worth (Competentie Belevingsschaal voor Adolescenten; CBSA) (35 items)
4. Perception of health (Just health Perception Questionnaire) (6 items)
5. Eating behavior (Dutch Eating Behavior Questionnaire, adolescent version) (33 items)
6. Eating behavior (Power of Food Scale) (15 items)
7. Eating behavior (Binge eating items of Children-Eating Disorder Examination Questionnaire (3 items)
8. Satisfaction with Think Slim Junior APP & intention to continue using the app (Usability Questionnaire) (17 items) (only measured at posttest)

Previous secondary outcome measures:
Measured at baseline and posttest (1 month) unless noted otherwise:
1. Quality of life (Kidscreen) (10 items) (also measured at 3 months and 6 months follow-up)
2. Wellbeing (Child Depression Inventory, CDI) (27 items) (also measured at 3 months and 6 months follow-up)
3. Wellbeing: global self-worth (Competentie Belevingsschaal voor Adolescenten; CBSA) (35 items)
4. Perception of health (Just health Perception Questionnaire) (6 items)
5. Eating behavior (Dutch Eating Behavior Questionnaire, adolescent version) (33 items)
6. Eating behavior (Power of Food Scale) (15 items)
7. Eating behavior (Binge eating items of Children-Eating Disorder Examination Questionnaire (3 items)
8. Satisfaction with Think Slim Junior APP & intention to continue using the app (Usability Questionnaire) (17 items) (only measured at posttest)

Overall study start date
24/08/2021

Completion date
31/08/2022

Eligibility

Key inclusion criteria
Adolescents (12-16 years old) with obesity (>140% overweight).

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
16 Years

Sex

Both

Target number of participants
70 (to realize N=50 agreements for participating in the RCT)

Key exclusion criteria
1. Comorbid medical disorders that cause (a part of) the weight gain (i.e. serious thyroid problems)
2. Youngsters with medical problems where obesity is secondary

Date of first enrolment
15/10/2021

Date of final enrolment
30/12/2021

Locations

Countries of recruitment
Belgium

France

Study participating centre
Medisch Pediatrisch Revalidatiecentrum Zeepreventorium
Koninklijke Baan 5
De Haan
Belgium
8420

Study participating centre
SSR Nutrition Obesité UGECAM Tza Nou & Centre Medical Infantile Romagnat
230 Rue Vercingétorix
La Bourboule
France
63000

Sponsor information

Organisation
Ghent University

Sponsor details

Faculty of Psychology and Educational Sciences
Department of Developmental Personality and Social Psychology
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Sponsor type
University/education

Website
https://www.ugent.be/en

ROR
https://ror.org/00cv9y106

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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

Intention to publish date
15/01/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary

Not expected to be made available