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Investigating the effectiveness of a universal mental health literacy program on mental well-being in Czech schools

Submission date
25/08/2022

Recruitment status
No longer recruiting

Registration date
26/08/2022

Overall study status
Completed

Last Edited
26/08/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There are no studies to evaluate the benefits of mental health literacy in pre-adolescence when individuals are at increased risk for the onset of mental health problems in the context of Central and Eastern Europe. This study aims to evaluate the effectiveness of a mental health literacy intervention (On My Mind) delivered by trained teachers to students between the ages of 11 and 13 years in Czechia. Four areas of evaluation will be conducted, including: teacher competencies and effectiveness of teacher training course; assessment of implementation process and fidelity; the effect of the intervention on student outcomes, and the cost-effectiveness of the intervention.

Who can participate?
Schools from Plzen or Karlovy Vary in Czechia will be selected at random to participate. These schools include publicly funded schools (municipality or region) where the average 6th-grade classroom size is less than 5 and the primary language of instruction is Czech.

What does the study involve?
This study involves teachers' participation in 24-hour training, ongoing online reflections and supervision, and the implementation of 20 lesson plans within the subject of health education, which students will receive either in grade 6 (2021-2022) or grade 7 (2022-2023).

What are the possible benefits and risks of participating?
There are no large anticipated risks associated with participating in this study, but the themes of mental health, relationship skills, communication, and emotions can lead to confronting or uncomfortable discussions. All students will have a choice to actively participate in activities or discussions, and the student’s teacher has been trained in the curriculum and how to facilitate healthy and safe learning on the topic of mental health, and has access to supervision and resources for professionals in the field of mental health should any student reach out for help. Participating in the program can improve mental health literacy and social and emotional skills, and promote mental well-being and access to help if necessary.

Where is the study run from?
National Institute of Mental Health (Czechia)

When is the study starting and how long is it expected to run for?
January 2020 to October 2023

Who is funding the study?
EEA Grants/Norway Grants (Belgium)

Who is the main contact?
Anna Kagstrom, anna.kagstrom@nudz.cz

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
115/21

Study information

Scientific Title
A mixed methods three-arm multi-cluster randomised controlled trial to investigate the effectiveness of a universal mental health literacy curriculum on teachers' and students' mental health and well-being in Czechia

Acronym
CRCT-MHL-Cz

Study objectives
A structured mental health literacy curriculum will result in better well-being outcomes than generic treatment as usual (TAU) (health education section of the educational framework in Czechia), in terms of:

H1: intervention effect on student outcomes of Universal Mental Health literacy for Adolescents, the Strengths and Difficulties Questionnaire (SDQ; Goodman, 2006), and the World Health Organization - Five Well-Being Index (WHO-5)
H2: the intervention will be cost-effective in comparison to TAU

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/06/2021, Ethics Committee of the National Institute of Mental Health (NIMH, Topolová 748, 250 67 Klecany, Czechia; +420 (0)283 088 312; Martin.Bares@nudz.cz), ref: 115/21

Primary study design
Interventional

Study design
Two-year long mixed methods three-arm multi-cluster randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Mental health and well-being

Interventions
The intervention is delivered at the classroom level. The selection of the schools was conducted in collaboration with the Czech School Inspection (CSI), who randomly selected eligible schools, then cohorts of students to be followed over the course of 2 years (2021-2023). Schools were randomly selected from the national registry of schools, including 75 from each region (Plzen and Karlovo Vary). Selected schools were then randomly assigned to one of the three arms of the randomized controlled trial (RCT): 1) Intervention Arm, 2) Delayed Intervention Arm, or 3) Control Arm. Following randomization at the school level, the number of 6th-grade classrooms in each school was identified based on the national registry and one classroom within each school was selected at random and the classroom teacher was invited to take part in the study. The two intervention arms (1 delayed intervention) receive the mental health literacy intervention ‘On My Mind’ each over the course of 1 school year within the subject 'health education'. Arm A consists of the intervention group receiving On My Mind curriculum within health education in grade 6; Arm B consists of the intervention group receiving the On My Mind curriculum in grade 7; and Arm C is an active control group, receiving normal school provision within the subject ‘health education.’

