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# Promoting mental health and well-being in schools: examining mindfulness, relaxation and strategies for safety and well-being in English primary and secondary schools—study protocol for a multi-school, cluster randomised controlled trial (INSPIRE)

Trials

UPDATE

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# Promoting mental health and well-being in schools: examining mindfulness, relaxation and strategies for safety and well-being in English primary and secondary schools—study protocol for a multi-school, cluster randomised controlled trial (INSPIRE)

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## Abstract

There are increasing rates of internalising difficulties, particularly anxiety and depression, being reported in children and young people in England. School-based universal prevention programmes are thought to be one way of helping tackle such difficulties. This paper describes an update to a four-arm cluster randomised controlled trial (http://www.isrctn.com/ISRCTN16386254), investigating the effectiveness of three different interventions when compared to usual provision, in English primary and secondary pupils. Due to the COVID-19 pandemic, the trial was put on hold and subsequently prolonged. Data collection will now run until 2024. The key changes to the trial outlined here include clarification of the inclusion and exclusion criteria, an amended timeline reflecting changes to the recruitment period of the trial due to the COVID-19 pandemic and clarification of the data that will be included in the statistical analysis, since the second wave of the trial was disrupted due to COVID-19.

**Trial registration** ISRCTN Registry ISRCTN16386254. Registered on 30 August 2018.

**Keywords** Adolescent, Young person, Children, Cluster randomised controlled trial, Mental health, Well-being, School-based

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## Introduction

This paper describes an update to a four-arm cluster randomised controlled trial (http://www.isrctn.com/ISRCTN16386254) [1], investigating the effectiveness of three different interventions when compared to usual provision, in English primary and secondary pupils. Due to the COVID-19 pandemic, the trial was put on hold and subsequently prolonged. Data collection will run until 2024.

## Inclusion/exclusion criteria

In addition to the original inclusion criteria for schools [1], schools are only eligible for participation in the trial if they sign a Memorandum of Understanding, data sharing agreement, and provide pupil lists to the research team. These criteria have been added to provide more clarity because they were already included in the process but had not been explicitly stated in the inclusion/exclusion criteria, so it was deemed necessary to be explicit that these steps are requirements.

## Timeline

Recruitment of schools for wave 1 opened in March 2018 and closed in September 2018. Schools recruited in wave 1 completed the baseline assessment in September to October 2018 (time 1), delivered the intervention from January to March 2019 and completed the follow-up assessment in May 2019 (3–6 months time point, time 2) and January to March 2020 (9–12 months time point, time 3).

Recruitment of schools for wave 2 opened in February 2019 and closed in June 2019. Schools recruited in wave 2 completed the baseline assessment in September to October 2019 (time 1) and delivered the intervention from January to the end of March 2020, with follow-up assessments due in May to June 2020 (time 2) and January to March 2021 (time 3). Due to the start of the COVID-19 pandemic in the UK in March 2020, delivery of the interventions could not be finalised, and the follow-up assessments due in May to June 2020 (time 2) could not be conducted (including the primary outcome). The follow-up assessment in January to March 2021 (time 3) was collected.

To achieve the required sample size, recruitment recommenced in January 2022 and closed in September 2022 (wave 3). Recruitment of schools for wave 3 opened in February 2022 and closed in September 2022. These schools will complete the baseline assessments in September to October 2022 (time 1), deliver the intervention from January to March 2023 and complete the follow-up assessments in May 2023 (time 2) and January to March 2024 (time 3). See the Supplementary material for an updated timeline.

Due to the challenges around data collection created by the COVID-19 pandemic, the following data will be available at the end of the trial:

- Wave 1: baseline (time 1), post-intervention (time 2) and 1-year follow-up (time 3)
- Wave 2: baseline (time 1) and 1-year follow-up (time 3)
- Wave 3: baseline (time 1), post-intervention (time 2) and 1-year follow-up (time 3)

## Statistical analysis of the primary outcome

As the primary outcomes for all trials remain unchanged and are measured at 3–6 months follow-up (time 2), only wave 1 and wave 3 data will be used for the primary outcome analysis. The original protocol proposed to estimate three mixed models, each comparing an active treatment with the control arm. We would like to clarify that these will be conducted separately for primary and secondary schools. These two contexts are significantly different in terms of the developmental stage of the children and also the educational setting, so it is deemed preferable to analyse them separately. The analytic strategy set out in the original protocol remains unchanged, with mixed models allowing for school-level clustering, control for baseline levels in the primary outcome and the minimisation variables. As outlined in the original protocol, the statistical power of the strategy allows for minimally detectable effect sizes (MDES) of MDES = .186 in primary and MDES = .173 in secondary schools. We will conduct sensitivity analyses to test for the differences between waves. As stated in the original protocol, a detailed statistical analysis plan will be written prospectively and made publicly available.

