The Zen Garden: A feasibility randomized controlled trial of an m-health tool for blended Competitive Memory Training for self-esteem problems

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Goal of this first pilot study is to explore the feasibility, acceptability and indications of clinical effects of the blended version of the COMET protocol for self-esteem, in comparison with the standard protocol of COMET therapy. While the...

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

Summary

ID

NL-OMON46777

Source ToetsingOnline

Brief title

The Zen Garden: a smartphone app for blended COMET therapy

Condition

• Other condition

Synonym low self-esteem, self-esteem problems

Health condition

(trans-diagnostic) symptoms of negative self-esteem

Research involving

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Human

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

Keyword: COMET, m-health, mobile app, self-esteem

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 patients (out of eligible ones) 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 (i.e., planted flowers and materials added to the planted flowers, flowers review time), while in the face-to-face condition patients are given a weekly diary form to keep track of frequency and duration of daily exercises. At the start of each session, therapists will review clients* homework in the previous week and will make a copy of the form.

* Therapy retention: difference in dropout rate between the two conditions.
* Time on task in the Zen Garden app (patients in the blended COMET group only): patients* 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

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), which is a global measure of patient perceptions of the treatment they received.

3. User experience with the Zen Garden app (the blended COMET group only), assessed during the post-intervention session:

* App usability assessed with the System Usability Scale (SUS; Brooke, 1996);
* Overall user experience will be measured with the User Experience
Questionnaire (UEQ, Laugwitz et al., 2006);

* The nested qualitative study with the pre-selected sub-sample of patients 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

* Improvement in self-esteem: Rosenberg Self-esteem Scale (RSES; Rosenberg,
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1965) and Self-Esteem Rating Scale * Short Form (SERS-SF; Lecomte et al., 2006) administered at both assessment time points.

* 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.

* 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

Low self-esteem is a prevalent symptom across different mental disorders (APA, 2013), including personality disorders, internalizing (e.g., anxiety, depression and eating disorders) and externalizing disorders (aggressive behavior and substance abuse), and is generally considered a non-specific risk factor in physical and mental health (Mann et al., 2004). The relationship between low self-esteem and mental health is very complex; self-esteem can increase the individual*s vulnerability to mental health problems but can also be the consequence of a variety of mental health difficulties, such as panic disorders and anxiety (Fennell, 2009; Sowislo & Orth, 2013). Addressing low self-esteem directly with targeted psychological interventions has the advantage of being a broad-spectrum treatment strategy that may consequentially improve or prevent the development and the exacerbation of mental health and social problems, especially when low self-esteem represents a vulnerability factor for the evolution of ongoing mental health and social problems.

An intervention that has proven quite successful in improving self-esteem is the Competitive Memory Training (COMET, Korrelbom et al., 2008, 2009b). The COMET is a brief (i.e., 7 or 8 sessions) trans-diagnostic cognitive intervention aimed at changing the maladaptive cognitive emotional networks underlying the expression of different psychopathological symptoms, including low self-esteem, but also obsessions, panic, worry and rumination. Originally designed to enhance low self-esteem (Korrelboom et al., 2008, 2009b), the COMET is based on Brewin (2006)*s notion that emotional and cognitive representations of concepts (such one*s self-image) are stored in long-term memory and compete with each other to be activated (i.e., competitive memory retrieval hierarchy). Some of these representations may be or become dysfunctional, and when too high in the retrieval hierarchy, they become more dominant and easily retrievable. The aim of any cognitive (behavioral) therapy is then to change the relative retrievability of different representations of emotional concepts, rather than directly modifying negative information. COMET targets dysfunctional thoughts by strengthening the positive cognitive emotional networks that are in competition with the more readily activated dysfunctional (negative) thoughts.

In the context of low self-esteem problems, the goal of COMET is to create stronger networks of functional self-referent representations that would compete with the dysfunctional ones, and to influence the relative activation of these *positive* networks by repeatedly relating them to personalized cues that are known to trigger the patient*s dysfunctional ideas and cognitions (i.e., conditioned stimuli) about his/her self-image (i.e., counterconditioning). Such COMET protocol for self-esteem problems has proved efficacious in addition to treatment as usual in enhancing self-esteem and reducing depression in patients with eating disorders (Korrelboom et al. 2009a), personality disorders (Korrelboom et al. 2011), depressive disorders (Korrelboom et al. 2012) and anxiety disorders (Staring et al., 2016), and has been further extended to target worry and rumination (Ekkers et al., 2011) and panic (Korrelboom et al., 2014).

