Grow it! Sophia: A smartphone application to identify mood problems and promote adaptive coping in adolescents with a chronic somatic condition.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54463

Source
ToetsingOnline

Brief title
Grow It! Sophia

Condition

- Other condition

Synonym
'anxiety', 'depression' or 'anxiety disorder', 'major depressive disorder'

Health condition

luchtweg-, maagdarmstelselontstekings-, hart-, nier-, lever-, huid-, oor-, bloed-, skeletspierstelselaandoeningen, auto-immuunziekten, chronische pijn, chirurgische

verrichtingen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Vrienden van Sophia

Intervention

Keyword: Adolescence, Chronic somatic condition, Emotional problems, Experience Sampling Method

Outcome measures

Primary outcome

The primary outcome measures are anxiety and depressive symptoms immediately after playing the app (T2) and coping. Anxiety is measured with the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS) and depressive symptoms with the Children Depression Inventory (CDI). Coping is measured daily by ESM with questions based on the FEEL-KJ, ERQ, CERQ and UCL. Thereby, participants will be categorized into three different mood profiles (*happy*, *typically developing*, and *at risk for depression*) based on ESM, to help disentangling *at risk* adolescents from *typically developing* teens regarding risk of depression.

Secondary outcome

Secondary outcomes are:

Questionnaires:

- Anxiety and depressive symptoms of the adolescent before playing the app (T1) and 3 months after finishing the app (T3 and T5).

- Coping

- Quality of life

- Emotional and behavioral problems

- Self-esteem

- Illness perception

ESM measures:

- Sleep quality and quantity

- Negative and positive affect

- Fatigue

- Loneliness

- Worry

- Physical pain

- Exercise

- Coping

- Health status

- Medication adherence

Study description

Background summary

Many adolescents are treated in the Sophia Children's Hospital for a chronic somatic condition. A large proportion of them (35-40%) have severe emotional problems such as anxiety, depression and post-traumatic stress symptoms as a result of the chronic somatic condition. Because of these emotional problems, they have lower quality of life, they function less well at school, they withdraw from social contacts and they show less adherence to therapy. Their

parents also often experience psychosocial problems as a result. Despite these alarming results, emotional problems are often unrecognized and untreated. This leads to long-term unnoticed suffering and shame.

Children's hospitals do not screen for emotional problems by default. For adolescents with a chronic medical condition, the threshold is often high to report that they have emotional problems, such as fear or sadness. Nor are there any valid tools to screen for emotional problems quickly and cost-effectively. An innovative smartphone application (mHealth) is developed together with eight departments of the Sophia Children's Hospital. Smartphone monitoring of emotions is extremely suitable, because adolescents are strongly inclined to use a fun and challenging app.

Study objective

The goal is to develop and research the smartphone app intervention to adolescents with a chronic medical condition
1) to offer an intervention with attractive and fun challenges to increase their emotional resilience and
2) to identify emotional problems based on the Experience Sampling Method (ESM).

Study design

Parallel-group randomized controlled study (RCT) with a psychosocial intervention group and a wait-list control group. The waiting list condition also receives the psychosocial intervention after three months.

There will be three measurements for the intervention group:
T1 = measurement of (online) questionnaires prior to smartphone serious game intervention
T2 = measurement of (online) questionnaires immediately after completion of smartphone serious game intervention
T3 = measurement of (online) questionnaires 3 months after completion of smartphone serious game intervention

There will be five measurements for the wait-list control group:
T1 = measurement of (online) questionnaires simultaneously with T1 of the intervention group
T2 = measurement of (online) questionnaires simultaneously with T2 of the intervention group
T3 = measurement of (online) questionnaires prior to smartphone serious game intervention
T4 = measurement of (online) questionnaires immediately after completion of smartphone serious game intervention
T5 = measurement of (online) questionnaires 3 months after completion of

smartphone serious game intervention

Intervention

Both groups receive the smartphone application Grow it! as an intervention. The intervention consists of challenges aimed at activation, changing from a passive to an adaptive coping style and having positive experiences.

Study burden and risks

The risks associated with participation are negligible and the burden is minimal.

Risks: not applicable

Burden: Filling in a micro-questionnaire 5 times a day for 4 weeks (1 to 2 minutes at a time). This may be perceived as somewhat onerous by some adolescents. A large number of questionnaires are administered to the adolescents and their parents at T1, T2, T3, and possibly T4 and T5. It has been ensured that the burden is minimal by keeping the number of online questionnaires and ESM micro-questions as short as possible. Furthermore, all measurements will take place online so that adolescents and parents do not have to visit the Sophia Children's Hospital.

The research aims to research the effectiveness of the Grow It! app among adolescents with a chronic medical condition and is therefore group-bound.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

Adolescents (10-18 years) with a chronic somatic condition, i.e. a condition which 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 (Van Hal et al., 2019), receiving treatment or routine examinations/checkups at the Erasmus MC-Sophia Children*s hospital.

Exclusion criteria

* Intellectual disability (IQ < 70) * Insufficient comprehension and proficiency of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-08-2021
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	17-05-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-09-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-05-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-09-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-04-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL75678.078.21