

Promoting mental wellbeing in schools using mindfulness, relaxation and strategies for safety and wellbeing

Submission date 30/08/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/09/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/08/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The majority of mental health difficulties start before adulthood, and there is evidence to suggest these difficulties may be increasing. Schools are ideally situated to provide support; most young people attend school and there are opportunities for support without attending specialist mental health services. The Department for Education has commissioned the Evidence Based Practice Unit and partners (University of Manchester, the University of Dundee, and London School of Economics) to evaluate the effectiveness of three programmes, Mindfulness, Relaxation and Strategies for Safety and Wellbeing, on mental health and wellbeing outcomes in schools.

Who can participate?

Primary or secondary schools across England are invited to participate, as long as they are willing to attend training in one of the following locations: London, Manchester, Durham, Bristol, Birmingham, or Leeds

What does this study involve?

This study involves pupils being allocated to one of three interventions (Mindfulness, Relaxation and Strategies for Safety and Wellbeing) or continuing with usual provision.

1. Mindfulness: This intervention is based on delivering mindfulness-based skills with a particular emphasis on activities which focus on the mind, the body and the world. It will be delivered by trained schools professionals with daily exercises lasting approximately five minutes from January – April 2019 or 2020 (depending on recruitment wave)
2. Relaxation: This intervention is based on delivering relaxation-based skills, with a particular focus on deep breathing and progressive muscle relaxation techniques. It will be delivered by trained school professionals with daily exercises lasting approximately five minutes from January – April 2019 or 2020 (depending on recruitment wave)
3. Strategies for Safety and Wellbeing: The focus of this programme is on mental health awareness within the context of developing safety behaviours, and identifying and accessing appropriate support networks. It consists of eight consecutive weekly lessons around 45 minutes, which are delivered by a trained school professional.

4. Usual Provision (Control): Schools will continue with usual practice without partaking in one of the above interventions.

What are the benefits or risks of participating?

This will help the government and researchers understand what interventions may help improve mental health and wellbeing in schools. Pupils may experience a decrease in mental health difficulties or increase in wellbeing, however this is not guaranteed. Young people may become aware of their own mental health and wellbeing which could cause discomfort or distress.

What research institutions are involved in the project?

This study is being run by the Evidence-Based Practice Unit, University of Manchester, the University of Dundee, and London School of Economics.

When is the study starting?

Preparation for the trial, including some initial piloting, began in September 2017. The estimated completion date by which findings will be collated and disseminated is June 2021.

Who is funding this study?

This study is being funded by the Department for Education (UK)

Who are the main contacts:

Dr Jessica Deighton, Jessica.deighton@annafreud.org

Dr Abigail Thompson, Abigail.thompson@annafreud.org

Study website

<https://www.annafreud.org/what-we-do/schools-in-mind/our-work-with-schools/education-for-wellbeing-programme/inspire/>

Contact information

Type(s)

Scientific

Contact name

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

EOR/SBU/2017/015

Study information**Scientific Title**

INterventions in Schools for Promoting Mental Wellbeing: Research in Education (INSPIRE)

Acronym

INSPIRE

Study objectives

Current study hypothesis as of 30/08/2019:

1. Young people receiving Mindfulness will report more favourable change in emotional difficulties at three-six and nine-twelve months follow up relative to baseline than those who receive the usual school curriculum
2. Young people receiving Relaxation will report more favourable change in emotional difficulties at three-six and nine-twelve months follow up relative to baseline than those who receive the usual school curriculum
3. Young people receiving Strategies for Safety and Wellbeing will report more favourable change in help seeking at three-six and nine-twelve months follow up relative to baseline than those who receive the usual school curriculum

Previous study hypothesis:

1. Young people receiving Mindfulness will report more favourable change in emotional difficulties at six and twelve months follow up relative to baseline than those who receive the usual school curriculum
2. Young people receiving Relaxation will report more favourable change in emotional difficulties at six and twelve months follow up relative to baseline than those who receive the usual school curriculum

