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

**Submission date**
28/03/2025

**Recruitment status**
No longer recruiting

**Registration date**
01/04/2025

**Overall study status**
Completed

**Last Edited**
01/04/2025

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Psychological help is not always readily available when patients need it, leaving many individuals struggling with their mental health without the support they require. The lack of immediate access to psychotherapy can contribute to the worsening of mental health conditions. In response to this challenge, the digital intervention "elona explore" was created as a low-threshold digital tool to offer psychological support, providing patients with immediate resources to manage their mental health and improve their well-being. This study aims to evaluate the efficacy and safety of the digital intervention elona explore in addition to treatment-as-usual (TAU), compared to TAU alone. Within TAU, patients are not restricted in the use of medical or psychological services that are available as usual care.

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) (F32.x or F33.x according to the ICD-10 criteria)

What does the study involve?
Participants will be enrolled in the study after psychotherapeutic consultation hour(s) at the study sites. Patients will be diagnosed during the consultation hour(s), as decided by the psychotherapist in the consultation hour(s), based on the Mini-DIPS.

Potential participants will be invited via online and offline advertising to the consultation hour(s) at the study sites. However, they will not be recruited from existing waiting lists of the study sites. Inclusion and exclusion criteria will be assessed by the participating therapist at the study site, who has received corresponding training on the study procedures.

Enrolment will take place after patients have been informed about the study and have signed the informed consent form at the study sites. After agreeing to take part in the study, participants will be randomized to one of the study conditions (intervention or control). Allocation to the study groups will be stratified according to the severity (mild, moderate, severe depression) of patients' depression (Group 1: F32.0 and F33.0, Group 2: F32.1 and F33.1, Group 3: F32.2 and F33.2) and according to the study site.

Participants assigned to the intervention group (IG) will receive access to the elona explore digital intervention in addition to TAU for 10 weeks, while participants assigned to the control group (CG) will only receive unrestricted access to TAU and will not use elona explore during the same period. CG will also be provided by elona explore application after 10 weeks, i.e., after the end of the study period.

What are the possible benefits and risks of participating?
Participants in the IG may benefit from improvements in their symptoms of depression and anxiety, overall functioning level, quality of life, self-efficacy, depression literacy, and social /occupational functioning, compared to the CG. 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 evaluated 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?
June 2024 to December 2025

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

Who is the main contact?
Prof. Dr. Andre Pittig
andre.pittig@uni-goettingen.de

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Mr Andre Pittig

### ORCID ID
https://orcid.org/0000-0003-3787-9576

### Contact details
Georg-August-Universität Göttingen
Georg-Elias-Müller Institute of Psychology
Department of Translational Psychotherapy
Kurze-Geismar-Str.1
Göttingen
Germany
37073
+49-551-39-29020
andre.pittig@uni-goettingen.de

# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
EX-M14DEP

# Study information

### Scientific Title
A randomized controlled study to evaluate a digital intervention for the treatment of unipolar depression in adults

### Study objectives
Efficacy hypotheses

Primary efficacy hypothesis
P1: There will be a difference in the improvement of depression symptoms (assessed with the PHQ-9, change from baseline) between patients receiving elona explore in addition to TAU and those receiving only TAU after 10 weeks of treatment.

Secondary efficacy hypotheses
S1: There will be a difference in the improvement of therapist-reported symptoms of depression (assessed with the MADRS, change from baseline) between patients receiving elona explore in addition to TAU and those receiving only TAU after 10 weeks of treatment.
S2: There will be a difference in the improvement of the general level of functioning (assessed with the GAF, change from baseline) between patients receiving elona explore in addition to TAU and those receiving only TAU after 10 weeks of treatment.
S3: There will be a difference in the improvement of anxiety symptoms (assessed with the GAD-7, change from baseline) between patients receiving elona explore in addition to TAU and those receiving only TAU after 10 weeks of treatment.
S4: There will be a difference in the improvement of quality of life (measured with the WHOQOL-BREF Psychological health subscale, change from baseline) between patients receiving elona explore in addition to TAU and those receiving only TAU after 10 weeks of treatment. (exploratory)
S5: There will be a difference in the improvement of general self-efficacy (measured with the GSE, change from baseline) between patients receiving elona explore in addition to TAU and those receiving only TAU after 10 weeks of treatment. (exploratory)
S6: There will be a difference in the improvement of depression literacy (measured with the D-Lit-R, change from baseline) between patients receiving elona explore in addition to TAU and those receiving only TAU after 10 weeks of treatment. (exploratory)
S7: There will be a difference in the improvement of work and social adjustment (assessed with the WSAS, change from baseline) between patients receiving elona explore in addition to TAU and those receiving only TAU after 10 weeks of treatment. (exploratory)

Linear mixed models with the intention-to-treat (ITT) data set will be used as the primary method of data analysis. For the missing values, imputation with Jump-to-Reference (J2R) algorithm will be used. In addition, per-protocol (PP) analyses will be performed as an additional sensitivity analysis. Primary and secondary efficacy 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.

