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The developing core adolescent emotional skills (DECADES) study

Submission date
19/05/2021

Recruitment status
No longer recruiting

Registration date
08/06/2021

Overall study status
Completed

Last Edited
17/01/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are lots of ways in which we can help people improve how they manage their emotions, and that this can impact how they understand their emotions and experiences. We will be investigating how learning specific skills can impact on mental health and wellbeing.

Who can participate?
This study is open to anyone aged 16-19 years, provided that you have access to a smart phone and the internet. Participation also requires that individuals be (1) not participate in a regular yoga and/or mindfulness class/workshop, (2) they not have participated in prior meditation training or a mindfulness-based stress reduction course, (3) are not experiencing chronic illness (e.g. epilepsy, chronic pain, cancer), (4) they lack fluency in English (5) do not have a recent diagnosis of, and are currently receiving medical/psychological treatment for, a mental health condition including (but not limited to) anxiety disorder, major depressive disorder or a traumatic stress disorder and (6) do not have a diagnosis of a neurodevelopmental condition such as Autism Spectrum Disorder or Attention Deficit/Hyperactivity Disorder.

What does the study involve?
The study involves 4 things. (1) Skills Training: You will be given a range of materials (including audio files, videos, and computer tasks) that will help you practice skills relating to understanding your emotions and experiences. You will need to do these each day. Each skills session will last about 10-15 minutes. (2) Short daily surveys: You will have an app downloaded to your phone. The app will ask you to answer certain questions throughout the day, and at the end of the day. (3) Questionnaires: We want to understand the impact that the skills training has on mental health and well-being. For that reason, you will be asked to complete questionnaires exploring your emotions, mood, mental health and well-being. This will involve some questions that are sensitive in nature. You will be asked to do these longer questionnaires about once a week. (4) Computer based tasks: At several points during the study, we will ask you to take part in some computer based tasks that you will be able to access online. These should take about half an hour each time you do them. The study is entirely remote. It is self-guided based on an App and website link that can be accessed using a laptop/PC.

What are the benefits and risks of participating?
None

Where is the study run from?
Medical Research Council - Cognition and Brain Sciences Unit, University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
February 2020 to December 2022

Who is the funder?
This project is funded by Wellcome Trust Strategic Award (co-led by Dr. Tim Dalgleish) (UK)

Who is the main contact?
Ms. Rachel Knight (Rachel.knight@mrc-cbu.cam.ac.uk)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Protocol for a randomized controlled trial investigating an intervention to boost decentering in response to distressing mental experiences during adolescence: The Decentering in Adolescence Study (DECADES)

Acronym
DECADES

Study objectives
This study will answer the following research questions:
1a. Is decentering training during adolescence associated with increased decentering reports relative to an active control condition?
1b. Is decentering training during adolescence associated with increased decentering in response to negative mental events relative to an active control condition?
2a. What is the impact of decentering training on youth mental health relative to an active control condition?

2b. What is the impact of decentering training on emotional reactivity towards momentary negative mental events relative to an active control?
3. What are the cognitive correlates of decentering training during adolescence?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/02/2020, Cambridge Psychology Research Ethics Committee (School of the Biological Sciences, 17 Mill Lane, Cambridge, CB2 1RX, UK; +44(0)1223 766894; Cheryl.Torbett@admin.cam.ac.uk), ref: PRE:2019.109

Study design
Randomized controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
To improve decentering and reduce psychological distress in a sample of young people at risk of depression

Interventions
Decentering training.
A 5-week psychological decentering training programme was developed based on our previous protocol. This involves audio-recorded scripts and an accompanying work book that guides participants through four types of decentering technique; this structure is partly based on a recent taxonomy of self-distancing (a construct closely related to decentering). The decentering techniques include: (Week 1) spatial distancing wherein individuals are taught to re-imagine negative memories from a physically distant perspective (e.g. ‘replay the memory but as if you’re a fly on the wall’); (Week 2) verbal distancing/cognitive defusion wherein individuals are taught to re-phrase negative self-relevant statements in a way that challenges its literal value and influence over affective behavior (e.g. replacing first person pronouns with one’s name); (Week 3) temporal distancing wherein individuals are taught to re-consider specific worries from a temporally distant future (e.g. ‘how would this seem in 5 years?’); and (Week 4) objective distancing wherein individuals are taught to adopt a third-person perspective towards negative memories. Week 5 is a revision week. These techniques were selected since they are directly targeted at how adolescents relate to and observe day-to-day psychological stressors.

Specifically, the goal is to teach adolescents concrete ways to generate an objective (or distanced) self-perspective in response to everyday feelings, thoughts and memories that are unpleasant. We assume this training will develop participants' decentering ability above their baseline levels.

Each week will involve 5 audio-recorded exercises (10-15 minutes) that will be made available using common streaming services. One exercise will be posted each weekday, Monday to Friday. The first two exercises (Monday and Tuesday) are brief mindfulness-based grounding exercises designed to promote open monitoring of psychological experiences and stressors. The next three exercises (Wednesday to Friday) are decentering training exercises as described above. Adherence to the programme will be encouraged by directly contacting the participants in week 1 and week 3 to discuss their experiences so far and allow troubleshooting. Participant engagement will be monitored by reviewing the number of completed workbook exercise at the end of the five weeks. Participants will also complete daily diaries. These will include five questions about the intervention and its application, such as "Did you complete any of the programme exercises today?" or "During the day, were you able to apply the skills you've learned from the exercises?". A participant's engagement in the trial will be discontinued if they elect to withdraw their participation or if they experience serious physical/mental health difficulties that necessitate medical or psychological intervention.

Physical and cognitive exercise.
A five week active control programme was developed as an active control condition. This contains two elements that roughly match the decentering training for time and cognitive engagement. First, guided physical movement routines will be completed in lieu of mindfulness grounding exercises (Monday-Tuesday). These movements are intended to emulate the physiological nature of grounding exercises but without an internal focus. Participants will watch short videos in which one member of the research team illustrates a basic series of body stretches. Accompanying audio provides additional direction and this was recorded using the same voices from the decentering training programme. Each video comprises 15 stretches, with each stretch held for 30 seconds and a 10 second break between stretches. The physical movements were selected for their ease and accessibility. Care was also taken to select movements that are safe and cater to a range of physical abilities.

Second, gamified versions of standard cognitive tasks will be completed in lieu of the decentering training (Wednesday-Friday). These games are intended to emulate the cognitive effort associated with decentering exercises. Each participant will have a link that allows them to select one of three games, which can be completed on a personal smart phone (for game outlines, see https://osf.io/aw6c5). Games include: (1) a Multi-Target Visual Search Task wherein participants search and respond to specific targets within a broader stimulus array; (2) a Go /NoGo Task wherein a speeded response is made in response to a 'go' signal but inhibited in response to a 'no go' signal: and (3) a Digit Recall Task wherein participants must recall a sequence on a number pad (i.e. a digit-span task). Adherence to the programme will be encouraged by contacting the participants in week 1 and week 3 to discuss their experiences. Engagement will be monitored by reviewing task completion rates and performance measures (response times and accuracy) at the end of the five weeks.

Following baseline assessment, participants will be stratified according to sex and depression severity (using the CES-D). They will then be randomly assigned to either the decentering training programme or the active control condition. This will be managed by the trial statistician using a minimization procedure. Participant allocation will be then shared with the research coordinator responsible for providing appropriate access links for the online intervention. Blinding at this stage is not possible as the trial is a psychological intervention.

Intervention Type
Behavioural

Primary outcome measure
Self-rated decentering as measured by the Experiences Questionnaire (EQ) at baseline, mid-intervention, and post-intervention

Secondary outcome measures
1. The situational use of decentering will be examined using Experience Sampling Methods (ESM). Two ESM items have been developed to estimate the momentary use of decentering in response to psychological stressors like difficult feelings, memories, or thoughts. ESM items will be delivered four times daily across a five day ESM baseline period and the five weeks of training.
2. Anxiety will be measured using the Revised Child Anxiety and Depression Scale-Short Version (RCADS-15) at baseline, mid-intervention, and post-intervention.
3. Depression will be measured using the Centre for Epidemiology Depression Scale (CES-D) at baseline, mid-intervention, and post-intervention.
4. Anger will be measured using the State-Trait Anger Expression Inventory-2 Child and Adolescent (STAXI-2) at baseline, mid-intervention, and post-intervention.
5. Psychological wellbeing will be measured using the Warwick Edinburgh Mental Well Being Scale (WEMWBS) at baseline, mid-intervention, and post-intervention
6. Psychosocial strengths/difficulties will be measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline and post-intervention

Overall study start date
03/02/2020

Completion date
23/12/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/12/2021:
1. Older adolescents (aged 16 - 19 years)
2. Access to a laptop/desktop computer and a personal smartphone device
3. Elevated Risk Group: Score of 16 or above on the Centre for Epidemiological Studies - Depression measure.

Previous inclusion criteria:
1. Older adolescents (aged 16 - 19 years)
2. Access to a laptop/desktop computer and a personal smartphone device

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
16 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
Two groups of older adolescents (n = 57 per group; age range = 16–19 years)

Total final enrolment
114

Key exclusion criteria
1. Currently take part in a regular yoga and/or mindfulness class/workshop
2. Have participated in prior meditation training or a mindfulness-based stress reduction course
3. Currently experiencing chronic illness (e.g. epilepsy, chronic pain, cancer)
4. Lack fluency in English
5. Have a recent diagnosis of, and are currently receiving medical/psychological treatment for, a mental health condition including (but not limited to) anxiety disorder, major depressive disorder or a traumatic stress disorder
6. Have a diagnosis of a neurodevelopmental condition such as Autism Spectrum Disorder or Attention Deficit/Hyperactivity Disorder

Date of first enrolment
01/09/2021

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
England

Ireland

United Kingdom

Study participating centre
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Sponsor type
Research council

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Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of this study will be disseminated through typical academic routes including poster /paper presentations at (inter)-national conferences, academic institutes and through publication in peer-reviewed journals. Given that some research questions are less exploratory than others, two key manuscripts are planned for the trial data. The first will describe the impact of training on self-rated decentering and mental health outcomes. The second will describe the exploratory research around the impact on cognitive performance measures. Findings will also be disseminated to the broader public through seminars and workshops with relevant stakeholders as well as online blogs and podcasts. These manuscripts will be completed and submitted for review irrespective of the nature of the observed effects.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Following the publication of the first manuscript, a fully anonymized dataset will be made available online on open-access databases whose servers are located within the UK or Europe. Data processing scripts and programming codes will also be made available online.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/03/2022	07/12/2022	Yes	No
Preprint results		11/12/2023	15/01/2024	No	No
Statistical Analysis Plan	version 2	20/04/2023	15/01/2024	No	No
Basic results		15/01/2024	17/01/2024	No	No