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Mindfulness, acceptance and reflection training by text message - an effectiveness trial investigating stress-reduction in the general population of Sweden

Submission date
29/05/2024

Recruitment status
No longer recruiting

Registration date
30/05/2024

Overall study status
Completed

Last Edited
04/12/2025

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
Psychosocial stress is a major public health concern, contributing to significant suffering and costs to society. There is a lack of effective intervention that could be offered at an early stage to those needing to reduce their stress in life. Recent advances in psychology have provided self-help exercises that are suitable to test as fully digital interventions. This study aims to test a 12-week digital course in mindfulness- and acceptance-based stress reduction and investigate its effectiveness.

Who can participate?
People above the age of 15 years who seek information online about stress and stress reduction

What does the study involve?
Participants will be randomly allocated to receive either daily exercises in mindfulness and acceptance or be directed to self-studies on a webpage with mental health information. Perceived stress and other measures of well-being will be measured before, after 12 weeks, as well as 6 and 12 months after the intervention.

What are the possible benefits and risks of participating?
A risk identified is that participants wait to seek professional help. To address this risk the digital platform will advise participants with symptoms of depression to seek additional help. Participation may, on the other hand, contribute to the acquisition of skills and perspectives that foster resilience and uncover a sense of strength and stability.

Where is the study run from?
H.K.H. Crown Princess Victoria Children's Hospital (Sweden)

When is the study starting and how long is it expected to run for?
February 2024 to November 2025

Who is funding the study?
Swedish Cancer Society

Who is the main contact?
Oskar Lundgren, oskar.lundgren@liu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Oskar Lundgren

ORCID ID
https://orcid.org/0000-0001-7883-3895

Contact details
H.K.H. Crown Princess Victoria Children's Hospital
Linköping
Sweden
58185
+46 (0)101030226
oskar.lundgren@liu.se

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Digital mindfulness, acceptance and reflection training for the general population - the Cultivating Resilience In Stressed People (CRISP) trial

Acronym
CRISP

Study objectives
The 12-week digital course in daily mindfulness and acceptance exercises is effective in reducing perceived stress among stressed people from the general population. Furthermore, improvements in perceived stress are mediated through acquired increases in equanimity.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/05/2024, Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: 2024-01974-01

Study design
Semi-blinded interventional randomized controlled effectiveness trial

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Treatment

Health condition(s) or problem(s) studied
People above the age of 15 years from the general population, who self-identify a need for stress reduction

Interventions
12 weeks of text message delivered mindfulness- and acceptance-based stress-reduction (AiM) vs 12 weeks of mental health self-study (control).

The effectiveness of a 12-week, text message delivered, mindfulness- and acceptance-based stress-reduction course will be investigated in a semi-blinded randomized controlled trial, in which the 12-week course will be compared to self-studies of mental health information. The study population will be people aged above 15 years seeking help online for stress and have access to a mobile phone.

Employing a Bayesian sequential design, the study will continuously monitor the primary outcome to calculate target criteria for when to stop recruiting, allowing for avoidance of both under- and over-recruitment. A measure of perceived stress (Cohen’s 10-item version) will be the primary outcome, and mediation analysis will reveal if improvements are mediated by acquired equanimity. Follow-up measures will be made at 3-, 6- and 12 months. Effectiveness will be analyzed with Bayesian regression models, and mediation will be analyzed by using a causal inference framework.

Randomization will be fully automated and computerized and neither research personnel nor participants will be able to influence allocation. Stratified block randomization (with random block sizes of 2 and 4) will be done based on self-reported history of serious disease during childhood.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 06/08/2025:
Perceived stress is measured using the 10-item version of Cohen's Perceived Stress Scale (PSS) at 3 months, 6 months and 1 year.

Previous primary outcome measure:
Perceived stress is measured using the 10-item version of Cohen's Perceived Stress Scale (PSS) at baseline, 1 month, 3 months, 6 months and 1 year

Key secondary outcome(s))
Current secondary outcome measures as of 06/08/2025:
1. Mental well-being is measured using the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) at 3 months, 6 months and 1 year.
2. Life satisfaction is measured using the 2-item Cantrils Ladder at 3 months, 6 months and 1 year.
3. Anxiety is measured using the General Anxiety Disorder-7 (GAD-7) scale at 3 months, 6 months and 1 year.
4. Depression is measured using the Patient Health Questionnaire-9 (PHQ-9) scale at 3 months, 6 months and 1 year.
5. Equanimity (mediator tested) is measured using the two-factor equanimity scale (EQUA-S) scale at 1 month, 3 months, 6 months and 1 year.

Previous secondary outcome measures:
1. Mental well-being is measured using the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) at baseline, 1 month, 3 months, 6 months and 1 year
2. Life satisfaction is measured using the 2-item Cantrils Ladder at baseline, 1 month, 3 months, 6 months and 1 year
3. Anxiety is measured using the General Anxiety Disorder-7 (GAD-7) scale at baseline, 1 month, 3 months, 6 months and 1 year
4. Depression is measured using the Patient Health Questionnaire-9 (PHQ-9) scale at baseline, 1 month, 3 months, 6 months and 1 year
5. Equanimity (mediator tested) is measured using the two-factor equanimity scale (EQUA-S) scale at baseline, 1 month, 3 months, 6 months and 1 year

Completion date
01/11/2025

Eligibility

Key inclusion criteria
1. People from the general population
2. Above the age of 15 years
3. Access to a mobile phone
4. Language skills (Swedish) to comprehend study information and questionnaires

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/06/2024

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
Sweden

Study participating centre
H.K.H. Crown Princess Victoria Children's Hospital
Universitetssjukhuset
Linköping
Sweden
58185

Sponsor information

Organisation
H.K.H. Crown Princess Victoria Children's Hospital

Funder(s)

Funder type
Charity

Funder Name

Cancerfonden

Alternative Name(s)
Swedish Cancer Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be available upon reasonable request from the study PI Oskar Lundgren (oskar.lundgren@liu.se).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/12/2025	04/12/2025	Yes	No