Improving treatment adherence in chronically ill adolescents and young adults.

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To test whether the Emma-app and/or a financial incentive can improve therapy adherence, clinical disease outcomes and quality of life in adolescents and young adults with a chronic health condition.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46629

Source
ToetsingOnline

Brief title
METT 2 study

Condition

- Other condition

Synonym
Chronic diseases

Health condition

Meerdere chronische aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Steun Emma

Intervention

Keyword: Adolescents, Chronic diseases, Therapy adherence, Young adults

Outcome measures

Primary outcome

The difference in adherence rates from baseline to endpoint and between the

different groups.

Secondary outcome

The difference in clinical disease outcomes and quality of life from baseline

to endpoint and between the different groups.

Cost-effectiveness analysis of the study.

Study description

Background summary

Many people suffer from a chronic health condition requiring daily medication intake, which affects them in their daily lives. To be adherent to therapy is important but difficult, especially for adolescents and young adults. Less than half of the chronically ill adolescents is adherent to therapy. Non-adherence leads to more comorbidities, increased health utilization with the additional higher costs and higher mortality rates. Many interventions to improve adherence have been evaluated, but no long-lasting solution has been found yet. In this modern age, where technology is more and more important, e-health seems promising to enhance several health outcomes. The Emma-application runs on a smartwatch and is a combination of a reminder- and monitoring system. What makes this app so unique, is the possibility to add a social community to give extra support to the patient. Financial incentives have shown great promise in previous research to change behavior and to enhance adherence. Adolescents seem to be very receptive for incentives and rewards.
In this study we will evaluate if the combination of the Emma-app and a

financial incentive can improve therapy adherence, disease outcomes and quality of life in adolescents and young adults with a chronic health condition, on daily treatment.

Study objective

To test whether the Emma-app and/or a financial incentive can improve therapy adherence, clinical disease outcomes and quality of life in adolescents and young adults with a chronic health condition.

Study design

This multicenter study will be conducted in three phases. The first phase is a prospective, longitudinal cohort study, with a duration of one year. The second phase is a single blinded, randomized controlled trial, with a duration of six months. The third and last phase is a follow-up period with a duration of six months.

Intervention

All participants will receive standard care. No extra visits or medical tests are necessary. After inclusion (at baseline), study participants will be monitored for six months. After six months, (T1), all study participants will receive a smartwatch, which has the Emma-app installed. After one year (T2), all non-adherent patients will be randomized into two groups: the first group will receive a financial incentive in the event of optimal adherence for six months. The second group will not receive this incentive. After 18 months there will be a follow-up period of six months to evaluate whether the effect of the financial incentive will last. The study will end after 24 months (T4).

Study burden and risks

The study participants will be asked to fill out Quality of life questionnaires on five occasions; at T0, T1, T2, T3 and T4. There are no extra hospital visits or medical tests required to participate. There are no risks associated with participation in this study. The extra burden is negligible.

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)
Elderly (65 years and older)

Inclusion criteria

Patients are adolescents and young adults (12-30 years old)
Patients have a chronic somatic disease
Patients use medication daily
Patient own a smartphone with an android- or ios-based operating system.
Patients have to choose a buddy.
Written informed consent of the participants and legal guardians (when underage)

Exclusion criteria

Patiënts that have a psychiatric condition, not a somatic disease.
Patiënts that do not have sufficient knowledge of the Dutch language.
No signed informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL62591.018.17