3. Young people receiving Strategies for Safety and Wellbeing will report more favourable change in help seeking at six and twelve months follow up relative to baseline than those who receive the usual school curriculum

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval committee: University College London ethics committee, approval reference number: 6735/009, approval date: 20/02/18

Study design

Interventional multicentre, cluster randomised trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request the participant information sheet

Health condition(s) or problem(s) studied

Mental health and wellbeing

Interventions

Current interventions as of 30/08/2019:

1. Mindfulness-based skills, emphasising the mind, the body and the world, delivered by trained schools professionals through five minute daily exercises from January – April 2019 or 2020 (depending on recruitment wave)
2. Relaxation-based skills, emphasising deep breathing and progressive muscle relaxation techniques, delivered by trained school professionals through five minute daily exercises from January – April 2019 or 2020 (depending on recruitment wave)
3. A mental health awareness programme, emphasising developing safety behaviours and identifying and accessing appropriate support networks, delivered by a trained school professional over eight consecutive, 45 minute weekly lessons.
4. Usual Provision (Control): Schools continue with usual practice without partaking in one of the above interventions.

Previous interventions:

1. Mindfulness-based skills, emphasising the mind, the body and the world, delivered by trained schools professionals through ten minute daily exercises from January – April 2019
2. Relaxation-based skills, emphasising deep breathing and progressive muscle relaxation

techniques, delivered by trained school professionals through ten minute daily exercises from January – April 2019.

3. A mental health awareness programme, emphasising developing safety behaviours and identifying and accessing appropriate support networks, delivered by a trained school professional over eight consecutive, 45 minute weekly lessons.

4. Usual Provision (Control): Schools continue with usual practice without partaking in one of the above interventions.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measures as of 30/08/2019:

Mindfulness and Relaxation Interventions:

1. Emotional difficulties will be measured using the online Short Mood and Feelings questionnaire (Angold, 1995) at baseline, 3-6 months and 9-12 months post intervention

Strategies for Safety and Wellbeing intervention:

1. Intended help seeking will be collected online and measured at baseline, 3-6 months, and 9-12 months post intervention. General Help-Seeking Questionnaire (Wilson et al., 2011)

Previous primary outcome measures:

Mindfulness and Relaxation Interventions:

1. Emotional difficulties will be measured using the online Short Mood and Feelings questionnaire (Angold, 1995) at baseline, 6 months and 12 months post intervention

Strategies for Safety and Wellbeing intervention:

1. Intended help seeking will be collected online and measured at baseline, 6 months, and 12 months post intervention. General Help-Seeking Questionnaire (Wilson et al., 2011)

Secondary outcome measures

Current as of 30/08/2019: Secondary measures will be measured at baseline, 3-6 months and 9-12 months post intervention

Previous: Secondary measures will be measured at baseline, 6 months and 12 months post intervention

Mindfulness and Relaxation intervention:

1. Positive wellbeing will be measured using the Huebner Life Satisfaction Scale (LSS) (Huebner, 1991)

2. Behavioural problems will be measured using the Me & My Feelings questionnaire (Deighton et al., 2013)

3. Support from school staff will be measured using the Student Resilience Survey (SRS) (Sun & Stewart, 2007) - School Connection subscale

4. Quality of life will be measured using the Child Health Utility 9D quality of life measure

5. The support and services received by participants will be measured using the short client service receipt of intervention (adapted for young people)

Strategies for Safety and Wellbeing intervention:

1. Positive wellbeing will be measured using the Huebner Life Satisfaction Scale (LSS) (Huebner, 1991)

2. Emotional difficulties will be measured using the Short Mood and Feelings questionnaire

(SMFQ) (Angold, 1995)

3. Behavioural problems will be measured using the Me & My Feelings questionnaire (Deighton et al., 2013)

4. Support from school staff will be measured using the Student Resilience Survey (SRS) (Sun & Stewart, 2007) - School Connection subscale