The COMET protocol for low self-esteem is currently deployed in the clinical practice (on top of treatment as usual) and the strong effectiveness and short duration prompted the development of an in-house web-based version of the therapy to be used in a blended format in one of the leading institutions delivering such intervention in the Netherlands (PsyQ). The main goal behind the idea of creating an e-health COMET program was to improve efficiency and cost-effectiveness of the treatment and increase its accessibility to patients in their daily routine. The blended COMET program was designed to alternate face-to-face sessions with the patients* independent use of the online platform every other week (i.e., weeks 2, 4 and 6 of the COMET protocol) and for daily exercises. However, the first pilots of the online program were not successful: a general lack of motivation to complete the online program was observed, with large drop-outs, very low adherence to the daily homework, and an overall negative feedback about the layout and structure of the online program. Therapists involved in the project also highlighted the difficulty of patients to stay motivated and keep up with the exercises and to autonomously go through the progressive stages of the protocol.

The high degree of therapist guidance, accountability and interactivity; the need of consistent exercising and rehearsing during daily homework, and the intensive nature of the intervention, are all factors that seem to lower compliance to treatment when delivered outside the face-to-face setting, as in the case of the negative results of the first online COMET program at PsyQ. Further feedback by COMET experts and therapists pointed out that also in the

full face-to-face version of the therapy patients do not completely comply or have difficulty in complying with the schedule of daily practice of the exercises learned during the therapy sessions (i.e., a minimum of 5-7 times a day for 5-10 minutes). Treatment adherence and intensive daily practice, which are necessary elements for a successful outcome, seem to be a general issue in the COMET clinical practice.

The information gathered during this phase of desk-research and interviews with multiple COMET practitioners grounded a new round of design and development of an e-health version of the COMET. The main idea was to keep the original blended format of the e-health version protocol (i.e., mix of face-to-face and independent work) but improve the design, content, usability and efficiency of the digital component of the therapy. A gamified e-health version of the COMET was then developed as a mobile smartphone application based on the concept of a playful garden.

A user-centered and iterative design approach has then been used to design and develop the app, by actively involving the end users of the app in the development process. The app design was reviewed and evaluated based on formative research (i.e., focus groups) conducted with a small group of COMET patients and therapists, who evaluated different game concepts and mock-ups in the early design phase. The concept of the Zen Garden was then put into production, with a continuous iterative evaluation of multiple, progressive prototypes of the app. These iterative rounds of evaluation have been conducted both in-house and with experienced COMET therapists, in order to reach a final version of the app approved both in terms of contents and intended use as an integral part of a revised COMET protocol, blending the face-to-face and digital components (more details presented in the Intervention section).

The resulting Zen Garden mobile app incorporates and gamifies the main principles of four out of the seven stages of the COMET protocol for self-esteem problems (i.e., weeks 2, 3, 4 and 6). The app is based on a playful garden concept to help enhancing the therapy experience and motivating clients to adhere to the treatment. The garden adopts the aspects of playful interaction, collection and progression as key elements of the game. Patients are encouraged to expand and grow their own garden of positive self-images, symbolized as plants and flowers, by collecting and *planting* positive self-referenced resources (stories, images, audios, etc.) to progressively add to the flowers. By later revisiting and reviewing them guided by a narrator voice throughout the therapy stages, the plants would blossom and grow bigger and the patients would strengthen the (counter)memories associated with their positive self-images. Overall, it is expected that this application would help supporting and improving the efficiency of the treatment in a blended format. Patients would autonomously engage with a proportion of the therapy outside the clinical setting, therefore empowering their self-reliance and self-management, but also reducing therapeutic costs in terms of time and effort for both the patient and the staff and health care institution.

Study objective

Goal of this first pilot study is to explore the feasibility, acceptability and indications of clinical effects of the 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 COMET treatment has the potential to increase treatment adherence (i.e., successful completion of homework assignments) and achieve positive therapeutic effects (increase in self-esteem and decrease in anxiety and depressive symptoms) with a less intensive format (i.e., fewer face-to-face COMET protocol.

Specifically, the study will address the following research questions:

1) What is the adherence and retention rate to 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

The study is a mixed-method, feasibility randomized clinical trial with a two-group parallel design. Patients are randomized over the two intervention conditions: one group will receive the standard COMET intervention for low self-esteem (Korrelboom et al., 2009, 2011, 2012), consisting of 7 face-to-face individual sessions with a trained therapist; and one group will receive the blended version of the COMET, with 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). Therapists involved in the study will deliver both therapy versions.

Before and at conclusion of the intervention, participants will complete a brief assessment session, including measures of self-esteem, depression and anxiety symptoms. Treatment acceptability and satisfaction will be assessed during the post-intervention assessment session. Patients assigned to the blended COMET group will also report about their user experience with the mobile app. Patients activity on the app during the intervention phase will be automatically recorded on the app, while weekly forms about homework exercises will be given to the patients receiving the standard COMET and reviewed with the therapist during their regular therapy sessions.

Nested within the main quantitative study, we will explore app users* views of the acceptability, usability and potential effectiveness of the app and its integration within the therapy, in qualitative interviews. 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 in individual interviews. The nested qualitative study is conducted concurrently with the quantitative study (i.e., *QUAN + qual* concurrent explanatory mixed-method design; Bishop, 2014) and is aimed to complement the quantitative findings and to capture different facets of patients* experience with the app and the blended treatment (e.g., how, when and why patients engaged with specific features of the app; what aspects of the app need revision or improvements; what is the experience with using an app in combination with the face-to-face session; how was the patients' experience with the integration of the app in the therapy stages).

