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A feasibility study to evaluate a digital intervention for treating unipolar depression in adults

Submission date
20/12/2023

Recruitment status
No longer recruiting

Registration date
20/12/2023

Overall study status
Completed

Last Edited
20/02/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Patients in need of psychotherapy typically have to wait a long time to start treatment. Long waiting times contribute to the chronification of mental disorders if no treatment is provided during this time. This highlights the importance of providing patients with adequate treatment during this time so that patients have reduced symptoms, feel supported, stay on the waiting list, and eventually receive the psychotherapy they need. To address this need, the digital intervention 'elona explore' was developed as a digital tool for the treatment of patients with depression, anxiety, or adjustment disorders during the waiting period.
This study aims to evaluate the feasibility and usability of the digital intervention elona explore in addition to treatment-as-usual (TAU) (i.e. waiting list for outpatient psychotherapy) in patients with depression. As part of TAU, patients are not restricted in the use of medical or psychological services that are available as usual care beyond the study participation.

Who can participate?
Patients aged 18 - 65 years and diagnosed with a depressive episode (single episode or recurrent episodes of mild, moderate, or severe depression)

What does the study involve?
Participants will be enrolled in the study after their first psychotherapeutic consultation hour(s) at the investigation sites, which will clarify the indication for psychotherapy. Patients will be diagnosed during the consultation hour(s) by the treating psychotherapist. If the patient cannot be offered an immediate psychotherapy place, they will be referred to the waiting list of the investigation site and invited to the study if they have also been diagnosed as suitable for this study. If regular psychotherapy can be offered, they will not be considered for this study.
If a sufficient number of patients cannot be recruited from the waiting list of the investigation site, further potential participants will be invited to the consultation hour(s) via online and offline advertising. The same diagnostic assessment procedure and recruitment procedure will apply to these participants.
Enrollment will take place after patients have been informed about the study and have signed the informed consent form at the study sites.

Participants will receive access to the elona explore digital intervention in addition to TAU for 10 weeks. They will be asked to complete questionnaires about their symptoms of depression, anxiety, quality of life, social/occupational functioning, perceived self-efficacy, and depression literacy at baseline (week 0), mid-term (week 5), and at the end of the study (week 10). For the clinician-rated questionnaires addressing symptoms of depression and the overall functioning level of the patient, participants will be invited to the study site for a diagnostic assessment at T0, T1, and T2. No procedures other than the assessment will be performed during these visits.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their symptoms of depression and anxiety, quality of life, social/occupational functioning, perceived self-efficacy, and depression literacy. Patients may experience symptom worsening, perceived dependence on the digital intervention, anxiety, or confusion due to potential device malfunction or user error. The level of potential risk is judged to be minimal. Therefore, the expected benefits clearly outweigh the expected risks.

When is the study starting and how long is it expected to run for?
December 2023 to June 2024

Who is funding the study?
Elona Health GmbH (Germany)

Who is the main contact?
Ece Atik, ece@elona.health

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EX-M13DEP-CIP Version 1.1

Study information

Scientific Title
A feasibility and effectiveness trial to evaluate a digital intervention for the treatment of unipolar depression in adults

Study objectives
Effectiveness hypotheses:

Primary hypothesis:
P1: Patients receiving access to elona explore in addition to TAU experience significant improvements in self-rated symptoms of depression (assessed with the Patient Health Questionnaire-9 [PHQ-9]) over 10 weeks of treatment.

Secondary hypotheses:
S1: Patients receiving access to elona explore in addition to TAU experience significant improvements in clinician-rated symptoms of depression (assessed with the Montgomery–Åsberg Depression Rating Scale [MADRS]) over 10 weeks of treatment.
S2: Patients receiving access to elona explore in addition to TAU experience significant improvements in symptoms of generalized anxiety (assessed with the Generalized Anxiety Disorder-7 [GAD-7]) over 10 weeks of treatment.
S3: Patients receiving access to elona explore in addition to TAU experience significant improvements in their quality of life (assessed with the World Health Organization-Brief Quality of Life Scale [WHOQOL-BREF] - Psychological health subscale) over 10 weeks of treatment.
S4: Patients receiving access to elona explore in addition to TAU experience significant improvements in clinician-rated overall functioning level (assessed with the Global Assessment of Functioning [GAF]) over 10 weeks of treatment.
S5: Patients receiving access to elona explore in addition to TAU experience significant improvements in work and social adjustment (assessed with the Work and Social Adjustment Scale [WSAS]) over 10 weeks of treatment.
S6: Patients receiving access to elona explore in addition to TAU experience significant

improvements in their general self-efficacy (assessed with the General Self Efficacy Scale [GSE]) over 10 weeks of treatment.
S7: Patients receiving access to elona explore in addition to TAU experience significant improvements in their depression literacy (assessed with the Depression Literacy Scale [D-Lit]) over 10 weeks of treatment.

Additionally, the proportion of patients who demonstrate a clinically significant improvement in the PHQ-9 will be measured.