On My Mind (Czech name: Všech Pět Pohromadě) is a universal program for schools, consisting of a curriculum and a teacher training course and an implementation manual. The curriculum consists of 20 lesson plans based on mental health literacy and social-emotional learning and is designed to be delivered over the course of a school year by trained teachers. The curriculum is designed to meet the developmental needs of 11-13 years old students and is delivered in the form of experiential, educational activities and discussions, with the teacher as a guide and role model for students. On My Mind teaches five main themes: mental health, emotional literacy, relationships, communication, and mental health first aid. The curriculum is intended to be

delivered over the course of a school year with a consistent teacher and class, averaging one lesson plan per week, as the knowledge and skills students learn are built upon in subsequent lessons.

Teacher training and manual:
All On My Mind teachers are provided with comprehensive training and a corresponding manual with necessary theoretical and practical information about delivering the curriculum. The training and manual aim to support successful implementation of the curriculum, including foundational knowledge, skills, and attitudes related to mental health literacy and social and emotional learning, and to provide hands-on practice delivering lesson plan components. The training is delivered over 3 days with 8 hours of content each day totalling 24 hours of training. Training is accredited by the Ministry of Education, Youth and Sports. Teachers are trained by professionals from the field of mental health and well-being covering topics such as mental health and mental health problems, the key role of teachers in the program, principles and theory of mental health literacy and social and emotional learning, self-care tools for the teachers, pedagogical skills important for delivering the curriculum, and theoretical and developmental underpinnings of the themes and activities within the curriculum.

Intervention Type
Behavioural

Primary outcome(s)
Students across all groups will participate in four waves of data collection (Fall 2021; Summer 2022; Fall 2022; Summer 2023) on the outcomes:
1. Mental health literacy measured using the Universal Mental Health Literacy Scale for Adolescents (UMHL-A)
2. Behaviors measured using a brief behavioral screening questionnaire, the Strengths and Difficulties Questionnaire (SDQ)

Key secondary outcome(s)
Students across all groups will participate in four waves of data collection (Fall 2021; Summer 2022; Fall 2022; Summer 2023) on the outcomes:
1. Depressive symptoms assessed using the nine-item Patient Health Questionnaire (PHQ-9)
2. Symptoms of anxiety assessed using the Generalized Anxiety Disorder scale (GAD-7)
3. Well-being assessed using the World Health Organization - Five Well-Being Index (WHO-5)

Completion date
01/10/2023

Eligibility

Key inclusion criteria
School-level criteria for inclusion:
1. Schools from Plzen or Karlovy Vary
2. Publicly funded schools (municipality or region)

Classroom-level criteria:
1. The primary language of instruction is Czech

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
1043

Key exclusion criteria
Since the intervention was delivered within the Czech school educational framework (RVP) for health education as a curriculum, the only stipulation for exclusion was not gaining informed consent from both the student and a parent/guardian.

At the cluster level, exclusion criteria include:
2. No special or practical school
3. The average 6th-grade classroom size <5
4. RVP framework does not include health education in both the 6th and 7th grade

Date of first enrolment
01/06/2021

Date of final enrolment
01/08/2021

Locations

Countries of recruitment
Czech Republic

Study participating centre
National Institute of Mental Health
Topolová 748
Klecany
Czech Republic
250 67

Sponsor information

Organisation
National Institute of Mental Health

ROR
https://ror.org/05xj56w78

Funder(s)

Funder type
Other

Funder Name
EEA Grants/Norway Grants

Alternative Name(s)
European Economic Area Grants, EEA Grants and Norway Grants, EEA and Norway Grants | Brussels, EEA and Norway Grants, The EEA and Norway Grants, Iceland Liechtenstein Norway grant Norway grants

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
Other than the authors no other entities have contractual agreements with regard to access to the final dataset. The datasets generated and/or analysed during the current study are not publicly available due to the ongoing research and the sensitive nature of the data.

IPD sharing plan summary
Not expected to be made available