ISRCTN75863224 https://doi.org/10.1186/ISRCTN75863224

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

Submission date
29/01/2026

Recruitment status
Recruiting

Registration date
02/02/2026

Overall study status
Ongoing

Last Edited
29/01/2026

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 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 over 18 years and diagnosed with burnout

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. 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). Participants assigned to the intervention group will receive access to the elona explore digital intervention in addition to TAU for 10 weeks, while participants assigned to the control group will only receive unrestricted access to TAU and will not use elona explore during the same period. The control group will also be provided with the 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 intervention group 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 control group. 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?
July 2025 to January 2028

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

Who is the main contact?
Anika Meißner, anika.meissner@uni-goettingen.de

Contact information

Type(s)
Public, Scientific

Contact name
Ms Anika Meißner

Contact details
Georg-August University of Göttingen
Georg-Elias-Müller Institute of Psychology
Department of Translational Psychotherapy
Kurze-Geismar-Str.1
Göttingen
Germany
37073
+49 (0)5513929022
anika.meissner@uni-goettingen.de

Type(s)
Principal investigator

Contact name
Prof Andre Pittig

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

Contact details
Georg-August University of Göttingen
Georg-Elias-Müller Institute of Psychology
Kurze-Geismar-Str. 1
Göttingen

Germany
37073
+49 (0)551 39 29020
andre.pittig@uni-goettingen.de

Additional identifiers

Study information

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

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/01/2026, Ethics Committee of the University of Göttingen (Georg Elias Müller Institute for Psychology, Goßlerstraße 14, Göttingen, 37073, Germany; +49 (0)551 39 - 21110; ethikkommission@psych.uni-goettingen.de), ref: 467

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
Burnout

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 burnout (Z73.0 based on ICD-10 criteria) is planned. Burnout diagnosis is based on the presence of the three core dimensions of burnout: (1) exhaustion, (2) depersonalization, and (3) subjective performance reduction, resulting from chronic workplace stress. To exclude other potential disorders, Mini-DIPS and the SCID-5 adjustment disorder module are applied. Randomization to the study groups will be stratified according to study sites. 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".

The RCT comprises two arms: 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 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 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 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 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 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 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 World Health Organization Well being index (WHO-5) at baseline (T0), 5 weeks after treatment start (T1) and 10 weeks after treatment start (T2)

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

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

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

Completion date
15/01/2028

Eligibility

Key inclusion criteria
1. Diagnosed with the following ICD-10 diagnosis: Z73.0: Burnout
2. Over the age of 18 years
3. Sufficient German language skills (in writing and reading)
4. Possess a smartphone (iOS or Android operating system) with internet access
5. Provide signed and dated informed consent
6. 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 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. 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
02/02/2026

Date of final enrolment
30/10/2027

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
Not expected to be made available