For evaluating the primary and secondary objectives of this study, pre-post study design will be used. Within-group t-tests will be used as the primary method of data analysis. Primary and secondary hypotheses will be tested in a fixed sequence procedure (hierarchical testing), where they will be tested in the predefined order until the first non-significant result.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/12/2023, Ethics Committee of University of Göttingen (Goßlerstraße 14, Göttingen, 37073, Germany; +49 (0)551 39 28200; ethikkommission@psych.uni-goettingen.de), ref: Nr. 362

Study design
Non-randomized interventional multicenter trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Treatment of unipolar depression in patients on the waiting list for outpatient psychotherapeutic treatment

Interventions
elona explore is a digital health application that provides patients with mental health disorders (depression, anxiety/panic disorders, OCD, adjustment disorders, and somatoform disorders) with interventions, techniques, helpful activities, exercises, and psychoeducational resources for the period they are on the waiting list for outpatient psychotherapy. By retrieving regular check-ups, elona explore responds individually to patients' mood records and adjusts the content accordingly. The application is intended for independent use by the patient and to assist in the self-management of symptoms of the patient's mental disorder. The treatment elements of elona explore are in line with current recommendations for the psychotherapeutic treatment of common mental disorders.

Participants will be enrolled in the study after their first psychotherapeutic consultation hour(s) at the investigation sites, which will clarify the indication for psychotherapy. Patients will be diagnosed during the consultation hour(s) by the treating psychotherapist. If the patient cannot be offered an immediate psychotherapy place, they will be referred to the waiting list of the investigation site and invited to the study if they have also been diagnosed as suitable for this study. If regular psychotherapy can be offered, they will not be considered for this study.

If a sufficient number of patients cannot be recruited from the waiting list of the investigation site, further potential participants will be invited to the consultation hour(s) via online and offline advertising. The same diagnostic assessment procedure and recruitment procedure will apply to these participants.

Enrollment will take place after patients have been informed about the study and have signed the informed consent form at the study sites.

Participants will receive access to the elona explore digital intervention in addition to TAU for 10 weeks. They will be asked to complete questionnaires about their symptoms of depression, anxiety, quality of life, social/occupational functioning, perceived self-efficacy, and depression literacy at baseline (week 0), mid-term (week 5), and at the end of the study (week 10). For the clinician-rated questionnaires addressing symptoms of depression and the overall functioning level of the patient, participants will be invited to the study site for a diagnostic assessment at T0, T1, and T2. No procedures other than the assessment will be performed during these visits.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
elona explore

Primary outcome(s)
Self-rated symptoms of depression measured with the PHQ-9 at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

Key secondary outcome(s))
Assessments will take place at baseline (T0), 5 weeks after treatment start (T1), and 10 weeks after treatment start (T2):
1. Clinician-rated symptoms of depression measured with the MADRS
2. Self-rated symptoms of generalized anxiety measured with the GAD-7
3. Psychological health measured with the psychological health subscale of the WHOQOL-BREF
4. Clinician-rated overall functioning level of the patient measured with the GAF
5. Work and social maladjustment measured with the WSAS
6. Self-efficacy measured with the GSE
7. Depression literacy measured with the D-Lit

Completion date
25/06/2024

Eligibility

Key inclusion criteria
All subjects must have been diagnosed with one of the following ICD-10 diagnoses:
F32.0: Mild depressive episode
F32.1: Moderate depressive episode
F32.2: Severe depressive episode

F33.0: Recurrent depressive disorder, current episode mild
F33.1: Recurrent depressive disorder, current episode moderate
F33.2: Recurrent depressive disorder, current episode severe

Subjects further need to:
1. Be at least 18 years old
2. Possess sufficient German language skills (in writing and reading)
3. Possess a smartphone (iOS or Android operating system) with internet access
4. Provide signed and dated informed consent and be 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
All subjects without the inclusion ICD-10 diagnosis criteria, as well as subjects with the following ICD-10 diagnoses, are excluded:
F00-F09: Organic, including symptomatic, mental disorders
F10-F19 Mental and behavioural disorders due to psychoactive substance use (except F17.1, F17.2, F17.3)
F20-F29: Schizophrenia, schizotypal and delusional disorders
F30: Manic episode
F31.0, F31.1, F31.2, F31.5, F31.6, F31.8, F31.9: Bipolar disorder current hypomanic or manic episode
F32.3: Severe depressive episode with psychotic symptoms
F33.3: Recurrent depressive disorder, current episode severe with psychotic symptoms

1. Subjects with acute suicidality (assessed via suicidality screening of the mini-DIPS at the initial screening)
2. Subjects who are currently enrolled or are planning to participate in a potentially confounding drug or device trial during the study
3. Subjects who are currently undergoing psychotherapy treatment (except consultation hours)
4. Subjects who intend to discontinue or change the dose of a psychopharmacological medication currently being taken or start a new psychopharmacological treatment in the next 10 weeks
5. Subjects who use another digital health application intended for mental health disorders
6. Subjects under the age of 18 years, subjects without any access to a smartphone (iOS or

Android operating system) with internet access
7. Subjects without German language proficiency

Date of first enrolment
27/12/2023

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
Germany

Study participating centre
Psychotherapie an der Königsallee Dr. Peter Neudeck
Grünstraße 23
Düsseldorf
Germany
40212

Study participating centre
Praxis am Volksgarten Dr. Peter Neudeck
Volksgartenstraße 36
Köln
Germany
50677

Study participating centre
AVT GmbH Akademie für Verhaltenstherapie
Venloer Str 47-53
Köln
Germany
50672

Sponsor information

Organisation
Elona Health GmbH

Funder(s)

Funder type
Industry

Funder Name
Elona Health GmbH

Results and Publications

Individual participant data (IPD) sharing plan
Participant level data (anonymized data) is available upon request from Ece Atik (ece@elona.health).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes