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Efficacy of CliMACT, a digital training for mental health promotion in youth with climate change-related distress

Submission date
23/10/2025

Recruitment status
Recruiting

Registration date
28/10/2025

Overall study status
Ongoing

Last Edited
23/10/2025

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
Efforts in mental health research have long focused on the management, care, and long-term outcomes of mental disorders. However, more recently, there has been a shift in focus towards mental health promotion and prevention of mental health conditions. In the light of the real-world threat of climate change, adaptive emotion regulation and the ability to engage in meaningful action are two important pillars to promote mental health. Previous research has demonstrated the feasibility of an Ecological Momentary Intervention (EMI), CliMACT, for young people with climate change-related distress. Evidence on the efficacy of CliMACT from a fully powered randomized controlled trial (RCT) is currently lacking. The CliMACT training is delivered via a smartphone app and 3 face-to-face sessions with a mental health professional. It is designed to support promote mental health and well-being, managing climate change-related distress and foster resilience.

Who can participate?
Adolescents and young adults aged 14-25 years, who experience climate change-related distress and impairment, can participate. Individuals with current diagnosis or treatment of a severe mental illness (psychotic disorders, bipolar disorder, severe major depressive disorder, borderline personality disorder), indications of acute endangerment of self or others, inability to give informed consent, or insufficient German language abilities will be excluded.

What does the study involve?
In this trial, participants will be randomly allocated to the experimental or the control condition, with an equal chance of being assigned to either condition. Participants in the experimental condition will receive the CliMACT training in addition to Care-As-Usual (CAU). This training will consist of three face-to-face sessions provided by a mental health professional and a smartphone application, which is geared towards transfer-ring the training into participants' daily life. Training components are based on principles of compassion-focused therapy and acceptance and commitment therapy.
Participation in the study will require participants to complete a total of three assessments, i.e., first at baseline (i.e., prior to randomization), at post-training (i.e., after the 6-week training

period), and at 3-month follow-up (i.e., 3 months after completing the training). All assessments will involve a period of 6 consecutive days of Ecological Momentary Assessment (EMA), which is a structured diary technique to assess expe-rience and behaviour in daily life, as well as the completion of questionnaires. The assessors of the research team will be blind to treatment allocation (i.e., will not be aware of whether a participant is in the control or experimental condition).

What are the possible benefits and risks of participating?
Based on preliminary findings from a feasibility study, participants in the experimental condition might experience beneficial effects of the training for their mental health. These beneficial effects can not be guaranteed for individual participants. However, this study is important because it aims to improve our under-standing of if and how the CliMACT training can best be used to help youth with climate change-related distress. Smartphone apps for monitoring mood and mental health have been used in research for about 20 years. The use of these technologies has been shown to be feasible in different user groups and no worsening of complaints occurred. The risk of adverse effects or discomfort is very low.

Where is the study run from?
The study is sponsored and run by the Central Institute of Mental Health (Germany).

When is the study starting and how long is it expected to run for?
From November 2025 to May 2027

Who is funding the study?
The ADVANCE project has received funding from the EU Horizon Programme under Grant Agreement No. 101080323

Who is the main contact?
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Additional identifiers

Protocol serial number
2025-659

Study information

Scientific Title
Efficacy of CliMACT, a digital training for mental health promotion in young people with climate change-related distress: a 2-arm, parallel-group randomized controlled trial

Acronym
CliMACT

Study objectives
The current randomized controlled trial aims to:
1. Test the efficacy of the CliMACT training, a hybrid EMI for mental health promotion in youth with climate change-related distress, in addition to public mental health care as usual (CAU), compared with CAU only; the primary hypothesis will be that climate change distress at post-training and 3-month follow-up (primary outcome) will be higher in the experimental condition (CliMACT + CAU) compared with the control condition (CAU only), while controlling for climate change distress at baseline.
2. Examine signals of beneficial effects of the CliMACT training on improving mental well-being, subjective happiness, quality of life (psychological and social domain), climate change impairment, psycho-logical distress, general psychopathology, momentary climate change distress, momentary climate change impairment, and momentary affect (positive, negative) at post-training and 3-month follow-up (secondary outcomes).
3. Examine signals of beneficial effects of the CliMACT training on improving coping, self-efficacy, mindfulness, resilience, psychological inflexibility, self-compassion, pro-environmental behaviour, internalized stigma, and self-stigma of seeking help, momentary self-efficacy, momentary value-based living, momentary emotion regulation, momentary emotional resilience, and momentary pro-environmental behaviour as putative mechanisms at post-training and 3-month follow-up (secondary outcomes).
4. Examine non-specific effective ingredients and mechanisms of change, i.e.