5. Mental health first aid Mental Health First Aid Intentions and Behaviours questionnaire (Hart et al., 2016)

6. Quality of life will be measured using the Child Health Utility 9D quality of life measure

7. The support and services received by participants will be measured using the short client service receipt of intervention (adapted for young people)

8. Stigma-related mental health knowledge of secondary school-age participants will be measured using the Mental Health Knowledge Schedule (MAKS) (Evans-Lacko et al., 2010)

9. Reported and intended behavioural discrimination of secondary school-age participants will be measured using the Reported and Intended Behaviour Scale (RIBS) (Evans-Lacko et al., 2011)

10. Attitudes towards mental health Attitudes Toward Mental Illness Questionnaire (Milin, et al., 2016)

Across all interventions:

1. Mental health literacy of teachers Mental Health Literacy and Capacity Survey for Educators questionnaire (Fortier et al, 2017), Teacher mental health literacy questionnaire (Jorm, 1997; Kutcher, 2015)

Overall study start date

01/11/2017

Completion date

31/03/2024

Eligibility

Key inclusion criteria

Primary schools:

1. Willing to deliver an intervention to one or two year four classes, and one or two year five classes

Secondary schools:

1. Willing to deliver an intervention to three year seven classes and three year eight classes

All schools:

Current inclusion criteria as of 30/08/2019:

1. Willing to be allocated to Mindfulness, Relaxation, Strategies for Safety and Wellbeing or continue with usual provision.

2. Willing to allocate five minutes per day for young people to practice mindfulness and relaxation skills for the spring term

3. Willing to allocate eight one hours lessons to deliver the Strategies for Safety and Wellbeing programme over the spring term.

4. Able to attend training in one of locations described above

5. Able to send teachers of delivery groups to training after October half term 2018/2019

6. Sign a MOU, data sharing agreement and provide pupil lists to the research team

Previous inclusion criteria:

1. Willing to be allocated to Mindfulness, Relaxation, Strategies for Safety and Wellbeing or continue with usual provision.
2. Willing to allocate ten minutes per day for young people to practice mindfulness and relaxation skills for the spring term
3. Willing to allocate eight one hours lessons to deliver the Strategies for Safety and Wellbeing programme over the spring term.
4. Within the area of either London, Birmingham and the Midlands, Bristol, Bath and Somerset, Durham and the North East or Manchester
5. Able to send teachers of delivery groups to training after October half term 2018/2019
6. Sign a MOU, data sharing agreement and provide pupil lists to the research team

Pupils:

1. Be in year groups 4, 5, 7 or 8
2. Parental consent and young person assent provided

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

17,600 participants over 224 schools (160 primary and 64 secondary)

Total final enrolment

28504

Key exclusion criteria

Schools:

1. Pupil referral units (PRU)

Date of first enrolment

01/03/2018

Date of final enrolment

31/07/2022

Locations**Countries of recruitment**

England

Scotland

United Kingdom

Study participating centre

Evidence Based Practice Unit (EBPU). University College London and Anna Freud National Centre for Children and Families.

4-8 Rodney Street

London

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Study participating centre

Manchester Institute for Education

Ellen Wilkinson Building, Oxford Road, M13 9PL

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Study participating centre

University of Dundee

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Sponsor information**Organisation**

University College London

Sponsor details

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Sponsor type
University/education

Website
<https://ethics.grad.ucl.ac.uk/index.php>

ROR
<https://ror.org/02jx3x895>

Funder(s)

Funder type
Government

Funder Name
Department for Education

Alternative Name(s)
Department for Education, educationgovuk, DfE

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal.
Report to the Department for Education

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan

We will provide an anonymised dataset with some variables removed if they would cause an individual to be identifiable (such as a looked after child with special educational needs). This will be undertaken with advice from the Department for Education.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/03/2023	27/03/2023	Yes	No