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Grow It! Sophia: investigating the Grow It! smartphone app used to identify mood problems and promote adaptive coping in adolescents with a chronic somatic condition

Submission date
25/04/2022

Recruitment status
No longer recruiting

Registration date
27/06/2022

Overall study status
Completed

Last Edited
15/03/2024

Condition category
Other

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

Plain English summary of protocol
Background and study aims
A chronic somatic condition is defined as a condition that lasts longer than 3 months, recurs more than three times a year and/or is related to long-term use of medication, treatments or help. Youth with chronic somatic conditions are at increased risk of anxiety and depression. Recent studies have indicated that 34-40% of adolescents with a chronic somatic condition experience significant levels of anxiety and depression, which is far more than in their healthy peers. A sharp increase in the prevalence of emotional problems is typically seen in adolescence. Such problems are related to social and academic impairments and reduced quality of life, as well as non-compliance with medical treatment recommendations, poor health, and an increase in medical costs by up to 50%. The aim of this study is to study a serious gaming application (Grow It! App) by:
1. Testing the effect of a psychosocial intervention aimed at promoting adaptive coping in adolescents with a chronic somatic condition
2. Examining the acceptance and effectiveness of the Grow It! smartphone application as a method of obtaining insights into the daily emotions and behavior of adolescents with a chronic somatic condition
3. Examining demographic and illness-related factors that predict or are associated with the effect of the psychosocial intervention.

Who can participate?
Children between 10 and 18 years, treated in the Erasmus MC- Sophia Kinderziekenhuis for a chronic somatic condition

What does the study involve?
Children will be randomly allocated to the intervention group (to use the app straight away for 4 weeks) or the control group (a waiting list period, starting using the app 4 months later). Anxiety and depression are measured at the start of the study, after using the app (week 5), and after 3 months.

What are the possible benefits and risks of participating?
The benefits for the adolescents are gaining more insight into their emotions, identifying problems more quickly and strengthening emotional resilience by completing challenges aimed at adaptive coping. The smartphone application also promotes self-reflection and being more physically active. There are no risks involved with participating in this study.

Where is the study run from?
Sophia Children's Hospital Rotterdam (Netherlands)

When is the study starting and how long it is expected to run for?
September 2020 to July 2024

Who is funding the study?
Erasmus Universitair Medisch Centrum Rotterdam (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
NL75678.078.21

Study information

Scientific Title
Grow It! Sophia: a smartphone application to identify mood problems and adaptive coping in adolescents with a chronic somatic condition

Acronym
Grow It! Sophia

Study objectives

Recent studies have indicated that 34-40% of adolescents with a chronic somatic condition experience significant levels of anxiety and depression. The aim of this study is to study a serious gaming smartphone application (GrowIt! App) by:
1. Testing the effect of a psychosocial intervention aimed at promoting adaptive coping in adolescents with a chronic somatic condition
2. Examining the acceptance and effectiveness of the GrowIt! smartphone application as a method of obtaining insights into the daily emotions and behaviour of adolescents with a chronic somatic condition
3. Examining demographic and illness-related factors that predict or are associated with the effect of the psychosocial intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2021, Erasmus MC Research Ethics Committee (Postbus 2040, 3000 CA, Rotterdam, Netherlands; +31 (0)207034428; metc@erasmusmc.nl), ref: NL75678.078.21

Primary study design
Interventional

Study design
Parallel-group randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Chronic somatic condition

Interventions
Participants are allocated to the experimental or control condition through computer-based, block-wise randomisation. Patients are assigned to blocks based on their chronic somatic condition. Assessments are not blind to condition, because the researchers are not involved in any of the assessments, and only the children and adolescents fill out online questionnaires. Consequently, indications for breaking the randomisation code are not applicable.

1. Active condition: use of the Grow It! app for 4 weeks
2, Waiting list condition: online questionnaires, and after a period of approx. 4 months use of the Grow It! app for 4 weeks

Intervention Type
Other

Primary outcome(s)
Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS) and the Children Depression Inventory (CDI) at baseline, after using the app (week 5), after 3 months (condition group T4 and T5)

Key secondary outcome(s)

1. Quality of life is measured using the Pediatric Quality of Life Inventory (PedsQL) Generic Core Scales at baseline, after 5 weeks and after 3 months (condition group T4 and T5)
2. Self-esteem is measured using the Rosenberg Self-Esteem Scale (RSES) at baseline, after 5 weeks and after 3 months (condition group T4 and T5)
3. Illness perception is measured using the Brief Illness Perception Questionnaire (B-IPQ) at baseline, after 5 weeks and after 3 months (condition group T4 and T5)
4. Emotional and behavioural problems are measured using the Child behaviour Checklist (CBCL) at baseline, after 5 weeks and after 3 months
5. Sleep quality and quantity are measured using a self-developed scale based on prior studies for 28 days once a day
6. Emotions are measured using a test based on the Positive and Negative Affect Schedule (PANAS) for 28 days, 5 times a day
7. Fatigue, loneliness and worry are measured using a self-developed scale based on prior studies for 28 days, 5 times a day
8. Physical pain is measured using the Numerical Rating Scale (NRS) for 28 days, 5 times a day
9. Events are measured using a self-developed scale based on prior studies for 28 days, 5 times a day
10. Coping is measured using a self-developed scale based on Fragebogen zur Erhebung der Emotionsregulation bei Kindern und Jugendlichen (FEEL-KJ), Emotion Regulation Questionnaire (ERQ), Cognitive Emotion Regulation Questionnaire (CERQ) and UCL for 28 days, once a day
11. Exercise questions are measured using a self-developed scale based on prior studies for 28 days, once a day
12. Medication adherence is measured using a self-developed question for 28 days, 5 times a day
13. Health status is measured using a self-developed scale for 28 days, 5 times a day

Completion date
18/07/2024

Eligibility

Key inclusion criteria
Adolescents (aged 10 - 18 years) undergoing treatment in the Sophia Children's Hospital Rotterdam for a chronic somatic condition (a condition that lasts longer than 3 months, recurs more than three times a year and/or is related to long-term use of medication, treatments or help)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
1. Intellectual disability (IQ <70)
2. Insufficient comprehension and proficiency of the Dutch language

Date of first enrolment
01/06/2021

Date of final enrolment
06/10/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC - Sophia Children's hospital
Wytemaweg 80
Rotterdam
Netherlands
3015 CN

Sponsor information

Organisation
Stichting Vrienden van Sophia - Lichtjesactie

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Universitair Medisch Centrum Rotterdam

Alternative Name(s)
Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Erasmus MC

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available due to privacy of the participants

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Aged 12 to 16 years	18/02/2022	19/05/2022	No	Yes
Participant information sheet	Aged 16 to 18 years	18/02/2022	19/05/2022	No	Yes
Participant information sheet	Parents	18/02/2022	19/05/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes