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Stay with me: an eHealth application for parents of overweight children

Submission date 17/10/2023	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/12/2023	**Overall study status** Ongoing	
Last Edited 10/09/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Parents play a crucial role in shaping children's dietary and activity behavior and are essential partners in treatment but are insufficiently involved. To address this concern, this study will evaluate a new eHealth tool for parents in the form of a mobile application. The tool will offer model-driven lifestyle change suggestions for parents to use in conjunction with inpatient or outpatient treatment for their child. The eHealth tool will be based on an existing online psycho-education platform for parents of children with overweight called 'Taking action', in which already many parental behavior change techniques according lifestyle (e.g. affecting children's dietary intake, physical exercises, sleep, family climate) are included, based on the model of Rhee (2008). This content will be combined with the input of parents and professionals on needs and preferences of use, gathered during focus groups and enriched with interactive tools, which are easy to add in an application. The application will consist of: 1) psycho-education, 2) tools to change behavior to deal with weight problems, and 3) motivation-enhancing elements for behavioral change.

Who can participate?
Parents who possess a smartphone and are fluent in either Dutch, French or English and have children who are overweight and between 5 and 14 years old.

What does the study involve?
Parents will use the app for 12 weeks. Variables will be assessed during different time points.

Where is the study run from?
Ghent University (Belgium)

When is the study starting and how long is it expected to run for?
June 2024 to December 2026

Who is funding the study?
The Kom Op Tegen Kanker foundation of Belgium

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

Contact information

Type(s)
Public, Scientific

Contact name
Miss Maurane Desmet

ORCID ID
http://orcid.org/0000-0001-6338-3078

Contact details
Henri Dunantlaan 2
Ghent
Belgium
9000
+32 495221500
Maurane.Desmet@Ugent.be

Type(s)
Principal Investigator

Contact name
Prof Caroline Braet

ORCID ID
http://orcid.org/0000-0003-2458-287X

Contact details
Henri Dunantlaan 2
Ghent
Belgium
9000
-
Caroline.Braet@Ugent.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Stay with me: an eHealth application for parents of children with overweight: a protocol for a mixed-method study

Acronym
Stay with me

Study objectives
An improvement in parent variables regarding parental skills, parental stress, the family climate, and family activities. We will explore the impact of parent characteristics (gender, ethnicity, marital status and SES). Third, we will evaluate treatment adherence. We expect a dose-response relationship, meaning that higher adherence will be significantly correlated with the outcome improvements.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted, Ethics committee U(Z) Ghent (C. Heymanslaan 10, Ghent, 9000 , Belgium; +32 (0)9 332 33 36; ethisch.comite@uzgent.be)

Study design
Interventional multiple baseline single case study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

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
Treatment of children with overweight - focus on parents

Interventions

The tool will offer model-driven lifestyle change suggestions for parents to use in conjunction with inpatient or outpatient treatment for their child. The eHealth tool will be based on an existing online psycho-education platform for parents of children with overweight called 'Taking action', in which already many parental behavior change techniques according lifestyle (e.g. affecting children's dietary intake, physical exercises, sleep, family climate) are included, based on the model of Rhee (2008). This content will be combined with the input of parents and professionals on needs and preferences of use, gathered during focus groups and enriched with interactive tools, which are easy to add in an application. The application will consist of: 1) psycho-education, 2) tools to change behavior to deal with weight problems, and 3) motivation-enhancing elements for behavioral change.

The intervention phase lasts 12 weeks. The baseline phase will last 3,5 or 7 weeks (multiple baseline design)

Intervention Type
Behavioural

Primary outcome measure
1. Parents' age, length and weight and variables linked to socio-economic status (education, profession, country of birth) measured before the baseline phases.
2. Parental feeding behavior will be assessed by the Child Feeding Questionnaire (CFQ) Dutch version before the baseline phases, weekly during baseline and intervention and after the intervention
3. Positive parental behavior will be assessed using a subscale of the Ghent Parental Behavior Scale – Short version (GPBS-S) before the baseline phases, weekly during baseline and intervention and after the intervention
4. Parenting stress will be assessed with the Short Form of the Dutch version of the Parenting Stress Index: the Nijmeegse Ouderlijke Stress Index (NOSIK) before the baseline phases, weekly during baseline and intervention and after the intervention
5. Emotion-coaching will be assessed using the Emotion-Coaching Dimension of the Short Form of the Emotion Related Parenting Styles (ERPS) questionnaire before the baseline phases, weekly during baseline and intervention and after the intervention
6. The adherence of the treatment will be extracted by the analytics generated by the application during the intervention. The number of days of app usage will be used.

Secondary outcome measures
We will also ask parents how they experienced using the app after the intervention via individual interviews.

Overall study start date
17/10/2023

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. The child’s age being between 5 and 14 years old
2. The child’s adjusted BMI >85th percentile
3. Parents possessing smartphone
4. Parents being fluent in either Dutch, French, or English

Participant type(s)
Other

Age group
Child

Lower age limit
5 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
Belgium

Study participating centre
AZ Jan Palfijn
Watersportlaan 5
Ghent
Belgium
9000

Study participating centre
Zeepreventorium
Koninklijke Baan 5
De Haan
Belgium
8420

Study participating centre
UZ Antwerpen
Drie Eikenstraat 655
Antwerpen
Belgium
2650

Study participating centre
UZ Brussel
Laarbeeklaan 101
Jette
Belgium
1090

Sponsor information

Organisation
Ghent University

Sponsor details
Department of Develomental, Personality and Social Psychology
Henri Dunantlaan 2
Ghent
Belgium
9000
+32 495221500
roma.rietjens@komoptegenkanker.be

Sponsor type
University/education

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

ROR

https://ror.org/00cv9y106

Funder(s)

Funder type
Charity

Funder Name
Kom op tegen Kanker

Alternative Name(s)
Fight Cancer

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

Results and Publications

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

Intention to publish date
01/08/2026

Individual participant data (IPD) sharing plan
The datasets generated during the study will be available upon request from Maurane.Desmet@Ugent.be

IPD sharing plan summary
Stored in non-publicly available repository