MYRIAD: My Resilience in Adolescence, a study examining the effectiveness and costeffectiveness of a mindfulness training programme in schools compared with normal school provision

Submission date 01/06/2016	Recruitment status No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 03/06/2016	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 14/08/2024	Condition category Mental and Behavioural Disorders	[] Individual participant data

Plain English summary of protocol

Background and study aims:

Adolescence is a time of change and development. Learning skills that build resilience has the potential to help adolescents navigate these challenges during their time at school and build a platform to serve them throughout their lives. Many secondary schools teach emotional health and wellbeing (ability to deal with life's challenges), believing that it can affect the way children learn, behave, and develop into adulthood. The project will compare existing, good quality social emotional learning that is already being taught in schools (known as 'teaching as usual') to a programme of study that is based on mindfulness techniques. The mindfulness programme, called '.b', has been developed by the Mindfulness in Schools Project and is a series of 10 lessons. The lessons are designed to appeal to young people and each one teaches a particular mindfulness skill. Mindfulness is a way of being present to experiences as they happen, rather than worrying about what has happened or might happen in the future. Participating teachers in schools allocated to the mindfulness group will be trained to deliver the programme to pupils. The aim of this study is to determine the impact of the mindfulness programme on the wellbeing of the pupils 1 year after the programme is delivered, but in addition it will look at the impact on teacher wellbeing and stress.

Who can participate?

Mainstream secondary schools in the UK, year 7 and 8 pupils who attend and their teachers.

What does the study involve?

The project will carry out a comparison of social and emotional learning, which is already being taught in schools, with a class-based mindfulness intervention (program). All of the schools participating in the project will carry on with their usual curriculum. However, in half of the participating schools a number of teachers will be trained in mindfulness intervention. Teachers in the mindfulness arm of the project complete a personal 8-week face-to-face mindfulness

course. Each weekly session lasts for around 2 hours and takes place on the school premises after school hours. This is then followed by 4-day mindfulness syllabus training. Teachers are then asked to teach the programme to classes of Year 8 and 9 pupils. Headteachers, teachers and pupils are asked to complete questions about their health and wellbeing at the start of the study and at up to a maximum of four further time points over a period of up to 3 years.

What are the possible benefits and risks of participating? If allocated to the mindfulness intervention group, participating teachers and schools benefit from receiving personal mindfulness training and CPD training. There are no known risks associated with this project.

Where is the study run from? The study is run from the University of Oxford and takes place in 76 secondary schools in England (UK)

When is study starting and how long is it expected to run for? June 2016 to December 2021

Who is funding the study? Wellcome Trust, ref: 104908/Z/14/Z (UK)

Who is the main contact? 1. Dr Kate Tudor (public), kate.tudor@psych.ox.ac.uk 2. Dr Willem Kuyken (scientific), willem.kuyken@psych.ox.ac.uk

Study website http://myriadproject.org/

Contact information

Type(s) Public

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Public

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers

Study information

Scientific Title

A cluster randomised controlled trial of the effectiveness and cost-effectiveness of a mindfulness training programme in schools compared with normal school provision: the MYRIAD trial

Acronym

MYRIAD (MY Resilience In ADolescents)

Study objectives

Current hypothesis as of 31/07/2020:

Mindfulness Training (MT) alongside normal school provision will be more effective and cost effective than normal school provision alone in improving pupils' self-reported risk for depression; social, emotional and behavioural functioning; and wellbeing, at 1 year follow up.