a) the association between working alliance (i. with the mental health professional; ii. with the smartphone app), training frequency, and change between baseline and post-training in coping self-efficacy, mindfulness (nonjudgment, nonreactivity), or psychological inflexibility with climate change related distress at post-training and 3-month follow-up, and
b) mediation of the effect of the CliMACT training on climate change distress at post-training and 3-month follow-up through changes in coping self-efficacy, mindfulness (nonjudgment, nonreactivity), and psychological inflexibility between baseline and post-training, and explore remaining candidate mechanisms in exploratory analyses.
5. Determine the economic costs, cost-effectiveness, and cost-utility of implementing the CliMACT training + CAU compared to CAU only.
6. Explore effects of the CliMACT training among participants with and without marginalized group status.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/10/2025, Ethics Committee II of the Medical Faculty Mannheim, Heidelberg University (Theodor-Kutzer Ufer 1-3, Mannheim, 68167, Germany; +49 (0)62138371770; ethikkommission-II@medma.uni-heidelberg.de), ref: 2025-659

Primary study design
Interventional

Study design
2 arm parallel-group assessor- and analyst-blinded randomized controlled trial

Study type(s)
Efficacy, Quality of life

Health condition(s) or problem(s) studied
Mental health promotion in young people with climate change-related distress.

Interventions
Control condition: CAU
Participants in the control condition will receive care as usual (CAU) broadly defined, which includes access to all standard health care and social services. CAU will include all public mental health care delivered according to local and national service guidelines and protocols by GPs, psychiatrists, clinical psychologists, school psychologists, social workers, psychological counsellors, and other public mental health practitioners available in the catchment areas.

Experimental condition: CliMACT + CAU
The CliMACT (Climate - Mind and ACT) training will be delivered over a 6-week training period and consist of an app-based Ecological Momentary Intervention (EMI), and three sessions with a trained mental health professional with a duration of 45-60 minutes administered on-site or using a certified and encrypted video conferencing system. The EMI is geared towards real-time and real-world transfer of training content, principles, and techniques from face-to-face sessions to individuals' daily lives using a smartphone-based application. The CliMACT training is based on principles of Compassion Focused Therapy (CFT) as well as Acceptance and Commitment Therapy (ACT). The app will include three kinds of delivery schemes for the training components: enhancing, consolidating, and adaptive.

- Enhancing: Participants are introduced to a new component and encouraged to practice the new compassion-focused or value-based-action exercise in order to train emotional resilience or meaningful activities. In weeks 1-3, 2 new CFT-based EMI components are introduced, respectively (total: 6). In week 2, an ACT-based EMI task gets introduced.

- Consolidating: Participants are asked to practice EMI components that have already been introduced as enhancing EMI components on the following days. When all new tasks have been introduced (week 4), participants are encouraged to practice tasks randomly presented. Consolidating EMI components can be completed in response to reminders at self-set times, or on demand.

- Adaptive: Participants' responses to short, daily EMA questionnaires on momentary affect (prompted 4-6 times/day on 5-7 days/week) provide the basis for delivering CFT-based adaptive components tailored to person, moment, and context. These are offered in moments of high negative affect, i.e., when ratings exceed the threshold of an individual's moving average on any negative affect item by >= 0.5 standard deviations. A prerequisite for the use of the moving average is that respondents have responded to at least seven EMA prompts within the past seven days. If this is not the case, a value of >= 4 on any negative affect item serves as threshold for adaptive EMI com-ponents.

- EMA-based monitoring and feedback: Moreover, CliMACT allows young people and mental health professionals to monitor young people's well-being by delivering visual feedback in terms of reported climate change-related events, activities, affect, and completed training components, via the app and a web-based dashboard function.

Intervention Type
Behavioural

Primary outcome(s)
Climate change distress assessed with the mean score of the climate change distress subscale (CCD) of the Climate Change Distress and Impairment scale (CC-DIS, Hepp et al., 2023) at post-training and 3-month follow-up

Key secondary outcome(s)
1. Quality of Life (emotional domain, social domain) is measured using the respective subscales of the World Health Organization Quality of Life (WHO-QoLBref, Whoqol Group, 1998) at baseline, post-training and 3-month follow up assessments
2. Subjective happiness is measured using the Subjective Happiness Scale (SHS, Lyubomirsky & Lepper, 1999) at baseline, , post-training and 3-month follow up assessments
3. Mental Well-being is measured using the Warwick–Edinburgh Mental Well-being Scale (WEMWBS, Tennant et al., 2007) at baseline, post-training and 3-month follow-up
4. Climate Change Impairment (CCI) is measured using the impairment subscale of the Climate Change Distress and Impairment Scale (CC-DIS, Hepp et al., 2023) at baseline , post-training and 3-month follow up assessments
5. General psychological distress is measured using the Core 10 (Barkham et al., 2013) at baseline, post-training and 3-month follow up assessments
6. General psychopathology is measured using the Brief Symptom Inventory (BSI-53, Derogatis, 1992; Franke, 2000) at baseline, post-training and 3-month follow up assessments
7. Momentary affect (positive affect, negative affect) is measured using ecological momentary as-sessment at baseline, post-training, and 4-week follow-up
8. Momentary climate change distress and impairment (CCD and CCI) is measured using

