Why wait? (Cost)effectiveness of an online transdiagnostic therapy for patients and their loved ones

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In the current study, we will analyze the (cost)effectiveness of an online, transdiagnostic positive psychology eHealth intervention for patients waiting for psychological out-patient treatment and their relatives. We expect that this intervention…

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

Summary

ID

NL-OMON57370

Source
ToetsingOnline

Brief title
(cost)effectiveness of an online transdiagnostic therapy

Condition

- Other condition

Synonym
Mental disorders (broad)

Health condition

Psychische stoornissen en gezonde deelnemers. Het betreft patiënten die wachten op basis en/of specialistische poliklinische zorg. Er zijn dus meerdere stoornissen mogelijk, zoals een depressieve- of angststoornis. Patiënten met psychotische of ernstig acute suïcidale klachten worden niet door Lionarons GGZ aangenomen, vanwege het ontbreken van een passend zorgaanbod. Daarnaast zullen 107 naasten geïncludeerd worden (gezonde deelnemers).

Research involving
Human

Sponsors and support

Primary sponsor: Open Universiteit
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: (cost) effectiveness, positive psychology eHealth intervention, transdiagnostic, waiting list

Outcome measures

Primary outcome

Below, parameters (A1, A2, A3, A4, A5) for assessing (cost) effectiveness will be described. While preliminary effectiveness of the eHealth PPI will already be rated in the RSCD, (cost) effectiveness will be determined rigorously in the RCT.Please note, that although we see (cost) effectiveness as our primary study objective and parameters, only the first parameter (positive mental health) is the primary outcome variable (baseline to 1 year follow-up post outpatient psychological treatment). The sample size calculation is based on this primary outcome variable.

A1. Positive mental health

In order to examine the primary objective, the frequency of positive mental health symptoms will be defined as the main study parameter. This parameter will be measured, using the Mental Health Continuum Short Form (MHC-SF), which is a clinically validated instrument aimed at assessing positive mental health across a range of emotional, psychological and social domains (Lamers et al.,

2011).

A2. Self-reported psychological symptoms

Self-reported psychological symptoms will be defined as the second parameter for examining the primary objective. This parameter will be operationalized, using the validated Brief Symptom Inventory (BSI), measuring the number of self-reported psychological symptoms across a range of domains that are clinically relevant in adults and adolescents (De Beurs & Zitman, 2005).

A3. Patient dropout

A parameter for patient dropout will be measured in all three treatment conditions, since patient dropout is an important clinical marker of treatment success (Arntz et al., 2023).

A4. Quality of life

First, general and objective quality of life is often considered an important parameter for health gains in the field of health economics. This parameter will be employed, using quality-adjusted Life Years (QALYs). In general, QALYs can be estimated, using utility scores from the EQ-5D-5L questionnaire (Feng et al., 2021; van Dongen et al., 2021), which is a prominent instrument in the field of cost effectiveness. However, the clinical meaning of generic EQ-5D-5L utility scores in patients with mental complaints has been criticized in the past (Pietersma et al., 2013). In order to address these concerns, adjusted utility scores (for computing quality of life in patients with mental

complaints) will be measured as well. This will be done, using the recently developed mental health quality-of-life questionnaire (Van Krugten et al., 2021) and the ICE-CAP-A questionnaire (Al-Janabi et al., 2012) for assessing positive capabilities in adults with accompanying Dutch tariffs (Rohrbach, Dingemans, Groothuis-Oudshoorn, et al., 2022).

A5. Societal costs

Second, a parameter for societal costs will be measured, including cost categories within the Dutch healthcare system and beyond. In general, 1-month consumption of health services in psychiatric patients will be measured, using the Tic-P Midi (Timman et al., 2015). In order to obtain the corresponding healthcare costs, consumption of health service use will be multiplied with the corresponding reference prices, using the ZIN guidelines (ZIN, 2024a, 2024b). Costs beyond the healthcare sector mainly include productivity losses in the workspace due to absenteeism (i.e. not being able to work) and presenteeism (i.e. reduced productivity at work due to health complaints). In order to measure these productivity losses within our research population, the Productivity Cost Questionnaire (PCQ) will be used (Bouwmans et al., 2015). Using a 1-month recall period in the PCQ, participants need to report their hours of absence (i.e. absenteeism) and the additional hours they needed to finish work due to health complaints (i.e. presenteeism). Estimated healthcare costs will be extrapolated to an extended time horizon that is not covered by the recall period. In chapter 8, we will elaborate on all statistical

techniques to quantify the aforementioned cost categories and utility scores.

Secondary outcome

Below, parameters (B1, B2, B3, B4) will be described regarding the added clinical effects of including loved ones. Loved ones are included in both the RSCD and RCT.

B1. Positive mental health

B2. Self-reported psychological symptoms

B3. Dropout

B4. Loved ones assessing patient recovery

Similar to the clinical parameters mentioned in (A), positive mental health, self-reported psychological symptoms and dropout (B1, B2, B3, B4) will be measured among patients and their loved ones in the second arm (eHealth PPI for patients and loved ones). While dropout will be measured statistically in this treatment arm, positive mental health and self-reported psychological symptoms will be measured, using the MHC-SF among loved ones. In this arm, loved ones will receive a different set of questionnaires to rate aspects of positive mental health in their own life (scenario 1) and to evaluate the psychological well-being of the patient they are related to (scenario 2).
In the former scenario, loved ones will receive distinct questionnaires to rate their own beliefs regarding self-compassion, savouring and optimism. In light of this purpose, the Self Compassion Scale - Short Form (SCS-SF), Savouring Beliefs Inventory (SBI) and Life Orientation Test - Revised (LOT-R) will be

used, respectively (Babenko & Guo, 2019; Ford et al., 2017; Hinz et al., 2017). In the latter scenario, loved ones will serve as a proxy for assessing a patient*s psychological well-being, which may be considered an important marker of treatment success. Loved ones will conduct this proxy rating for the patient they are related to, using the validated Patient Health Questionnaire (PHQ-9). Although the PHQ-9 is often used for self-administration, it can also be used as a proxy instrument to rate well-being and depressive symptoms in other people (Rooney et al., 2013). Patients and loved ones are allowed to interact while moving through the eHealth PPI, which may enhance protective resources and may positively affect dropout rates. Lastly, relational satisfaction will be measured among patients and their loved ones in the second arm, using the Relational Satisfaction Scale (RSS) (Anderson et al., 2001).

(C). Parameters for the third objective (moderation effects)

Below, parameters (C1, C2, C3, C4, C5) for assessing moderation effects will be described. These effects will be assessed in both the RSCD and RCT.

C1. Demographics (age, gender, socioeconomic status)

C2. Clinical profiles (diagnosis, symptom severity, comorbidity)

C3. Type of received treatment at Lionarons GGZ

C4. Treatment expectations

C5. Engagement

To thoroughly explore the moderating effects on our eHealth PPI, a

comprehensive understanding of moderating parameters (C1, C2, C3, C4, C5) is essential. The objective is to understand how different moderating parameters * such as diagnosis, age, gender, type of received mental health care, and treatment expectations*affect the relationship between the three intervention arms and the primary outcomes mentioned in A (i.e. positive mental health and cost-effectiveness). Socioeconomic status will be determined, using information on income, labour type and education.

(D). Parameters for the fourth objective (modelling of personalized treatment): By examining which patient characteristics are most likely associated with positive treatment effects and reduced dropout, personalization of the eHealth PPI will be possible. This procedure may inform beneficial adjustments regarding the eHealth PPI aimed at enhancing its effectiveness for individual users. The abovementioned parameters on clinical characteristics and demographics will be used again to assess implications for personalized eHealth PPI (D1, D2, D3, D4, D5). The efficacy of the eHealth PPI will always depend on certain variables, which holds true for most psychological treatments. The PPI is transdiagnostic and can be applied to various mental health problems, as it focusses on enhancing general protective factors that can be helpful for everyone, instead of decreasing disorder specific risk factors. We agree that the effectiveness of the PPI may differ between subgroups (e.g., based on demographic factors, type of mental health symptoms), and will explore for whom the PPI is most beneficial. This analysis will only take place in the RCT study.

D1. Demographics (age, gender, socioeconomic status)

D2. Clinical profiles (diagnosis, symptom severity, comorbidity)

D3. Type of received treatment at Lionarons GGZ

D4. Treatment expectations

D5. Engagement

To facilitate personalization of the eHealth PPI, an exploration of potentially different treatment effects for different levels of the variables mentioned above (D1, D2, D3, D4, D5) will be performed. This will be done, using multilevel modelling techniques. These techniques allow for modelling of treatment effects based on individual characteristics. This analytical process involves a detailed examination of the variables mentioned above. In general, all modeling analyses aim to explore whether and how the efficacy of the eHealth PPI depends on demographic factors (such as age, gender, and socioeconomic status), clinical profiles (including diagnosis, symptom severity, and comorbid conditions), treatment expectations and engagement with the eHealth platform.

(E). Parameters for the fifth objective (process evaluation)

Below, the parameters used in our process evaluation (E1, E2, E3, E4, E5) will be explained. Process evaluation is especially relevant in the RSCD. To a lower extent, process evaluation will also take place in the RCT.

E1. Acceptability

E2. Feasibility

E3. Adherence

E4. Engagement

E5. Accessibility

The implementation of the transdiagnostic eHealth PPI (in the RSCD and RCT) necessitates a detailed evaluation of several key process parameters (E1, E2, E3, E4, E5) among patient participants. Prior to organizing the RSCD, two stakeholder meetings will take place aimed at rating the eHealth PPI from a patient perspective, based on the mentioned process parameters. These parameters are crucial for understanding the intervention's practicality, user experience, and overall impact. Feasibility, which will be operationalized through specific items in process questionnaires like the System Usability Scale (SUS), assesses the practicality of applying and accessing the intervention. Acceptability, gauged through scales measuring user satisfaction within process questionnaires, evaluates how the intervention is received by its intended audience. Usability, a critical parameter that can be directly measured by the SUS, focuses on the ease with which users can navigate and engage with the digital platform. Adherence measures the extent to which participants follow the intervention guidelines. Engagement, assessable through analytics of user interactions recorded in the eHealth platform and supplemented by questionnaire data, examines the depth of participant interaction with the intervention's content. Lastly, accessibility, crucial for understanding the intervention's reach, can be assessed through questions related to participants' ease of access based on their technological literacy

and resources. In the scheduled RCT, the mentioned SUS will be used to capture

relevant dimensions of user experience regarding the eHealth PPI.

Study description

Background summary

Dutch mental healthcare is facing financial constraints due to an increasing demand for treatment, while also battling with staff shortages, resulting in long wait-lists for mental health treatment. Since a long waiting list period is negatively associated with the chance of mental recovery and increases the chance of premature therapy dropout, waiting lists in mental health care are a significant social problem.
An online, transdiagnostic positive psychology eHealth intervention helps patients to use their strengths and increase their well-being. As a result, such an intervention can reduce mental complaints and risk factors that lead to the development of mental disorders. Furthermore, it is expected that the eHealth PPI can contribute to a reduced chance of therapy dropout and an increased chance of therapy success during later outpatient mental health treatment. Offering the same intervention to loved ones can further promote the patient's recovery and have positive effects for loved ones who may also struggle with complaints.

Study objective

In the current study, we will analyze the (cost)effectiveness of an online, transdiagnostic positive psychology eHealth intervention for patients waiting for psychological out-patient treatment and their relatives. We expect that this intervention will optimize clinical outcomes during the waiting list period. We also expect that this intervention will be cost-effective, compared to the control condition in which no intervention is received during the same waiting list period. Finally, we expect that the involvement of relatives will further increase clinical effectiveness and cost-effectiveness.

Study design

Study 1: replicated single case design
In order to evaluate the acceptability of the transdiagnostic, eHealth PPI, a replicated single case design (RSCD) will be deployed and monitored carefully, including 10 participants (5 patients and 5 loved ones) at different measurement intervals. This design choice generally allows for early identification of intervention working mechanisms, including potential facilitators and barriers (Vlaeyen et al., 2022).

Study 2: randomized controlled trial
Following completion of the RSCD, a three-arm randomized controlled trial (RCT) will be applied to evaluate the (cost) effectiveness of our transdiagnostic, eHealth PPI.

The following three treatment arms will be used:
Arm (1): eHealth PPI for patients during the wait-list, followed by a scheduled treatment as usual for the patients at Lionarons GGZ.
Arm (2): eHealth PPI for patients and loved ones during the wait-list, followed by a scheduled treatment as usual for the patients at Lionarons GGZ.
Arm (3): treatment as usual (TAU): No PPI during the wait-list, followed by a scheduled treatment as usual for the patients at Lionarons GGZ.

Intervention

The eHealth Positive Psychology Intervention (PPI) aims to promote four protective factors, including: self-compassion, positive focus, savouring and optimism. The intervention is considered transdiagnostic, because the underlying treatment mechanism are not tailored to a specific treatment diagnosis. In other words, the intervention can essentially be applied to (almost) all mental disorders.

These four factors are addressed over a period of eight weeks and consist of 9 modules. Each module consists of: an introductory text, a video, additional text in a drop-down menu, one or more exercises and homework assignments. We refer to the research protocol for more information about the intervention.

Study burden and risks

Although formally unknown, there may be small risks related to a transdiagnostic eHealth PPI for patients with various mental health problems, including: (1) the eHealth PPI may unintentionally lead to patients feeling misunderstood because they do not feel that their burden is seen, due to the strong focus on resilience, (2) a potential gap between the patient's knowledge and the required level of knowledge to use eHealth, (3) patients may experience a burden related to the time spent on completing the various questionnaires, (4) other, unforeseen side effects that are currently unknown. Assuming that some of these risks may actually occur during the study, we do not expect them to occur frequently. Measures will be taken to effectively reduce the chance of encountering these potential risks during the study.

In addition, it is possible that mental health problems may worsen during the study. This is especially possible in the control condition. Given previous research findings, this is not expected to happen during the eHealth intervention, but it cannot be ruled out either. Although there will be weekly guidance (except for the control condition), health monitoring will not take

place daily. Therefore, each online module will contain the following disclaimer:
Firstly, online support during this intervention will be provided via e-mail. Your e-mails may not be read and answered daily. Therefore, this form of communication may not be sufficient in emergency situations. If you develop symptoms or the symptoms worsen, you should contact your local GP immediately. A psycho-educational plan will be developed that focuses on guiding patients who need additional mental health support. This psycho-educational plan will inform patients exactly how to seek help from their GP and psychologists.

To limit the second risk, a user-friendly eHealth interface will be developed together with Embloom and Open University. To evaluate important process evaluation markers, the eHealth PPI will be tested in a replicated single case design (RSCD) prior to full implementation in our RCT. In addition, two stakeholder meetings will be organized to further tailor the intervention from the patient perspective. By combining all measures, we aim to tailor the development of the intervention as much as possible to our target group.

To reduce the third risk, a selection of short questionnaires will be used that aim to answer all the research objectives. The total measurement times will be minimized to avoid overburdening the patients. This can also guarantee the validity of the obtained data and reduce the amount of missing data due to patient dropout.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Participants (patients and their loved ones) are at least 18 years old
- Participants are able to speak and read Dutch
- Participating patients have obtained a referral for a treatment in Dutch general of specialized mental healthcare
- Each participating patient has a loved one willing to participate in the study trial. If patients are randomized to the second arm (eHealth PPI for patients and loved ones), these patients and their loved ones can participate together in the eHealth PPI.

Exclusion criteria

- Patients suffering from severe acute suicidality
- Patients diagnosed with a psychotic disorder or complaints
- Patients and loved ones without access to internet

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	428
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-03-2025
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL87751.096.24