

Neuro-cognitive effects of mindfulness training in secondary school pupils

Submission date 25/02/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/03/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/08/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Governmental education policy is trying to improve mental health and awareness by promoting well-being for teaching staff and pupils alike; however, the policy does not include clear advice on which evidence-based interventions (methods) can effectively address these concerns. This study will introduce an age-appropriate mindfulness-based programme (Foundation .b) for secondary school students, in order to find out if this could be a potential solution to the low levels of well-being found within school environments. Research in adults has found that mindfulness practice influences the brain structures that regulate attention and emotion processing, allowing people to use their mental resources more effectively and adopt a positive attitude. This study will extend such research to an adolescent group, where some evidence has already shown mindfulness to help extend attention span. Adolescents are known to still be developing their brain regions important for attention. This makes them an exciting group for potential study. The current experiment aims to find out the links between mindfulness practice and potential markers of attention, emotion processing and emotion regulation in the brain. We will also be looking at links between mindfulness practice and related self-report questionnaires, as well as the health economic benefits of mindfulness training.

Who can participate?

Participating pupils will be volunteers from Year 12 and 13 studying in the participating schools.

What does the study involve?

Two schools are allocated to receive the intervention this year and the two other schools will receive the intervention at the end of the study. Students will be asked to fill out questionnaires at different times during the study. They will also undergo a scan called electroencephalography (EEG) to monitor brain activity. This will take about an hour to complete and will be conducted individually for each pupil in a room provided by the school. These sessions will involve a portable EEG system of two laptops, an amplifier, and EEG cap. Participants will be seated comfortably and fitted with an EEG cap and electrodes. Once the cap is fitted, the scalp under each electrode will be gently cleaned with alcohol, and electrolyte gel (containing abrasive sterile sand) will be applied to the electrode site to ensure good conductivity. The scalp site will be scrubbed gently with disposable cotton buds to enhance contact. The gel, which contains sodium, water and a gentle abrasive, is chloride free and non-allergenic, but in very rare cases

can cause slight skin abrasions or reddening of the scalp for participants with sensitive skin. Experimenters will be careful to ask participants about their comfort level, and to reassure participants to mention something if the cap set-up becomes uncomfortable. As testing is occurring within the school, standard hair washing procedures cannot apply but participants will be requested to not wear any hair products and if possible to wash their hair on the morning of testing. School shower facilities are available for anyone who would like to wash their hair after completing EEG testing, but a wet towel and disposable hair brush will also be provided. Two electrodes are placed above and below the left eye to record eye movements. Participants will also undergo a paced-breathing exercise (3 minutes). Heart rate will be calculated using computer software.

What are the possible benefits and risks of participating?

Each school is receiving free teacher training in a mindfulness curriculum (up to six places per school), which would otherwise cost around £700 per teacher. This is a valuable course that the schools can continue to include in their curriculums once the project is over. The intervention schools already have access to these teacher courses, and the control schools will have access to the courses once the project is completed. In terms of benefits to the pupils themselves, both intervention and control participants are gaining first-hand experience of modern psychological testing methods. Talks are also being given for all students on the neuroscience of mindfulness in November 2013 and May 2014. This should provide students with an insight into current psychological methods and theories, a chance to learn more about what PhD research entails, and an opportunity for pupils to ask general questions about post-graduate life and learning.

Where is the study run from?

The participating schools are in Wales, UK:

Training Arm - Ysgol Friars and Bryn Elan

Control Arm - Ysgol John Bright and Eirias High School.

When is study starting and how long is it expected to run for?

November 2013 to November 2014

Who is funding the study?

Bangor University (UK)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NA

Study information

Scientific Title

Neuro-cognitive effects of mindfulness training in secondary school pupils: a non-randomised controlled trial

Study objectives

That a mindfulness training programme for adolescents will improve markers of attention, emotion processing, psychophysiological regulation, well-being and mindfulness, while also being cost-effective within the context of school-based interventions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Bangor University Ethics Committee, Ref: 2013-11284-A10082 Amendment to Neuro-cognitive effects of mindfulness training in secondary school pupils

Study design

Feasibility pilot study with waiting-list control group

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

School

Study type(s)

Quality of life

Participant information sheet

ERP Study Information Sheet and Debrief Form
Questionnaire Study Information Sheet and Debrief Form

Health condition(s) or problem(s) studied

6th form adolescents in secondary school education

Interventions

The mindfulness course is the .b Foundation program, which has been designed by the Mindfulness in School Project (MiSP) research group. It is a school-taught course that our intervention classes will learn over nine 50-minute sessions, taught by their normal PSHE teachers. There will also be the optional session covering issues of Neuroscience and Mindfulness, which can be taught by the project Principal Investigator (PI). This additional session would take place after the Easter school break, and hence after post-training data collection.

Two schools have been allocated to receive the intervention this year (Ysgol Friars and Ysgol Bryn Elan) and two matched schools function as the control group with no intervention (Eirias High School and Ysgol John Bright). The control schools will receive training in the intervention at the end of the study period.

Three time points for data collection: pre-training baseline (01/2014), post-training (04/2014), and follow-up (09/2014).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Five Facet Mindfulness Questionnaire (FFMQ; Baer, Smith, Hopkins, Krietemeyer & Toney, 2006)

2. Computer tasks:

The attention task will follow an oddball paradigm with four simple shapes. Participants will be directed to respond (press the spacebar) when the target shape (a blue-coloured diamond, 10% of items) appears on screen. The distracter oddballs (10%) will include another diamond but white in colour, and a novel star shape. The frequent condition (70%) is a larger blue-coloured diamond. There will be three blocks, and in-between blocks participants will be asked to self-report their mind wandering behaviour using a measure designed for the trial (attached with supporting documents). The task takes around 13 minutes to complete. The emotion processing task also using the oddball paradigm, displays emotional faces from the Karolinska database (Lundqvist et al., 1998). The target stimuli to be responded to using the spacebar will be happy (12.5% of items) and sad (12.5% of items) faces, while the frequent condition will be repetitions of one male and one female neutral face. This task can be completed in around 10-minutes.

The measures are all being taken at baseline, post-training (2-months), and follow-up (8-months).

Secondary outcome measures

1. Perceived Stress Scale (PSS; Cohen, Kamarck & Mermelstein, 1983)

2. Toronto Empathy Questionnaire (TEQ; Spreng, McKinnon, Mar, & Levine, 2009)

3. Meta-cognitions Questionnaire - Adolescent Version (MCQ-A; Cartwright-Hatton et al., 2004)

4. The World Health Organisation, Well-Being Index 5-item version (WHO-5; Bech, Gudex, & Johansen, 1996)
5. General Health Questionnaire 12-item version (GHQ-12; Goldberg & Williams, 1988)
6. EQ-5D-5L (EQ-5D; EuroQol Group, 2008)
7. Time Spent in Mindfulness Practice questionnaire (for training group only, designed for the study)
8. Acceptability questionnaire (for training group only, designed for the study)

The measures are all being taken at baseline, post-training (2-months), and follow-up (8-months).

Overall study start date

07/01/2014

Completion date

01/11/2014

Eligibility

Key inclusion criteria

1. The participant must be enrolled in 6th Form from one of the four schools included in this project
2. Training group participants must be enrolled in their schools mindfulness course starting end of January 2014
3. The participant must be able to give informed consent

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

80 (ERP), 100 (Questionnaires)

Total final enrolment

87

Key exclusion criteria

1. If they do not speak English or Welsh
2. Current neurological problems, psychiatric problems, and current use of medication that could influence performance, would all exclude participants from participation in ERP testing

Date of first enrolment

07/01/2014

Date of final enrolment

01/11/2014

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Bangor University

Bangor

United Kingdom

LL57 2AS

Sponsor information

Organisation

Centre for Mindfulness Research and Practice (UK)

Sponsor details

in School of Psychology, Bangor University

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Sponsor type

Research organisation

ROR

<https://ror.org/006jb1a24>

Funder(s)

Funder type

University/education

Funder Name

Bangor University (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016	07/08/2019	Yes	No