ISRCTN16328317 https://doi.org/10.1186/ISRCTN16328317

Pilot study to test a digital health program for the blended therapy of unipolar depression and anxiety disorder in adults

Submission date
25/01/2022

Recruitment status
No longer recruiting

Registration date
26/01/2022

Overall study status
Completed

Last Edited
10/08/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Over the past decade, there has been a growing interest in internet-delivered cognitive behavioral therapy (iCBT) solutions for the treatment of cognitive and psychological disorders. These programs consist of digital interventions based on cognitive behavioral therapy (CBT) that are usually delivered via the internet through a smartphone or computer. Internet-delivered CBT programs provide several advantages, for example, they can be readily accessed when needed and they can drastically increase the functional capacity of the healthcare system. The aim of this study, which is the pilot of ISRCTN11129335 (https://www.isrctn.com/ISRCTN11129335), is to test a digital health program for the combined treatment of unipolar depression and anxiety disorder in adults.

Who can participate?
Patients aged 18 to 65 years old with depression or anxiety disorders receiving cognitive behavioral therapy (CBT) in outpatient clinics

What does the study involve?
Participants will get access to a digital health application (Elona) in addition to their outpatient psychotherapy aiming to support and amplify the therapeutic process. This group of patients will be compared to another group of patients that receives conventional cognitive behavioral therapy and access to the app after their participation in the study. All patients will fill out an online questionnaire at the beginning, middle (after 6 weeks) and end of the 12-week period of their participation. The study will take place in outpatient clinics, including the university outpatient clinic of the HHU Düsseldorf as the main research center.

What are the possible benefits and risks of participating?
Participants could benefit from a better and/or faster recovery in their symptoms, while the negative effects of the smartphone program are relatively small due to the constant weekly face-to-face therapy sessions. It is expected that patients receiving both CBT and the support of the digital health application will report fewer symptoms and/or greater improvement in other areas of their personal life than patients receiving CBT without additional support. As all

patients will be receiving CBT, which is a validated and efficient psychotherapeutic approach, the risks of the intervention are low.

Where is the study run from?
Heinrich-Heine-Universität Düsseldorf (Germany)

When is the study starting and how long is it expected to run for?
April 2021 to September 2022

Who is funding the study?
1. Heinrich-Heine-Universität Düsseldorf (Germany)
2. Elona Health GmbH (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EL-P01DEP

Study information

Scientific Title
Pilot study to evaluate a digital health application for the blended treatment of unipolar depression and anxiety disorder in adults

Study objectives

Primary hypotheses:
P1: Patients receiving blended cognitive-behavioural therapy (bCBT) with Elona experience stronger improvements in depression symptoms (assessed with the BDI-II) compared to patients receiving treatment as usual (TAU) after 6 and 12 weeks of treatment.
P2: Patients receiving bCBT with Elona experience stronger improvements in anxiety symptoms (assessed with the BAI) compared to patients receiving TAU after 6 and 12 weeks of treatment.

Secondary hypotheses:
S1: Patients receiving bCBT with Elona experience stronger improvements in depression symptoms (assessed with the PHQ-9) compared to patients receiving TAU after 12 weeks of treatment.
S2: Patients receiving bCBT with Elona experience stronger improvements in anxiety symptoms (assessed with the GAD-7) compared to patients receiving TAU after 12 weeks of treatment.
S3: Patients receiving bCBT with Elona experience stronger improvements in their quality of life (assessed with the WHOQOL- BREF) compared to patients receiving TAU after 12 weeks of treatment.
S4: Patients receiving bCBT with Elona experience stronger improvements in their work and social adjustment (assessed with the WSAS) compared to patients receiving TAU after 12 weeks of treatment.
S5: Patients receiving bCBT with Elona experience stronger improvements in their self-efficacy (assessed with the SWE) compared to patients receiving TAU after 6/12 weeks of treatment.
S6: Patients receiving bCBT with Elona experience stronger improvements in their mental health literacy (assessed with the MHLS) compared to patients receiving TAU after 6/12 weeks of treatment.
S7: Patients receiving bCBT with Elona show higher adherence (assessed through self- and psychotherapist-report) compared to patients receiving TAU after 6/12 weeks of treatment.
S8: Patients receiving bCBT with Elona report fewer therapy-related negative events compared to patients receiving TAU after 6/12 weeks of treatment.
S9: Patients receiving bCBT with Elona show a stronger working alliance (assessed through self- and psychotherapist-report) compared to patients receiving TAU after 6/12 weeks of treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/01/2022, Heinrich-Heine-University Duesseldorf Ethics Committee (Moorenstrasse 5, Dusseldorf, 40225 , Germany; +49 (0)211 81-19591; Ethikkommission@med.uni-duesseldorf.de), ref: 2021-1470_1

Primary study design
Interventional

Study design
Multi-centre randomized single-blind controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unipolar depression and anxiety disorders

Interventions
Elona is a digital health application that supports patients in outpatient psychotherapy in the treatment of mental illnesses (depression, anxiety/panic disorders, hypochondriacal disorders) through an intelligent delivery of therapeutic content between regular therapy sessions. With Elona, psychotherapists can assign interventions, helpful activities, exercises and psychoeducational resources that provide patients with information and treatment techniques related to their mental illness. Thus, 400 different types of interventions, techniques, exercises, and psychoeducation based on CBT are available beyond the regular therapy session through the Elona smartphone application. The content is based on current and evidence-based therapeutic methods in cognitive behavioral therapy (CBT). By using psychometric questionnaires and exercises, Elona individualizes the content to the needs of the patient. The application is designed to strengthen the active cooperation and participation of patients in outpatient psychotherapy and to integrate therapeutic contents into the daily life of the patient.

To test the effectiveness and safety of Elona an RCT for patients with a clinical diagnosis of depression (including ICD-10: F32.x, F33.x, F34.x) or anxiety disorder (including ICD-10: F40.x, F41.x) based on ICD-10 criteria is planned. The RCT comprises two arms: Participants assigned to the treatment group will get access to the Elona device. The other group will get access to Elona after 12 weeks. All groups will have full access to TAU (weekly face-to-face psychotherapeutic treatment in CBT) over a 12-week period. For the primary and secondary objectives, for each patient group (depression and anxiety) a 2x3 intention-to-treat analyses (pre vs. mid vs. post) design will be used.
Participants assigned to the treatment group are able to work with those as an add-on to TAU.

After agreeing to the informed consent, randomization will take place during enrolment in the electronic data capture system (EDC) via the therapists in an online randomization tool.

Assessments will take place at baseline (T0), mid 6-week treatment (T1) and 12-week after treatment start (T2) as a self-report. Patients' self-report data are collected, including basic demographic questions via the EDC. The questionnaire includes the German version of the Beck Depression Inventory Version 2 (BDI II) (Kühner et al., 2007), the Beck Anxiety Inventory (BAI) (Margraf & Ehlers, 2007), the Penn State Worry Questionnaire (PSWQ) (Glöckner-Rist & Rist, 2006), the Patient Health Questionnaire (PHQ-9) (Spitzer et al., 1999), German Version: PHQ-9 (Löwe et al., 2004), the Generalized Anxiety Disorder 7 (GAD-7) (Löwe et al., 2015) and the brief version of the quality of life scale by the World Health Organization (WHOQOL- BREF) (Angermeyer et al., 2002) to assess medical benefits. Additionally, patients will provide data on patient-relevant and structural improvements measures such as the Work and Social Adjustment Scale (WSAS) (Mundt et al., 2002), German version: ASAS (Heissel et al., 2021), a self-efficacy scale (SWE) (Jerusalem & Schwarzer, 2003), the Negative Effects Questionnaire (NEQ) (Rozental et al., 2019), Working Alliance Inventory - Kurzform (WAI-SR) (Wilmers et al., 2008) and the Mental Health Literacy Scale (MHLS) (O'Connor & Casey, 2015).

Also, patients will further receive four non-standardized 5-point Likert scale items to measure therapy adherence.

Psychotherapists will also provide an objective third-party report on the WAI-SR and patients' therapy adherence.

