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A randomized controlled study to evaluate a digital intervention for treating adjustment disorders in adults

Submission date
06/07/2023

Recruitment status
Stopped

Registration date
06/07/2023

Overall study status
Stopped

Last Edited
07/03/2025

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 (transition from acute to chronic) 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 created as a digital tool for treatment for patients during the waiting period.
The aim of this study is to evaluate the effectiveness and safety of the digital intervention elona explore in addition to treatment-as-usual (TAU) compared to TAU alone (i.e. waiting list for outpatient psychotherapy). 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 adjustment disorders

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), as decided by the treating psychotherapist on the basis of the Mini-DIPS. 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 (by the treating psychotherapist based on the Mini-DIPS) and recruitment procedure will apply to these participants.
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). Participants assigned to the intervention group (IG) will receive access to the elona explore digital intervention in addition to TAU for a period of 10 weeks, while participants assigned to the control group (CG) will only receive TAU and will not use elona explore during the same time period.

What are the possible benefits and risks of participating?
Participants in the IG may benefit from improvements in their perceived stress, symptoms of depression and anxiety, quality of life, social/occupational functioning, perceived self-efficacy, and mental health literacy 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 judged to be minimal. Therefore, the expected benefits clearly outweigh the expected risks.

Where is the study run from?
Elona Health GmbH (Germany)

When is the study starting and how long is it expected to run for?
February 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)
Scientific

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Additional identifiers

Protocol serial number
EX-M11ADJ-CIP Version 1.1

Study information

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

Study objectives
Effectiveness hypotheses:

Primary hypothesis:
P1: Patients receiving access to elona explore in addition to TAU experience greater improvements in their perceived stress (assessed with the Perceived Stress Scale-10 (PSS-10)) compared to patients receiving TAU over 10 weeks of treatment.

Secondary hypotheses:
S1: Patients receiving access to elona explore in addition to TAU experience greater improvements in symptoms of depression (assessed with the Patient Health Questionnaire-9 (PHQ-9)) compared to patients receiving TAU over 10 weeks of treatment.
S2: Patients receiving access to elona explore in addition to TAU experience greater improvements in symptoms of generalized anxiety (assessed with the Generalized Anxiety Disorder-7 (GAD-7)) compared to patients receiving TAU over 10 weeks of treatment.
S3: Patients receiving access to elona explore in addition to TAU experience greater improvements in their quality of life (assessed with the World Health Organization-Brief Quality of Life Scale (WHOQOL-BREF) - Psychological health subscale) compared to patients receiving TAU over 10 weeks of treatment.
S4: Patients receiving access to elona explore in addition to TAU experience greater improvements in work and social adjustment (assessed with the Work and Social Adjustment Scale (WSAS)) compared to patients receiving TAU over 10 weeks of treatment.
S5: Patients receiving access to elona explore in addition to TAU experience greater improvements in their general self-efficacy (assessed with the General Self Efficacy Scale (GSE)) compared to patients receiving TAU over 10 weeks of treatment.
S6: Patients receiving access to elona explore in addition to TAU experience greater improvements in their mental health literacy (assessed with the Mental Health Literacy Scale (MHLS)) compared to patients receiving TAU over 10 weeks of treatment.

Additionally, the proportion of patients who demonstrate a clinically significant improvement in the PSS-10 will be compared between the two intervention conditions.

Safety hypothesis:
P1: Patients receiving access to elona explore in addition to the TAU do not experience a higher number of or more serious adverse events than TAU.

Mixed linear models with the intention-to-treat (ITT) data set will be used as the primary method of data analysis. For the missing values, multiple imputation will be used. In addition, per-protocol (PP) analyses will be performed as an additional sensitivity 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 16/05/2023, Ethics Committee University of Mannheim (Ethikkommission Schloss, Mannheim, 68161, Germany; N/A; ethik@mail.uni-mannheim.de), ref: EK Mannheim 18/2023

Primary study design
Interventional

Study design
Multicenter interventional randomized controlled trial

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Treatment of adjustment disorders in patients on the waiting list for the 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.

To test the effectiveness and safety of elona explore, a randomized controlled trial (RCT) with patients who are on the waiting list for outpatient psychotherapy with a clinical diagnosis of adjustment disorders (including F43.2 based on ICD-10 criteria) is planned.

The RCT comprises two arms. Randomization will be achieved 1:1. Participants assigned to the 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 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 2 (time: pre, post) 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 effectiveness objective:
Perceived stress measured using PSS-10

Primary safety objective:
Number and seriousness of adverse events measured using patient records

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. Symptoms of depression measured with the PHQ-9
2. Symptoms of generalized anxiety measured with the GAD-7
2. Psychological health measured with the psychological health subscale of the WHOQOL-BREF
3. Work and social maladjustment measured with the WSAS
4. Self-efficacy measured with the GSE
5. Mental health literacy measured with the MHLS

Completion date
30/06/2024

Reason abandoned (if study stopped)
Lack of funding/sponsorship

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 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 under the age of 18, subjects without any access to a smartphone (iOS or Android operating system) with internet access
3. Subjects without German language proficiency

If a subject 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 by the principal investigator.

Date of first enrolment
12/07/2023

Date of final enrolment
30/03/2024

Locations

Countries of recruitment
Germany

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

Study participating centre

Praxis am Volksgarten Dr. Peter Neudeck
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Study participating centre
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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