ecological momentary assessment at baseline, post-training, and 4-week follow-up
9. Coping self-efficacy is measured using the Coping self-efficacy scale (CSES – including subscales: problem-solving, stopping unpleasant experience, support from friends and family, Bode, 2022; Chesney et al., 2006) at baseline, post-training, and 3-month follow-up
1. Self-compassion is measured using the Self-Compassion Scale (SCS-D (short form), Hupfeld & Ruffieux, 2011) at baseline, post-training, and 3-month follow-up
2. Mindfulness is measured using the Five Facet Mindfulness Questionnaire (FFMQ – including sub-scales: observing, describing, acting with awareness, nonjudging, nonreactivity, Baer et al., 2008) at baseline, post-training, and 3-month follow-up
3. Psychological inflexibility is measured using the Acceptance and Action Questionnaire (AAQ-II, Bond et al., 2011) at baseline, post-training, and 3-month follow-up
4. Internalized stigma and experiences of discrimination are measured using an adapted version of the Internalized Stigma of Mental Illness-scale (ISMI, Sibitz et al., 2013) and Major Experiences of Discrimination measure total number of experiences (MED, Williams et al., 1997) at baseline, post-training, and 3-month follow-up
5. Resilience is measured using the RS-11 Resilience Scale (Schumacher et al., 2005; Wagnild & Young, 1993) at baseline, post-training, and 3-month follow-up
6. Pro-environmental behaviour (subscales: personal, collective) is measured using an adapted version of the Pro-Environmental Behavior measure (PEB, Stanley et al., 2021) at baseline, post-training, and 3-month follow-up
7. Self-stigma of seeking help is measured using the Self-Stigma of Seeking Help Scale (SSOSH-10, Vogel et al., 2006) at baseline, post-training, and 3-month follow-up
8. Momentary self-efficacy is measured using ecological momentary assessment at baseline post-training, and 3-month follow-up
9. Momentary emotional resilience is measured using ecological momentary assessment at baseline, post-training, and 3-month follow-up
10. Momentary emotional regulation (acceptance, avoidance) is measured using ecological momentary assessment at baseline, post-training, and 3-month follow-up
11. Momentary pro-environmental behavior is measured using ecological momentary assessment at baseline, post-training, and 3-month follow-up
12. Momentary value-based living is measured using ecological momentary assessment at baseline post-training, and 3-month follow-up
13. Resource consumption (costs related to care and service use) will be measured using an adapted version of the Client Service Receipt Inventory (CSRI) QUATRO (Chisholm et al., 2000; Patel et al., 2013) at baseline, post-training, and 3-month follow-up
14. Productivity loss is measured using the Work Productivity and Activity Impairment Questionnaire (WPAI, Reilly et al., 1993) at baseline, post-training, and 3-month follow-up
15. Health-related quality of life will be measured using the EQ-5D-Y (Rabin & Challo, 2001; Wille et al., 2010) at baseline, post-training, and 3-month follow-up
16. Resource use for intervention implementation will be measured continuously throughout the project by both project documentation and a time recording template of project staff, researchers, and implementing partners, who are involved in the implementation of the training.
17. Active ingredients are measured using the Working Alliance Inventory (WAI-SR, Hatcher & Gillaspi, 2006) and Mobile Agnew Relationship Measure (mARM, Berry et al., 2018) at post-training, and CliMACT training component assignment measured during training
18. Training frequency is measured using the number of attended sessions and the number of completed consolidating and adaptive EMI components during the training
19. Participant satisfaction is measured using a debriefing questionnaire (Schick et al., 2021) and the Mobile App Rating Scale (MARS-G, Messner et al., 2020) at post-training
20. Fidelity to intervention protocol is measured using a component checklist and the ACT-Fidelity Measure (ACT-FM, O'Neill et al., 2019) during training
21. Adverse events, as occurring during study participation

22. Adverse trial effects are measured using the ATE measure by Hutton et al. (2015) at post-training
23. Marginalized group status is measured using equity-relevant sociodemographic indicators (first or second generation migrant; ethnicity != White-German; <= 3 on McArthur Scale of subjective social status of the family of origin; education (or current school) lower than university entrance diploma (or lower than grammar school, if still in school) at baseline

Completion date
01/05/2027

Eligibility

Key inclusion criteria
1. Aged between 14 and 25 years
2. Scores of >=3.5 for the Distress subscale AND >=2.3 for the Impairment subscale on the Climate Change Distress and Impairment scale (Hepp et al., 2023)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 Years

Upper age limit
25 Years

Sex
All

Key exclusion criteria
1. Current treatment for or diagnosis of a severe mental illness (F32.2, F32.3, F20, F22-29, F30.x, F60.3)
2. indications of acute endangerment of self and others
3. Not able to give informed consent or in case of minors: no consent by parents/legal guardians
4. Insufficient language abilities in the available languages: German

Date of first enrolment
01/11/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Germany

Study participating centre
Central Institute of Mental Health
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Sponsor information

Organisation
Central Institute of Mental Health

ROR
https://ror.org/01hynnt93

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The data set will be available upon reasonable request from the principal investigator (Ulrich. Reininghaus@zi-mannheim.de), given permission by ethics approval and study publication strategy.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes