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Healthy Learning Mind

Submission date
05/10/2015

Recruitment status
No longer recruiting

Registration date
13/10/2015

Overall study status
Completed

Last Edited
17/12/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The transition into adulthood is a period of rapid change which can be very stressful. There is a great deal of pressure on teenagers, from teachers, their parents and even their peers. It is thought that many teenagers are not able to cope with stressful situations as well as adults. Becoming overloaded with stress can trigger serious mental health problems such as anxiety or depression. The amount of under-18s with mental health problems is growing, and effective ways of coping with stress could help to keep the situation under control. One of the best ways of dealing with stress is by learning ways to cope with the everyday situations that can be stressful. There are many ways of doing this such as learning to become more aware of yourself and the environment around you (mindfulness) and relaxation techniques so that situations that would normally be stressful are less so. The aim of this study is to find out whether teaching school age children mindfulness or relaxation techniques can improve their well-being and help them learn ways of coping with stress.

Who can participate?
Students in grades 6-8 of participating schools, their parents and teachers.

What does the study involve?
Participating schools are randomly allocated to three groups. Students attending schools in the first group, take part in a nine week mindfulness programme, which has been specially designed to help them to be more aware of their own feelings and what is going on around them. These students are also given mindfulness exercises to practise at home. Students attending schools in the second group take part in a nine week programme called “Relax”, which is designed to teach relaxation skills and emphasising the connection between mind, body and spirit (holistic approach). This programme involves both group sessions and exercises they can do at home. Students attending schools in the third group continue as normal and do not take part in any programmes in the study period. Participants take questionnaires at the start of the study, after 9 weeks, 6 months and 12 months to test their emotional well-being and coping skills (emotional resilience). Parents and teachers of participants also complete questionnaires about any changes in the students.

What are the possible benefits and risks of participating?
Possible benefits are that mindfulness and emotional well-being may improve among participants. There are no risks of participating in the study.

Where is the study run from?
Schools located in southern Finland

When is the study starting and how long is it expected to run for?
January 2014 to May 2016

Who is funding the study?
1. Folkhälsan Research Center (Finland)
2. University of Helsinki (Finland)
3. Signe and Ane Gyllenberg Foundation (Finland)
4. Juho Vainio Foundation (Finland)
5. Mats Brommels Foundation (Sweden)
6. Yrjö Jahnsson Foundation (Finland)

Who is the main contact?
Mrs Salla-Maarit Volanen

Study website
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Cluster-randomized controlled trial on the comparative effectiveness of a school-based mindfulness and relaxation interventions on stress resilience, mental health and well-being among 12-15 year old students

Study objectives
The mindfulness intervention program will better promote stress-resilience, mental health and well-being among participants compared to a standard relaxation program in a school context.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Helsinki Ethical review board, 07/02/2014, ref: 1/2014

Study design
Cluster randomized control study with three study arms

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Quality of life

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
Health promotion

Interventions
Participating schools are randomly allocated to the intervention group, the control group or the non-treatment group:

Intervention group: Participants take part in a nine week mindfulness programme designed for adolescents aged 11-18 years. The programme consists of nine group sessions once a week and mindfulness home practices designed to improve emotional awareness, sustained attention, and attentional and emotional regulation.

Control group: Participants receive a standardised relaxation program called “Relax”. The “Relax” programme aims to produce relaxation skills and holistic wellbeing for the control group attendants. Participants attend nine weekly sessions which are divided in two parts: relaxation exercises and group discussion about different topics e.g. stress, relaxation, smartphones

upsides and downsides, sleep, exercising, food and attitude. Relaxation includes progressive muscle relaxation, a breathing exercise, visualisation, “choose your emotion for rest of the day” and short brake for regaining energy.

Non-treatment group: Participants are not given a programme to attend but are asked to fill out the same questionnaires as participants in the other groups at the same time points (except for the short questionnaire after the fifth lesson). The non-treatment group will receive a shorter well-being course after the one year follow-up has been conducted.

Data is collected at baseline, in the middle of the intervention at the 5th session (a short questionnaire), after the intervention at 9 weeks after baseline, and 6 months after baseline from the same participants (children, their parents and teachers). Additionally, data will be collected from students 12 months after the baseline. Also a linkage to main health (or health related) registers will be done among all participating students who have given their consent for it.

Intervention Type
Behavioural

Primary outcome measure
1. Resilience is measured using the Resilience Scale (RS14) at baseline, 9 weeks, 6 months and 12 months
2. The children’s and adolescents’ mental health was measured with the Finnish version of the Beck Depression Inventory (RBDI) at baseline, 9 weeks, 6 months and 12 months
3. Well-being is measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 9 weeks, 6 months and 12 months

Secondary outcome measures
Pupils:
1. Children’s and adolescents’ cognitive performance and emotions are measured using the following questionnaires at baseline, after the 5th lesson, 9 weeks, 6 months and 12 months:
1.1. Stress in Children (Osika et al. 2007)
1.2. Rumination and Reflection Questionnaire (Trapnell & Campbell 1999)
1.3. Happiness, OECD Better Live Index (level of happiness)
1.4. Satisfaction with life, (SWLC-C, Diener et al., 1985)
1.5. Quality of Life, KINDL-R (Ravens-Sieberer 2001)
1.6. Positive and negative emotions PANAS (Watson et al., 1988)
1.7. Compassion/self-kindness, Compassion Questionnaire (Neff 2003)
1.8. Mindfulness, Child and Adolescent Mindfulness Measure (CAMM, Greco &Baer 2011)
1.9. Personality Inventory TIPI (Gosling et al., 2003)
1.10. Psychological flexibility, The Cognitive Emotion Regulation Questionnaire (CERQ, Garnefski et al., 2007)
1.11. Health behavior, WHO: Health behavior in school-aged children (HSB, king et al., 1996)
2. The psycho-physiological measures are determined by measuring skin conductance response, heart rate and electrocardiography wusing mobile Nexus instruments from the psychology laboratory from a sub set of 160 students at baseline, 9 weeks and 6 months
3. Neuropsychological measures (development and cognitive functioning are measured using NEPSY-II, WISC-IV (Wechsler Intelligence Scale for Children) and D-KEFS (Delis-Kaplan Executive Function System) from a sub set of 160 students at baseline, 9 weeks and 6 months
4. Stress levels are determined using hair cortisol analysis on hair samples collected in spring 2016

Parents:
Parental emotional and conduct problems, attention and social relationships/behavior is measured using the Strengths and Difficulties Questionnaire Parent Form, Executive function /attention questionnaire and the Quality of Life questionnaire at baseline, 9 weeks and 6 months

Teachers:
1. Attention and social relationships/behavior is measured using the Strengths and Difficulties Teacher Form at baseline, 9 weeks and 6 months
2. Classroom environment is measured using the Classroom Environment Scale at baseline, 9 weeks and 6 months

Overall study start date
01/01/2014

Completion date
31/05/2016

Eligibility

Key inclusion criteria
Pupils:
1. Must be enrolled in the recruited schools (in grades 6-8)
2. Must give written consent

Parents/caregivers:
1. Must be parents/caregivers of recruited students
2. Must give written consent

Teachers:
Must be teachers/homeroom teachers of the participating students

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
N=3000

Total final enrolment
3519

Key exclusion criteria
Severe mental health/neurological problems

Date of first enrolment

01/10/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Finland

Study participating centre
Folkhälsan Research Center/University of Helsinki (Dept of Public Health)
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Sponsor information

Organisation
Folkhälsan Research Center/University of Helsinki (Dept of Public Health) (Finland)

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Sponsor type
Research organisation

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ROR
https://ror.org/05xznzw56

Funder(s)

Funder type
University/education

Funder Name
Folkhälsan Research Center

Funder Name
Helsingin Yliopisto

Alternative Name(s)
University of Helsinki, Helsingfors Universitet, Universitas Helsingiensis, HY, UH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Funder Name
Signe ja Ane Gyllenbergin Säätiö

Alternative Name(s)
Signe and Ane Gyllenberg Foundation, Signe och Ane Gyllenbergs Stiftelse

Funding Body Type
Private sector organisation

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

Location
Finland

Funder Name
Juho Vainion Säätiö

Alternative Name(s)
Juho Vainio Foundation, Reppy Institute

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
Finland

Funder Name
Mats Brommels Foundation

Funder Name
Yrjö Jahnssonin Säätiö

Alternative Name(s)
Yrjö Jahnsson Foundation

Funding Body Type
Private sector organisation

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

Location
Finland

Results and Publications

Publication and dissemination plan
Intention to publish the results of the study in a number of research articles.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/07/2016		Yes	No
Results article		01/06/2021	28/06/2021	Yes	No
Results article		14/07/2022	02/08/2022	Yes	No
Results article		15/12/2024	17/12/2024	Yes	No