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Feasibility of a digital training for mental health promotion in young people with climate change related distress

Submission date
04/11/2024

Recruitment status
No longer recruiting

Registration date
06/11/2024

Overall study status
Completed

Last Edited
18/12/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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 light of the real-world threat of climate change, one priority target population for mental health promotion are youth with climate change-related distress. The aim of this feasibility trial is to establish the feasibility of conducting a confirmatory RCT and delivering CliMACT, a digital training for mental health promotion in youth. The feasibility RCT further aims to explore the initial effects of this training.

The CliMACT training is delivered via a smartphone application and 3 face-to-face sessions with a mental health professional. It is designed to promote mental health and well-being, manage 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) and/or significant reduction of psychosocial functioning, 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 transferring the training into participants' daily life. Training components are based on principles of compassion-focused therapy as well as 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-intervention (i.e., after the 6-week training period), and at 4-week follow-up (i.e., 4 weeks 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 experience and behaviour in daily life. 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?
There are no direct benefits to participants from participating in this study. However, this study is important because it aims to improve our understanding of how the CliMACT training can best be used to help young people 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?
September 2024 to August 2025

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?
1. Prof. Ulrich Reininghaus
ulrich.reininghaus@zi-mannheim.de
2. Dr. Leonie Fleck
Leonie.Fleck@zi-mannheim.de

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Prof Ulrich Reininghaus

ORCID ID
https://orcid.org/0000-0002-9227-5436

Contact details
J5
Mannheim
Germany
68159
+49 62117031931
ulrich.reininghaus@zi-mannheim.de

Type(s)
Public

Contact name
Dr Leonie Fleck

ORCID ID
https://orcid.org/0000-0002-3970-4887

Contact details
J5
Mannheim
Germany
68159
+49 62117032370
leonie.fleck@zi-mannheim.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2024-597

Study information

Scientific Title
Feasibility and initials signals of efficacy of a digital training for mental health promotion in young people with climate change-related distress

Acronym
ADVANCE

Study objectives
The current feasibility trial aims to:
1. Examine the feasibility of the trial methodology (based on recruitment, randomization, retention)
2. Examine the feasibility of delivering the CliMACT intervention (based on participant satisfaction, participant adherence, fidelity to the intervention protocol) and explore its specific and non-specific active ingredients (working alliance towards mental health professional and with smartphone application, CliMACT training components)
3. Examine the feasibility of the measure on cost of care and service use and quality of life for economic evaluation
4. Explore signals of efficacy of the CliMACT intervention on candidate outcomes, i.e., positive mental health (quality of life (including psychological and social domain), happiness, and mental well-being), climate change distress and psychological distress, as well as on momentary affect and momentary climate change distress at post-training and 4-week follow-up
5. Explore signals of effects of the CliMACT intervention on candidate mechanisms of change, namely self-compassion, mindfulness, psychological inflexibility, self-efficacy, resilience,

proenvironmental behaviour, emotion regulation, internalized stigma and experience of discrimination, self-stigma of help-seeking, as well as on momentary emotional resilience, momentary self-efficacy, momentary pro-environmental behaviour, and momentary value attainment at post-training and 4-week follow-up
6. Examine the feasibility of establishing credibility criteria for a priori planned subgroup analyses by exploring the distribution of indicators for equity, and explore effects of the CliMACT intervention among participants with and without marginalized group status

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/09/2024, 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: 2024-597

Study design
Two-arm parallel-group assessor-blinded feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Other

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

Interventions
In a 2-arm, parallel-group, assessor-blinded randomised controlled trial (RCT), service users will be randomly allocated to the CliMACT training in addition to Care-As-Usual (experimental condition) or the control condition of CAU only. 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 EMI consists of three different task delivery schemes and monitoring:
- Enhancing: In the course of the intervention phase, participants are successively introduced to new tasks based on CFT or ACT.
- Consolidating tasks: Tasks that are already known to the participant (i.e., have been practiced as enhancing tasks) will be offered as consolidating tasks, encouraging practice. The offer of available consolidating tasks is therefore extended each week.
- Interactive tasks: Participants' responses to short, daily Ecological Momentary Assessment questionnaires on momentary affect and climate distress provide the basis for delivering interactive tasks tailored to person, moment, and context, e.g., when participants score high on momentary climate distress or negative affect.