Previous hypothesis:

Mindfulness Training (MT) alongside normal school provision will be more effective and cost effective than normal school provision alone in improving pupils' self-reported risk for depression; social, emotional and behavioural functioning; and wellbeing, at 2 years follow up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Oxford Medical Sciences Inter-divisional Research Ethics Committee (IDREC), 23/05/2016, ref: R45358/RE001

Study design Superiority cluster randomised controlled parallel group trial

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s) School

Study type(s) Prevention

Participant information sheet

Information sheets for schools, teachers, parents and pupils can be found here: http://myriadproject.org/

Health condition(s) or problem(s) studied

Mental wellbeing

Interventions

Randomisation of schools to intervention and control arms ('Teaching as usual') will be stratified and will be carried out by an independent statistician. The following stratification variables will be considered, with final decisions taken once schools have been recruited: School size (large /small), type of school (selective/non-selective, independent/non-independent, mixed/single gender, school quality measure e.g. OFSTED), geographic location (urban/rural and region) and level of deprivation (below or above median of children eligible for free school meals).

'Teaching as Usual' group: Schools will continue to teach their usual scheduled lessons.

Mindfulness Training group: Schools will be trained in the mindfulness (MT) programme to be included in the school curriculum the following school year. The training programme to deliver the MT programme curriculum involves teachers first participating in an 8-week MBCT programme, adapted for the general (non-clinical) population, to support the development of their resilience and mindfulness skills (eight 2 hour sessions per week, with an all-day mindfulness session supported by a digital app to facilitate mindfulness practice during and after the 8 week course). They will then attend a 4-day training workshop to learn how to deliver the MT in schools.

Schools, teachers and pupil will be followed up for 2 years after the pre-intervention measures.

Intervention Type Mixed

Primary outcome measure

1. Risk for depression is measured using Centre for Epidemiologic Studies Depression Scale (CES-D)

2. Socio-emotional and behavioural functioning is measured using Strengths and Difficulties Questionnaire (SDQ - Pupil)

3. Well-being is measured using Warwick-Edinburgh mental well-being scale (WEMWBS)

Primary outcome measures are for pupils only and will be taken at five timepoints: Baseline, preintervention, 3 months post-intervention (or equivalent), 1-year (1 year after pre-intervention) follow-up, and again at 2-year follow-up (2 years after pre-intervention).

Secondary outcome measures

Current secondary outcome measures as of 17/12/2020:

Students:

1. Drug and alcohol use assessed using a measure devised for this study

2. Anxiety is measured using anxiety subscales from the Revised Child Anxiety and Depression Scale (RCADS)

3. Mental health assessed using the Strengths and Difficulties Questionnaire (SDQ-Teacher rated)

4. Student level attainment is measured using information taken from the National Pupil Database (NPD)

5. Self-harm and suicidal ideation assessed using a brief measure designed for the study

6. Mindfulness skills are measured using the Child-Adolescent Mindfulness Measure (CAMM)

7. Health-related quality of life is measured using the Child Health Utility instrument (CHU-9D) and the Child and Adolescent Service Use Schedule (CA-SUS)

Teachers:

1. Well-being is measured using the Maslach Burnout Inventory (MBI Educator survey)

2. Self-efficacy is measured using the Teacher's Self-efficacy Scale (TSS)

3. Classroom mindfulness is measured using the Mindfulness in Teaching Scale

4. Stress is measured using the Perceived Stress Scale (PSS)

5. Depression is measured using the Patient Health Questionnaire (PHQ-9)

6. Anxiety is measured using the Generalised Anxiety Disorder questionnaire (GAD-7)

7. Personal mindfulness is measured using the Five Facet Mindfulness Questionnaire, short form (FFMQ-FS)

Schools:

1. School ecology/climate is measured using sub-scales most relevant to the intervention from the School Climate and Connectedness Survey (SCCS)

2. School level attainment, for example GSCE results, is determined using information taken from the National Pupil Database (NPD)

Study outcomes will be measured at five time points: baseline (school and teacher as well as primary measures for all pupils from Years 7 and 8); pre-intervention;3 months post-intervention (or equivalent); 1-year (1 year after pre-intervention) follow-up; and again at 2-year follow-up (2 years after pre-intervention).

Previous secondary outcome measures as of 03/08/2020:

Students:

1. Students' executive processing is measured using the Behaviour Rating Inventory of Executive Function, self and teacher rated versions (BRIEF2)

2. Drug and alcohol use assessed using a measure devised for this study

3. Anxiety is measured using anxiety subscales from the Revised Child Anxiety and Depression Scale (RCADS)

4. Mental health assessed using the Strengths and Difficulties Questionnaire (SDQ-Teacher rated)

5. Student level attainment is measured using information taken from the National Pupil Database (NPD)

6. Self-harm and suicidal ideation assessed using a brief measure designed for the study

7. Mindfulness skills are measured using the Child-Adolescent Mindfulness Measure (CAMM)

8. Health-related quality of life is measured using the Child Health Utility instrument (CHU-9D) and the Child and Adolescent Service Use Schedule (CA-SUS)

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7. Personal mindfulness is measured using the Five Facet Mindfulness Questionnaire, short form (FFMQ-FS)

Schools:

1. School ecology/climate is measured using sub-scales most relevant to the intervention from the School Climate and Connectedness Survey (SCCS)

2. School level attainment, for example GSCE results, is determined using information taken from the National Pupil Database (NPD)

Study outcomes will be measured at five time points: baseline (school and teacher as well as primary measures for all pupils from Years 7 and 8); pre-intervention;3 months post-intervention (or equivalent); 1-year (1 year after pre-intervention) follow-up; and again at 2-year follow-up (2 years after pre-intervention).

Previous secondary outcome measures:

Students:

1. Students' executive processing is measured using the Behaviour Rating Inventory of Executive Function, self and teacher rated versions (BRIEF)

- 2. Peer relationships are measured using the Resistance to Peer Influence Scale (RPIS)
- 3. Drug and alcohol use

4. Anxiety is measured using anxiety subscales from the Revised Child Anxiety and Depression Scale (RCADS)

- 5. Strengths and Difficulties Questionnaire (SDQ)
- 6. Student level attainment is measured using information taken from the National Pupil Database (NPD)
- 7. Self-harm and suicidal ideation
- 8. Mindfulness skills are measured using the Child-Adolescent Mindfulness Measure (CAMM)
- 9. Health-related quality of life is measured using the Euroqol 5D 5 level (EQ-5D-Y)

Teachers:

- 1. Well-being is measured using the Maslach Burnout Inventory (MBI Educator survey)
- 2. Self-efficacy is measured using the Teacher's Self-efficacy Scale (TSS)
- 3. Classroom mindfulness is measured using the Mindfulness in the Classroom questionnaire
- 4. Stress is measured using the Perceived Stress Scale (PSS)
- 5. Depression is measured using the Patient Health Questionnaire (PHQ-9)
- 6. Anxiety is measured using the Generalised Anxiety Disorder questionnaire (GAD-7)

Schools:

1. School ecology/climate is measured using sub-scales most relevant to the intervention from the School Climate and Connectedness Survey (SCCS)

2. School level attainment, for example GSCE results, is determined using information taken from the National Pupil Database (NPD)

Study outcomes will be measured at five time points: baseline (school and teacher as well as primary measures for all pupils from Years 7 and 8); pre-intervention; three-months post-intervention (or equivalent); one-year (1 year after pre-intervention) follow-up; and again at two-year follow-up (2 years after pre-intervention).

Overall study start date

01/06/2016

Completion date

20/12/2021

Eligibility

Key inclusion criteria

School:

- 1. Able to fulfil SEL/PSHE assessment
- 2. Have pupils in key stage 3
- 3. Are mainstream UK schools
- 4. Have English speaking curriculum
- 5. Have at least 5 teachers that meet criteria for inclusion

6. Be able to timetable into the normal curriculum the mindfulness programme taught by the trained teachers if allocated to training arm of the trial

Teacher:

1. Have Qualified Teacher status (QTS) or 2 years teaching experience

2. Have a permanent contract with the school, or likely to be in the same school for next 3 years 3. Be available to attend an 8 week personal mindfulness course consisting of a 2 hour class each week together with a 'silent day' which is usually on a Saturday and then attend a further course to be trained in the mindfulness programme (4 full days optionally residential) in the current school year

4. Be willing to complete measures for the project

5. Be happy to deliver the mindfulness programme to pupils in school following training

Pupil:

- 1. In year 7 or 8 of school
- 2. Are in a school and a class taking part in the trial
- 3. Has good comprehension of written and spoken English
- 4. In case of needing additional support, has teaching assistant available

Participant type(s)

Healthy volunteer

Age group Mixed

Sex

Both

Target number of participants 76 schools and 5700 pupils

Total final enrolment 8072

Key exclusion criteria

Current exclusion criteria as of 31/07/2020: School: 1. School has current OFSTED rating of 'Inadequate'

- 2. School has no substantive head teacher
- 3. Special educational needs school
- 4. Already implementing a mindfulness programme

Teacher:

1. Be a Newly Qualified Teacher (NQT)

2. Have already completed an 8-week face-to-face mindfulness course or the '.b' training provided by Mindfulness in Schools Project

3. Be currently identified as unsatisfactory in their performance management cycle

Pupil: No exclusion criteria

Previous exclusion criteria: School:

1. School has current OFSTED rating of 'Inadequate'

- 2. School has no substantive head teacher
- 3. Special educational need school

Teacher:

- 1. Be a Newly Qualified Teacher (NQT)
- 2. Have already completed an eight week face to face mindfulness course or the '.b' training provided by Mindfulness in Schools Project
- 3. Be currently identified as unsatisfactory in their performance management cycle

Pupil: No exclusion criteria

Date of first enrolment 06/06/2016

Date of final enrolment

31/12/2018

Locations

Countries of recruitment England

United Kingdom

Study participating centre

University of Oxford Oxford Mindfulness Centre Department of Psychiatry Warneford Hospital Warneford Lane Headington Oxford United Kingdom OX3 7JX

Sponsor information

Organisation University of Oxford (UK)

Sponsor details Clinical Trials and Research Governance Joint Research Office Block 60 Churchill Hospital Old Road Headington Oxford England United Kingdom OX3 7LE

Sponsor type University/education

ROR https://ror.org/052gg0110

Funder(s)

Funder type Charity

Funder Name Wellcome Trust

Alternative Name(s)

Funding Body Type Private sector organisation

Funding Body Subtype International organizations

Results and Publications

Publication and dissemination plan

Data will be analysed and the results of the study will be written up as soon as possible thereafter, with the intention of publishing the outcomes in high quality peer reviewed journals in line with the MYRIAD dissemination policy.

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

Nort provided at registration

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
<u>Protocol</u> article	protocol	26/04 /2017		Yes	No
<u>Protocol file</u>	version V2.0	27/07 /2020	03/08 /2020	No	No
<u>Other</u> publications	baseline data on association between school-level factors and pupils' mental health	04/03 /2021	08/03 /2021	Yes	No
<u>Protocol</u> <u>article</u>	protocol update	07/04 /2021	09/04 /2021	Yes	No
<u>Other</u> publications	Association between depression, pain and suicidality	01/09 /2021	23/06 /2021	Yes	No
<u>Other</u> publications	Secondary analyses	13/07 /2022	13/07 /2022	Yes	No
<u>Other</u> publications	Trial extension following COVID-19 pandemic	13/07 /2022	13/07 /2022	Yes	No
<u>Results</u> article	Effectiveness and cost-effectiveness results	12/07 /2022	13/07 /2022	Yes	No
<u>Results</u> article	Effects on teacher mental health and school climate	12/07 /2022	13/07 /2022	Yes	No
<u>Results</u> article	Students' responsiveness and perspectives	22/05 /2023	30/05 /2023	Yes	No
<u>Other</u> publications		13/12 /2022	14/08 /2024	Yes	No
<u>Other</u> publications	secondary analysis	20/10 /2023	14/08 /2024	Yes	No