Intervention

COMET protocols for sef-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 checklists to evaluate treatment integrity.

The standard COMET

The standard COMET therapy lasts 7 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

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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 COMET

The blended version of the COMET therapy 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. During the first COMET session, the therapist introduces the app to the patient and its main goal. 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 participants build a network of positive self-evaluations and images. To plant a flower, participants 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, participants 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 users 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 participants 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 in the blended COMET protocol last between 45 and 60 minutes each, except for the first one, which lasts between 60 and 90 minutes to allow the patient to get acquainted with the app together with the therapist. In the first session, the patient will install the app and will then be further familiarized with the apps* functions by the therapist. Together, they will identify the negative self-image(s) and enter it (or them) as an area in the Zen Garden app, followed by planting the first flower symbolizing the first self-referent positive image/story. The first session will be concluded with an overview of the tasks the patient can expect for the following weeks. The second session is scheduled four weeks after the first session. By that time, the patients will have practiced with self-referent stories, imagination, pictures, self-verbalization, body posture, facial expression and music using the Zen Garden app. The patient will share the *garden* of positive images in the app with the therapist at the beginning of the second session (session 5 in the standard COMET protocol). The therapist and the patient will discuss the progress the patient made with the app and any hardship the patient may have experienced while doing the daily exercises. In the second part of the session, the therapist will continue with the standard content of the session, i.e., the counter-conditioning. Counter-conditioning is used to form associations between cues that previously triggered low self-esteem and the enhanced positive images the patients have been practicing. Patients will continue practicing the counter-conditioning exercises at home while using the app. The second session will be concluded with an overview of the tasks the patient can expect for the following week.

During the third and last session of the blended COMET protocol, the patient will share the entire garden with the therapist as to evaluate the progress that has been made. At conclusion, the generalization of the new positive self-esteem in the future will be discussed.

Study burden and risks

All clients participating in the study will receive an active treatment alongside their treatment as usual. 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., 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 a blended, less intensive therapy protocol, compared to the standard, more intensive protocol.

The burdens that are connected to participation in this study may impose some extra work to patients, which is yet minimal and fully related to the treatment goals. In addition to their regular therapy, patients will only be asked to fill in a few questionnaires at the beginning and end of the study. Patients are under the consistent care and monitoring of their therapist, including agreed weekly contacts outside of therapy sessions. This is particularly relevant for clients assigned to the blended COMET condition during the *homework* weeks of independent use of the app (weeks 2, 3, 4, and 6), where fewer therapist-patient face-to-face contacts will occur.

A less intensive face-to-face therapy protocol may increase the risk of sub-optimal therapy outcome(s) or rebound of negative symptoms, due to the lower amount of direct contact with the therapist, fewer formal therapy sessions and their substitution with an m-health tool. If a patient shows signs of intense distress or exacerbation of pathological symptoms the therapist will inform the research staff and the treating specialist, the patient will be immediately withdrawn from the study and, if deemed appropriate by the treating specialist, start over with the standard COMET intervention. Furthermore, clients receiving the blended COMET intervention are free to request and discuss with their therapist the possibility of receiving the full COMET intervention at conclusion of the study.

The burden for therapists involved in the study is compensated by the reduced intensity of the blended COMET protocol. Although being involved in the study requires the therapists to carry out a list of extra tasks, the delivery of the blended COMET protocol includes only 3 out of the 7 standard face-to-face sessions, hence saving around four hours for each patient in the blended COMET group. These hours are then used to compensate for the time spent on the extra activities.

All therapists will deliver both versions of the COMET protocol. Before starting the study, they will be trained to integrate and use the app within the blended COMET protocol by the main COMET designer, Prof. Kees Korrelboom, and the main researcher at PsyQ, who is experienced with the Zen Garden app. Besides delivering the therapy, extra tasks the therapists are asked to do involve proposing the study to potential patients, collecting the weekly diary forms from clients in in the standard COMET therapy, and extracting the routine summary about each session/contact with the clients. Therapists can always refer tot the researcher in place at PsyQ who will support them across all the tasks they are required to do in the study procedure.

Contacts

Public PsyQ, subdivision of Parnassia Group

Lijnbaan 4 Den Haag 2512 VA NL **Scientific** PsyQ, subdivision of Parnassia Group

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

1) Aged 18+

2) Proficiency in the Dutch language *

3) A score < 28 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:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	30
Туре:	Anticipated

Medical products/devices used

Generic name:	ZenGarden mobile application
Registration:	No

Ethics review

Approved WMO	
Date:	21-09-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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: 23311 Source: NTR Title:

In other registers

Register	
ССМО	
OMON	

ID NL65039.058.18 NL-OMON23311