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A study to evaluate a digital intervention for treating adjustment disorder in adults

Submission date
14/01/2026

Recruitment status
Recruiting

Registration date
15/01/2026

Overall study status
Ongoing

Last Edited
03/02/2026

Condition category
Mental and Behavioural Disorders

[X] 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 effects 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 over 18 years and diagnosed with adjustment disorders (F43.2 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) by the psychotherapist, based on the Mini-DIPS and the SCID-5 adjustment disorder module.

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). Randomization to the study groups will be stratified according to study sites.

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 with elona explore application after 10 weeks, i.e., after the end of the study period.

Study assessments will be at baseline as part of the initial screening (T0), after 5 weeks (T1), and after 10 weeks (T2) of treatment. Patient-rated outcome measures will be collected through online questionnaires sent to patients by e-mail. Therapist-rated outcome measures will be conducted in on-site interviews with the patient held at T0, T1, and T2.

What are the possible benefits and risks of participating?
Participants in the IG may benefit from improvements in their perceived stress, general level of functioning, self- and therapist-rated symptoms of depression, self-rated symptoms of anxiety, quality of life, overall symptom alleviation, 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.

Where is the study run from?
Georg-August University of Göttingen (Germany)

When is the study starting and how long is it expected to run for?
February 2026 to December 2027

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

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
A randomized controlled study to evaluate a digital intervention for the treatment of adjustment disorders in adults

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/12/2025, Ethics Committee of the Georg Elias Müller Institute for Psychology (Georg-August-Universität Göttingen Georg-Elias-Müller-Institut für Psychologie Goßlerstraße 14, Goettingen, 37073, Germany; +49 551 39 - 21110; ethikkommission@psych.uni-goettingen.de), ref: 464

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Adjustment disorders (F43.2 based on ICD-10 criteria)

Interventions
elona explore is a digital health application that provides patients with mental health disorders (depression, anxiety/panic disorders, OCD, adjustment disorders, burnout 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 adjustment disorder (F43.2 based on ICD-10 criteria) is planned.

The RCT comprises two arms: 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 (see below), 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)
1. Perceived stress level measured using the Perceived Stress Scale-10 (PSS-10) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

Key secondary outcome(s))

1. Therapist-rated overall functioning level of the patient measured using the Global Assessment of Functioning (GAF) score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

2. Symptoms of depression measured using the Patient Health Questionnaire (PHQ-9) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

3. Therapist-reported symptoms of depression measured using the Montgomery-Asberg Depression Rating Scale (MADRS) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

4. Symptoms of anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

5. Quality of life measured using the World Health Organization Well-being index (WHO-5) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

6. Therapist-rated overall symptom level measured using the Clinical Global Impression- Severity (CGI-S) score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

7. Therapist-rated overall symptom improvement measured using the Clinical Global Impression-Improvement (CGI-I) score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

8. Work and social maladjustment measured using the Work and Social Adjustment Scale (WSAS) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

Updated 30/01/2026. Previous key secondary outcomes:
1. Symptoms of anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)
2. Symptoms of depression measured using Patient Health Questionnaire (PHQ-9) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)
3. Therapist-rated overall functioning level of the patient measured using the Global Assessment of Functioning (GAF) score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)
4. Therapist-reported symptoms of depression measured using the Montgomery-Asberg Depression Rating Scale (MADRS) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)
5. Quality of life measured using the World Health Organization Wohlbefindensindex (WHO-5) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)
6. Work and social maladjustment measured using the Work and Social Adjustment Scale (WSAS) total score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)
7. Therapist-rated overall symptom level measured using the Clinical Global Impression-Improvement (CGI-I) score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)
8. Therapist-rated overall symptom improvement measured using the Clinical Global Impression-Severity (CGI-S) score at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

Completion date
15/12/2027

Eligibility

Key inclusion criteria
All subjects must have been diagnosed with the following ICD-10 diagnosis:
F43.2: Adjustment disorders

Subjects further need to:
1. Be over the age of 18 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. Be willing to comply with the protocol

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
All individuals without the included ICD-10 diagnosis, 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 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. 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.
6. If an individual underwent psychotherapy three months prior to enrolling, study participation is not possible.
7. 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
04/02/2026

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
Germany

Sponsor information

Organisation
Elona Health GmbH

Funder(s)

Funder type

Funder Name
Elona Health GmbH

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date