Intervention Type
Behavioural

Primary outcome(s)

Group 1 (patients with depression):
Depression symptoms measured using the 5-point (Likert Scale) BDI-II online questionnaire at the beginning of the treatment and after 6 and 12 weeks

Group 2 (patients with anxiety):
Anxiety symptoms measured using the 5-point (Likert Scale) BAI online questionnaire at the beginning of the treatment and after 6 and 12 weeks

Key secondary outcome(s)
Groups 1 and 2:
1. Quality of life measured using the 5-point (Likert Scale) WHOQOL- BREF online questionnaire at the beginning of the treatment and after 6 and 12 weeks
2. Work and social adjustment measured using the 9-point (Likert scale) WSAS (ger.: ASAS) online questionnaire at the beginning of the treatment and after 6 and 12 weeks
3. Self-efficacy measured using the 4-point (Likert scale) SWE online questionnaire at the beginning of the treatment and after 6 and 12 weeks
4. Negative effects measured using the 5-point (Likert scale) NEQ online questionnaire at the beginning of the treatment and after 6 and 12 weeks
5. Working alliance measured using the 5-point (Likert scale) WAI-SR online questionnaire at the beginning of the treatment and after 6 and 12 weeks
6. Mental health literacy measured using the 5-point (Likert scale) MHLS online questionnaire at the beginning of the treatment and after 6 and 12 weeks
7. Willingness to comply with homework or interventions, measured using non-standardized items 5-point (Likert Scale) online questionnaire at the beginning of the treatment and after 6 and 12 weeks

Completion date
01/09/2022

Eligibility

Key inclusion criteria
1. All participants must have been diagnosed with one of the following ICD-10 diagnoses:
F32: Depressive episode
F32.0: Mild depressive episode
F32.1: Moderate depressive episode
F32.2: Severe depressive episode without psychotic symptoms
F32.8: Other depressive episodes
F32.9: Depressive episode, unspecified

F33: Recurrent depressive disorder
F33.0: Recurrent depressive disorder, current episode mild
F33.1: Recurrent depressive disorder, current episode moderate
F33.2: Recurrent depressive disorder, current episode severe without psychotic symptoms
F33.8: Other recurrent depressive disorders
F33.9: Recurrent depressive disorder, unspecified

F34: Persistent mood [affective] disorders
F34.0: Cyclothymia

F34.1: Dysthymia
F34.8: Other persistent mood [affective] disorders
F34.9: Persistent mood [affective] disorder, unspecified

F40.0 Agoraphobia
F40.00 Agoraphobia without panic disorder
F40.01 Agoraphobia with panic disorder
F40.1 Social phobias
F40.2 Specific (isolated) phobias
F40.8 Other phobic anxiety disorders
F40.9 Phobic anxiety disorder, unspecified

F41.0 Panic disorder [episodic paroxysmal anxiety]
F41.1 Generalized anxiety disorder
F41.2 Mixed anxiety and depressive disorder
F41.3 Other mixed anxiety disorders
F41.8 Other specified anxiety disorders
F41.9 Anxiety disorder, unspecified

F45.2 Hypochondriacal disorder

2. Participants need to be between the age of 18 and 65 years
3. Participants need to possess sufficient German language skills (in writing and reading)
4. Participants need to possess a smartphone (iOS or Android operating system) with internet access
5. Participants need to provide signed and dated informed consent and are willing to comply with the protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. All participants without the inclusion ICD-10 diagnosis criteria as well as participants with the following ICD-10 diagnoses are excluded:
1.1. F0x.x: Organic, including symptomatic, mental disorders
1.2. F1x.x Mental and behavioural disorders due to psychoactive substance use (except F17.x)

1.3. F2x.x: Schizophrenia, schizotypal and delusional disorders
1.4. F31: Bipolar affective disorder
1.5. F32.3: Severe depressive episode with psychotic symptoms
1.6. F33.3: Recurrent depressive disorder, current episode severe with psychotic symptoms
2. Individuals with acute suicidality (operationalized via BDI-II screening question greater than 1 or first checkup) are excluded from this study first checkup)
3. Participants under the age of 18 years
4. Participants without any access to a smartphone (iOS or Android operating system) with internet access
5. Participants without German language proficiency
If a participant is currently enrolled or is planning to participate in a potentially confounding drug or device trial during the study, enrollment into this study needs to be pre-approved

Date of first enrolment
27/01/2022

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
Germany

Study participating centre
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Sponsor information

Organisation
Heinrich Heine University Düsseldorf

ROR
https://ror.org/024z2rq82

Funder(s)

Funder type
University/education

Funder Name
Heinrich-Heine-Universität Düsseldorf

Alternative Name(s)
Heinrich Heine University Düsseldorf, HHU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

Germany

Funder Name
Elona Health GmbH

Results and Publications

Individual participant data (IPD) sharing plan
Participant level data (anonymised data) is available upon request from Jan Kalde (jan.kalde@hhu.de), there is participant consent for 10 years for other research institutions, but only including bCBT studies in Germany.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.2		26/01/2022	No	No