- Monitoring: The app offers young people and mental health professionals the ability to monitor their mental health and well-being weekly in terms of events, completed training components, activities, and well-being and their associations via a dashboard function.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment is measured using the monthly recruitment rate in the month of the highest recruitment rate
2. Randomization is measured using the number of participants successfully randomized after successful screening
3. Retention is measured using the percentage of retained participants at post-intervention and 4-week follow-up
4. Feasibility of cost of care measures for economic evaluations is measured using EQ-5D-Y (Rabin & Challo, 2001) and CSRI (Chisholm et al., 2000) at baseline, post-intervention, and 4-week follow-up
5. Satisfaction is measured using a debriefing questionnaire and the Mobile App Rating Scale (MARS-G, Messner et al., 2020) at post-intervention
6. Participant adherence is measured using the number of attended sessions and the number of completed consolidating and interactive EMI tasks during intervention
7. Fidelity to intervention protocol is measured using a component checklist and the ACT-Fidelity Measure (ACT-FM, O'Neill et al., 2019) during intervention
8. Active ingredients are measured using the Working Alliance Inventory (WAI-SR, Hatcher & Gillaspi, 2006), Mobile Agnew Relationship Measure (mARM, Berry et al., 2018), and CliMACT training components at post-intervention and during intervention
9. Mental well-being is measured using the Warwick–Edinburgh Mental Well-being Scale (WEMWBS, Tennant et al., 2007) at baseline, post-intervention, and 4-week follow-up
10. Quality of life, including emotional and social domains, is measured using the World Health Organization Quality of Life (WHO-QoLBref, WHOQOL Group, 1998) at baseline, post-intervention, and 4-week follow-up
11. Subjective happiness is measured using the Subjective Happiness Scale (SHS, Lyubomirsky & Lepper, 1999) at baseline, post-intervention, and 4-week follow-up
12. Climate change distress is measured using the Climate Change Distress and Impairment Scale (CCDIS, Hepp et al., 2023) at baseline, post-intervention, and 4-week follow-up
13. General psychological distress is measured using the Core 10 (Barkham et al., 2013) at baseline, post-intervention, and 4-week follow-up
14. General psychological distress is measured using the Brief Symptom Inventory (BSI-53, Derogatis, 1992) at baseline, post-intervention, and 4-week follow-up
15. Momentary affect is measured using ecological momentary assessment at baseline, post-intervention, and 4-week follow-up
16. Momentary climate change distress is measured using ecological momentary assessment at baseline, post-intervention, and 4-week follow-up
17. Self-efficacy is measured using the General Self-Efficacy Scale (GSE, Schwarzer & Jerusalem, 1995) at baseline, post-intervention, and 4-week follow-up
18. Emotion regulation is measured using the Cognitive Emotion Regulation Questionnaire (CERQ, Garnefski et al., 2002) at baseline, post-intervention, and 4-week follow-up
19. Resilience is measured using the Connor-Davidson Resilience Scale (CD-RISC, Connor & Davidson, 2003) at baseline, post-intervention, and 4-week follow-up
20. Self-compassion is measured using the Self-Compassion Scale (SCS-D, Hupfeld & Ruffieux, 2011) at baseline, post-intervention, and 4-week follow-up

21. Mindfulness is measured using the Five Facet Mindfulness Questionnaire (FFMQ, Baer et al., 2008) at baseline, post-intervention, and 4-week follow-up
22. Psychological inflexibility is measured using the Acceptance and Action Questionnaire (AAQ-II, Bond et al., 2011) at baseline, post-intervention, and 4-week follow-up
23. Internalized stigma and experiences of discrimination are measured using an adapted version of the Internalized Stigma of Mental Illness-Skala (ISMI, Sibitz et al., 2013) and Major Experiences of Discrimination measure (MED, Williams et al., 1997) at baseline, post-intervention, and 4-week follow-up
24. Self-stigma of seeking help is measured using the Self-Stigma of Seeking Help Scale (SSOSH-10, Vogel et al., 2006) at baseline, post-intervention, and 4-week follow-up
25. Pro-environmental behavior is measured using an adapted version of the Pro-Environmental Behavior measure (PEB, Stanley et al., 2021) at baseline, post-intervention, and 4-week follow-up
26. Momentary self-efficacy is measured using ecological momentary assessment at baseline, post-intervention, and 4-week follow-up
27. Momentary emotional resilience is measured using ecological momentary assessment at baseline, post-intervention, and 4-week follow-up
28. Momentary pro-environmental behavior is measured using ecological momentary assessment at baseline, post-intervention, and 4-week follow-up
29. Momentary value attainment is measured using ecological momentary assessment at baseline, post-intervention, and 4-week follow-up
30. Adverse events, as occurring
31. Adverse trial effects are measured using Hutton et al. (2015) at post-intervention
32. Marginalized group status is measured using equity-relevant sociodemographic indicators at baseline

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
25/08/2025

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

Total final enrolment
52

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) AND/OR significant reduction in functioning in the past 30 days (WHODAS 2.0, (WHO, 2010) >=41).
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
15/11/2024

Date of final enrolment
14/05/2025

Locations

Countries of recruitment
Germany

Study participating centre
Central Institute of Mental Health
J 5
Mannheim
Germany
68159

Sponsor information

Organisation
Central Institute of Mental Health

ROR
https://ror.org/01hynnt93

Funder(s)

Funder type
Government

Funder Name
EU Horizon Programme

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?
Protocol article		05/12/2025	18/12/2025	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes