

Evaluation of a therapy-supportive app in youth mental healthcare.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON45494

Source

ToetsingOnline

Brief title

Evaluation of a therapy-supportive app in youth mental healthcare.

Condition

- Psychiatric disorders NEC

Synonym

addiction, psychiatric disorders, psychiatry, substance abuse

Research involving

Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)

Source(s) of monetary or material Support: NWO call 2012 CLICKNL

Intervention

Keyword: eHealth, Gamification, Youth mental healthcare

Outcome measures

Primary outcome

Acceptance of Luca modules

- * Frequency of use of Luca modules by therapists and youngsters and amount of set and achieved goals by youngsters
- * Experiences of therapists and youngsters
- * Attitude of therapist towards eHealth

Therapy progression of youngsters

- * Psychological wellbeing
- * Therapy retention
- * Substance use
- * Motivation for therapy

Sociodemographic and individual characteristics of youngsters

- * Demographic variables
- * Personality traits

See page 7, 8 and 9 in the protocol for more details about the study parameters and the questionnaires

Secondary outcome

None

Study description

Background summary

An important development in (youth) mental healthcare is the application of online interventions as an addition to and improvement of care. These interventions can be designed to be used fully online and *stand-alone* or designed in such a way that they should be combined with face-to-face contacts with therapists (*blended care*). Mental healthcare prefers some type of support by therapists, and thus prefers blended care. To improve the frequency of use of an app in mental healthcare, and lower possible resistance of therapists and youngsters, designers often apply different design strategies. A promising strategy is called *gamification*, that aims to enhance the involvement of a client with the online therapy by applying game-elements. Gamification is applied in different ways in (youth)mental healthcare, but not systematically studied. This makes it almost impossible to know when and how is strategy works within this context.

Study objective

The overall aim of this study is to generate a first impression about the usability of the therapy-supportive Luca app with youngsters in youth mental healthcare. For this purpose, we will ask the following research questions:

1. How do therapists and youngsters accept the Luca app, regarding frequency of use and experiences with the app?
2. Is a higher frequency of use of the Luca app related to a better therapy progression (i.e. course of complains, therapy retention, motivation for therapy and substance use)?
3. Is the Luca app with a gamified therapy-goals module more frequently used compared to the Luca app with a non-gamified therapy-goals module?
4. Do youngsters that received the Luca app with a gamified therapy-goals module have a better course of complains, therapy retention, motivation for therapy and less substance use compared to youngsters that received the Luca app with a non-gamified therapy-goals module?

Study design

This study is a non-controlled (and thus non-randomized) prospective study, with 60 youngsters of the youth mental healthcare institutions Brijder Jeugd and Lucertis, that receive the therapy-supportive Luca app in the context of out-patient cognitive behavioural therapy (CBT, their regular therapy).

Pre-tests will take place at the start of their therapy and post-tests after eight weeks. The first 30 youngsters who, according to their registration at the therapy centre, participate in the study receive - besides CBT - the Luca app with a non-gamified therapy goals module and the following 30 youngsters

receive the Luca app with a gamified therapy goals module.

Intervention

In this study we will evaluate a therapy-supportive app that has been developed by Brijder Jeugd, De Jutters and Lucertis Kinder- en Jeugdpsychiatrie and is currently being implemented in these three companies of Parnassia Groep as part of regular therapy. The Luca app supports patients to also work on their therapy at home. To use Luca, patient and therapist both download the Luca app. The therapist can, with permission of a client, see what the client has described in the Luca app.

The Luca app consists of different therapy-supportive modules:

- * Diary: In this module a client can register his/her mood, the situations he/she encounters and how he/she is doing.
- * Medication alarm: In this module a client can set when (what days of the week and time of the day) he/she has to take specific medication.
- * Activity list: In this module the client can make a list of the things he/she wants to do.
- * Emergency plan: In this module a therapist and client set an emergency plan that can help a client if he/she is not doing well.
- * Chat: A client and therapist keep contact with each other by using the chat function.
- * Auxiliaries: In this module a client registers *auxiliaries* that a client can call if he/she is not doing well or experiences difficulties (like family members or friends).
- * Therapy-goals: In this module a therapist and client first set long-term goals that focus on that what the client wants to achieve during therapy. These are transformed into achievable short-term goals for behavioural change in the daily life of the client.

To study the added value of gamification on the therapy progression (course of complaints, therapy retention, motivation for therapy and substance use), we have designed two different versions of one module, i.e. the therapy-goals module. One version of the therapy-goals module is gamified and the other version is not-gamified. With both versions, youngsters and their therapists can set therapy related goals, but the gamified version also exist of some game-elements that suit the target group. For example, youngsters can estimate the difficulty of the goals they set and estimate their expectation that they will achieve these goals and rewards. By achieving goals they work towards rewards they have set with their therapist. Their progression in setting and achieving goals is also visualized by using a using mountain as a metaphor.

The Luca app also consists of three other non-therapy supportive modules, on which we will not focus during the study. These are: a personal non-therapy-related goals module (where youngsters can set their own goals - without any contact with their therapist - that do not have a direct link with

their therapy), an information module (for more information about Luca), and a profile module (where the client can change his or her profile).

Study burden and risks

Youngsters who participate in this study receive access to a therapy-supportive app that could enhance their therapy progression. The results of this study will also provide insights in the evaluation, frequency of use and relation with therapy progression (i.e., course of complains, therapy adherence, motivation for therapy and substance use) and the (possible) added value of gamification. The burden and risks that are related to participation in this evaluation study are minimal. Because the app is used voluntarily, participants will only (in addition to their regular therapy) have to fill in questionnaires at the beginning and end of the study. The extra tasks that therapists will be asked to do, are signing-up adolescents after the first therapy session, note down the treatment retention of the participants and fill in some questionnaires.

Playing specific games can be addictive for some type of youngsters. Therefore, applying game-elements when treating youngsters that are sensitive to addiction or youngsters with psychiatric problems should be done in a careful way. Youngsters with problematic game or gambling behaviour will therefore be excluded from participation of this study. Besides, participating therapists will be instructed to be alert and to exclude youngsters if they show this type of behaviour. Concluding, typical games that can be addictive are Massive Multiplayer Online Role-playing Games (MMORPGs). MMORPGs have a strong social aspect, fantasy world and can be played online. These *addictive* entertainment games are definitely more sensitive to addiction compared to our therapy-supportive *serious game*. The most important reason for this is that our game has a *serious content* (i.e. the therapy) and consists of less immersive game-elements. The game has also been designed with experts from addiction care to exclude possible unexpected addiction effects as much as possible. Therefore, we expect that a possible risk on addiction or problematic behaviour are limited.

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

- Willingness to participate in the evaluation study (written informed consent)
- At intake an indication for individual CBT for substance addiction or other psychiatric disorder
- Age 12 * 22 years old
- Owning a smartphone

Exclusion criteria

- Problematic gaming or gambling behaviour
- Clinical admission < 3 months prior to the start of therapy
- (Mild) intellectual disability (MID)
- Acute psychotic or suicidal complaints
- Insufficient command of the Dutch language

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 21-02-2018

Enrollment: 60

Type: Actual

Ethics review

Approved WMO

Date: 25-01-2017

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

Approved WMO

Date: 23-10-2017

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20030

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL58493.058.16
OMON	NL-OMON20030