Safety analyses
We will compare the number of adverse events and serious adverse events, and the number of patients who have experienced an adverse event or a serious adverse event between those who had access to elona explore in addition to TAU and patients who received TAU alone. Chi² tests will be applied.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 12/02/2025, Georg-August-University Goettingen, Georg-Elias-Müller-Institute of Psychology Ethics Committee (Waldweg 26, Goettingen, 37073, Germany; +49 (0) 551 / 39-28201; ethikkommission@psych.uni-goettingen.de), ref: 412

## Study design
Interventional multicenter randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment, Safety, Efficacy

## Health condition(s) or problem(s) studied
Treatment of unipolar depression as part of treatment as usual

## Interventions
The 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. 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.

To test the efficacy and safety of elona explore, a randomized controlled trial (RCT) with patients with a clinical diagnosis of depression (F32.x or F33.x based on ICD-10 criteria) is planned.

The RCT comprises two arms. Randomization will be carried out using a variable block length approach and will be completed using the randomization function of the electronic data capture (EDC) tool "Climedo". Participants assigned to the intervention group (IG) will receive access to the elona explore digital application in addition to the treatment as usual (TAU) for 10 weeks. Within TAU, patients are not restricted in the use of medical or psychological services that are available as usual care. The control group (CG) will receive only TAU for 10 weeks. The CG will receive access to the elona explore application after the study period. For evaluating the primary and secondary objectives of this study, a 2 (group: IG, CG) x 3 (time: baseline (week 0), 5 weeks, 10 weeks) study design will be used.

## Intervention Type

Device

### Phase
Not Applicable

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

### Primary outcome(s)
Assessments will take place at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2):

Primary efficacy objective
Change of symptoms of depression measured using the Patient Health Questionnaire (PHQ-9)

Safety objective
Adverse events and serious adverse events measured using data collected in case reports

### 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. Change of therapist-reported symptoms of depression measured using the Montgomery Asberg Depression Rating Scale (MADRS) from T0 to T2
2. Change of patients' therapist-rated overall functioning level measured using the Global Assessment of Functioning (GAF) from T0 to T2
3. Change of symptoms of anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7) from T0 to T2
4. Change of quality of life measured using the World Health Organization Quality of Life Brief Version (WHOQOL-BREF) Psychological health subscale from T0 to T2 (exploratory)
5. Change of general self-efficacy measured using the General Self Efficacy Scale (GSE) from T0 to T2 (exploratory)
6. Change of depression literacy measured using the Depression Literacy Scale Revised (D-Lit-R) from T0 to T2 (exploratory)
7. Change of work and social maladjustment measured using the Work and Social Adjustment Scale (WSAS) from T0 to T2 (week 10) (exploratory)

### Completion date
31/12/2025

## 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 between the ages of 18 and 65 years
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
5. 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 individuals without the included ICD-10 diagnoses, as well as individuals with the following comorbid 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

Further exclusion criteria are as follows:
1. Patients who are currently undergoing psychotherapy (at the point of enrollment)
2. Patients who plan to terminate or change the dose of their current medication that was prescribed for a mental health disorder, or those who plan to start taking a prescription medication prescribed for a mental health disorder within the next 10 weeks (a stable dose of medication three months before enrollment in the trial is allowed).
3. Patients who are currently using a digital health application for a mental health disorder (at the point of enrollment)
4. Individuals with acute suicidality (assessed via suicidality screening of the mini-DIPS at the initial screening)
5. Individuals without any access to a smartphone (iOS or Android operating system) with internet access

6. Individuals with insufficient German language proficiency
7. If an individual is currently enrolled or is planning to participate in a potentially confounding drug or device trial during the study, enrollment into this study is not possible.
8. If an individual underwent psychotherapy three months prior to enrolling, study participation is not possible.
9. It should be noted that the influence of concomitant treatments (especially psychotherapy) is intended to be reduced. Therefore, patients should not be recruited from an existing waiting list.

### Date of first enrolment
31/03/2025

### Date of final enrolment
15/10/2025

## 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

## 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

## 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 |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |