The Zen garden app: evaluation of a mobile app supporting the COMET therapy for self-esteem problems

No registrations found.

Ethical review   Positive opinion
Status   Recruiting
Health condition type   -
Study type   Interventional

Summary

ID

NL-OMON23311

Source
NTR

Brief title
The Zen Garden: a smartphone app for blended COMET therapy

Health condition

(trans-diagnostic) symptoms of negative self-esteem

Sponsors and support

Primary sponsor: PsyQ, subdivision of Parnassia Group
Source(s) of monetary or material Support: NWO grant 314-99-102 (NextLevel project)

Intervention

Outcome measures

Primary outcome

1) Feasibility of the blended COMET protocol in comparison to the standard face-to-face COMET: recruitment time and inclusion rate (required time to include patients and amount of eligible patients willing to participate in the study after referral by the primary therapist);

therapy adherence (difference in amount of completed homework exercises between the two conditions: these are monitored automatically by the mobile app, while in the face-to-face condition patients are given a weekly diary form to keep track of frequency and duration of daily exercises); therapy retention (difference in dropout rate between the two conditions); time on task in the blended COMET group only (participants' total activity with the mobile app is, i.e., app usage logs, including frequency and duration of app logins and activity in the app and amount of tasks or actions performed in the app).

2) Difference in treatment acceptability/satisfaction between the two COMET versions: patients' expectancies about the treatment will be assessed and compared between the two groups with the Credibility and Expectancy Questionnaire (CEQ; Devilly & Borkovec, 2000) at the end of the first COMET session. At the post-intervention assessment, patients' satisfaction with the intervention will be assessed with the Client Satisfaction Questionnaire-8 (CSQ-8; Larsen et al., 1979).

3) User experience with the Zen Garden app (blended COMET group only), assessed during the post-intervention session: app usability will be assessed with the System Usability Scale (SUS; Brooke, 1996) and overall user experience will be measured with the User Experience Questionnaire (UEQ, Laugwitz et al., 2006). A nested qualitative study with a pre-selected sub-sample of participants receiving the blended COMET will provide a more nuanced picture of a) patients' appraisal of the mobile app design and their experience with using the app during the therapy, and b) the integration of the app itself within the blended COMET protocol.

Secondary outcome

1) Improvement in self-esteem: Rosenberg Self-esteem Scale (RSES; Rosenberg, 1965) and Self-Esteem Rating Scale – Short Form (SERS-SF; Lecomte et al., 2006) administered at both assessment time points.
2) Improvement in depression and anxiety symptoms: Beck Depression Inventory II (BDI-II; Beck et al., 1996) and State Anxiety subscale of the State Trait Anxiety Inventory (STAI; Spielberger, 1983) administered at both time points.
3) At a descriptive level, therapists' total amount of time spent per patient, including sessions and weekly contact with patients, will be recorded as a proxy of cost-effectiveness.

Study description

Background summary

Goal of this first explorative study is to test the feasibility, acceptability and preliminary effectiveness of a blended version of the COMET protocol for self-esteem, in comparison with the standard protocol of COMET therapy. While the standard COMET therapy involves 7 face-to-face sessions, the blended version combines a lower amount of face-to-face sessions (i.e., 3 instead of 4) with the use of the Zen Garden mobile application throughout the remaining 4 sessions. The study will explore if the blended version of the COMET treatment has the potential to achieve positive therapeutic effects and treatment adherence (i.e., successful

completion of homework assignments) with a less intensive format (i.e., fewer face-to-face contacts), compared with the standard, more intensive face-to-face COMET protocol delivered in an outpatient specialized mental healthcare institution (PsyQ).

Clients randomized to the blended COMET condition will have access to a therapy-supportive app that could enhance their therapy progression and adherence (i.e., improve completion of daily homework) while reducing the intensity and costs of weekly face-to-face sessions. The results of this study will also provide insights in the acceptability and experience, app usage pattern and relation with the therapy progression and goals of the blended, less intensive therapy protocol, compared to the standard, more intensive protocol.

Study objective

Due to the preliminary and exploratory nature of the study there are neither hypotheses nor expectations about the effects of the blended intervention against the standard one.

The study will address the following research questions:
1) What is the adherence and retention rate in the blended COMET protocol in comparison to the standard version (e.g., amount of completed homework exercises and drop-out rate)?
2) What is the patients' experience and acceptability with the blended COMET therapy in comparison to the standard COMET therapy?
3) What is the patients' experience with the blended COMET therapy and the mobile app?
4) What are the effects of the blended COMET protocol on self-esteem?
5) What are the secondary effects of the blended COMET protocol on depression symptoms?

Study design

Before and at conclusion of the intervention patients will complete a brief assessment session, including measures of self-esteem, depression and anxiety symptoms. Both the standard and blended COMET therapy lasts 7 weeks (1 session per week).

At conclusion of the post-assessment session, a selected sub-sample of patients assigned to the blended COMET group will be further invited to participate to the qualitative study on their experience with the app and the blended therapy.

Intervention

COMET protocols for self-esteem primarily involve 1) the identification of the negative self-opinion, 2) the identification of positive characteristics and behaviors that are incompatible with the negative self-opinion, and 3) enhancing the retrievability and experiencing of these positive characteristics. Both the standard and the blended version of the COMET therapy are fully manualized for both therapists and patients. At the start of the therapy, all patients are provided with a comprehensive treatment manual in which the rationale, background and specific procedures, and homework assignments of the treatment are specified. The patient manual for the blended COMET protocol includes the integration of the app use into the therapy steps and an additional 'tutorial' on how to use the app.

Therapists will fill in a checklist including a list of treatment procedures detailed for each COMET session (cf. Staring et al., 2016). The researchers will then screen the checklist data

to evaluate treatment integrity.

The standard therapy lasts seven sessions of 45-60 minutes each and consists of several steps, all aimed at strengthening the patient's positive self-opinions and making them more competitive. All steps are repetitively practiced during the therapy sessions and in homework assignments. First, the negative self-image is identified. Next, a credible but incompatible and more positive self-image, based on personal characteristics, acts, and experiences, is formulated. This positive self-image is strengthened by writing small self-referent stories about real-life instances in which these positive personal characteristics had been active. During the next few sessions, these instances are made more emotionally salient by imagining these scenes, backing them up with positive self-verbalizations (session 2), body posture and facial expression (session 3), and music (session 4); all these are selected by the patients themselves and believed to promote the experience of positive self-esteem. Then, in sessions five and six counter-conditioning is introduced in order to form new associations between cues that formerly activated low self-esteem and the newly enhanced representations of positive self-esteem. In the final (seventh) session, after discussion of the latest homework, the therapy progress and achieved goals are evaluated and the generalization of the new representations of positive self-esteem in the future is discussed.

The blended version of the COMET intervention involves the use of the Zen Garden app along the therapy steps involving the completion of progressive exercises and homework to strengthen the activation and rehearsal of the positive self-referent events chosen by the patient. The blended therapy includes fewer face-to-face sessions (session 1, 5, and 7) in conjunction with the independent use of the Zen Garden mobile app during homework weeks (weeks 2, 3, 4, and 6). Upon logging in for the first time, patients are asked to enter maximum five different negative self-esteem elements. Each of the negative self-images would act as an "area" in the Zen Garden. Positive self-images counteracting the negative self-esteem evaluations are planted as flowers in these areas to help patients build a network of positive self-evaluations and images. To plant a flower, patients need to enter a credible statement of their positive self-image (i.e. "I regularly help other people"). The plants could be grown further by progressively attaching self-referenced resources (i.e., self-reference stories, images and audios) to the plants, similarly to what is done along steps 2-4 of the standard COMET protocol. In each week, patients are provided with a task list, which will help in guiding them on their goals for the therapy. Notifications are sent periodically through push notification on the mobile phone, to remind patients about completing the therapy tasks. In addition, a voice narrator in the form of a virtual avatar is present in the application and will guide the patients through the various therapy stages (e.g., explaining the importance of each step in the therapy, giving instructions on what to do, etc.). In order to review their positive self-images, patients will need to click on the previously added positive self-image resources, which are attached to the flowers in the form of "spirits" floating around them. The narrator voice will guide patients through the review process, adopting a narrative style that is meditative in nature (e.g., "close your eyes… try to visualize the memories" etc.). This is done to help strengthen the memories of their positive self-images. The three face-to-face sessions are similar in contents to the standard therapy, while also integrating the Zen Garden app in the review of patients' homework and therapeutic goals.

Contacts

Public
University of Amsterdam
Marilisa Boffo

0031642839480
Scientific
University of Amsterdam
Marilisa Boffo

0031642839480

Eligibility criteria

Inclusion criteria

1) Aged 18+
2) Proficiency in the Dutch language
3) A score < 26 on the Rosenberg Self-Esteem Scale (RSES, Rosenberg, 1965), which corresponds to at least 1 standard deviation (SD)
below the mean RSES score for the Dutch healthy population (Schmitt & Allik, 2005)
4) Ability to mention at least one positive aspect of one's self-image, which does not need to be 'felt' as convincing for the patient
5) Stable medication use (type and dosage) in the past month and willingness of both patient and treating physician to keep it stable during the study period (about 8 weeks) 6) Owning a smartphone

Exclusion criteria

1) Current alcohol or drug abuse or addiction disorder
2) Bipolar or psychotic disorder
3) Following another treatment specifically targeting self-esteem problems
4) Having followed a COMET intervention in the past 12 months without success

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2018
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	30-07-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46777
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7915
CCMO	NL65039.058.18
OMON	NL-OMON46777

Study results