### Roles and responsibilities

As this is an ongoing trial, there have been various people undertaking similar roles at different stages, outlined below. JD is the principal investigator. NH is the implementation lead. DH was the trials manager for waves 1 and 2. AT is the trials manager for wave 3. AL supported in between trial managers. JS was the data manager for waves 1 and 2, with ongoing support for wave 3. ET is the data manager for wave 3. ES is the qualitative lead. AM was the research officer/school liaison lead for waves 1 and 2, with ongoing support for wave 3. KN is the research officer/school liaison lead for wave 3. RM and EA were research assistants. JB is the trials statistician. PP provides expertise in measures and statistical analysis. BM provides expertise in evaluating

mindfulness practices. EB was the health economist for waves 1 and 2. SL is the health economist for wave 3.

**Abbreviations**

| | |
|---|---|
| AEs | Adverse events |
| DMC | Data monitoring committee |
| GDPR | General Data Protection Regulation |
| MDES | Minimally detectable effect sizes |
| SAEs | Serious adverse events |
| UCL | University College London |

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-023-07238-8.

**Additional file 1.**

**Authors' contributions**

NH, EA, RM and ES led the decisions for the process and implementation strand of the project. EB led the decisions for the economic strand of the project and contributed to the writing of this section of the protocol. SL led the decisions for the economic strand for wave 3. JB led the statistical and study design elements of the project. PP led the measures and their psychometric properties as well as mediation and moderation analysis. JS led the decisions relating to data management for waves 1 and 2. ET led the decisions relating to data management for wave 3. DH, supported by AM, led the decisions relating to trial management for waves 1 and 2. AT, supported by KN, led the decisions relating to trial management for wave 3. DH also led the ethical procedures for waves 1 and 2 and contributed to the writing of this section of the protocol. AT led the ethical procedures for wave 3. BM provided input and expertise into mindfulness practices and measures. KN checked for consistency across waves. JD is the principal investigator, conceptualised the overall trial design and has the final decision sign-off. A measures group consisting of PP, JD, DH, AM, NH, EA, RM, JS, EB and JB finalised the measures for the trial. AL wrote this update which AT finalised. The authors read and approved the final manuscript. A Wider Advisory Group consisting of DH, PP, NH and PS provided ongoing advice.

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This research was commissioned and funded by the Department for Education. The department selected the interventions to be trialled and also chairs an advisory group the researchers report to regarding the progress and quality of the research. However, the department had no role in the design of this study and will not have any role in the analyses, interpretation of the data or decision to submit results. The views expressed are those of the authors and not necessarily those of the Department for Education. JD was (in part) supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North Thames at Bart's Health NHS Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

**Availability of data and materials**

An anonymised quantitative dataset generated and/or analysed during the current study will be available in 2024 once the study has finished. A decision regarding storage location is yet to be finalised. Please contact the principal investigator or trials manager for further information.

## Declarations

**Ethics approval and consent to participate**

Ethics approval for this study was granted by the University College London (UCL) Research Ethics Committee (6735/009 and 6735/014). Research data will be processed and stored in line with the General Data Protection Regulation (GDPR). Schools that express an interest in taking part and are deemed eligible will be required to have a member of their senior leadership team sign a Memorandum of Understanding and data sharing agreement.

*Pupil data*: Consent for pupils to take part will require different processing depending on the data being collected. For outcome (effectiveness) data, opt-out consent will be used when sending letters to parents/carers of pupils who have been selected by schools to take part. Parents/carers who wish to opt out their children will be asked to return an opt-out form to the research team. A survey password will not be created for pupils that are opted out, and this is flagged to schools in a timely manner to prevent these pupils from taking part in the surveys. GDPR-compliant data deletion processes will be enforced when pupils are opted out after taking part in the surveys.

Pupils whose parents have not opted out of the evaluation will be given the option to assent to take part through reading an online information sheet and ticking an online assent form. Pupils that start the survey can stop and/or opt out at any time. Pupils that do not tick the assent form will not be allowed to complete the survey. All information sheets outline confidentiality procedures for collecting, processing and storing data. Teachers are asked not to look directly at pupils' screens when they are filling out answers. They are also provided with a crib sheet of the more difficult words in the survey that young people may struggle with, in order for them to assist pupils from the front of the classroom.

*Other survey data*: Opt-in consent will be required for all other data, including all surveys completed by staff.

*Qualitative data*: Opt-in consent will be required for all interviews and focus groups. All individuals will be required to read an information sheet, detailing what will happen, and for those that are happy to proceed, to sign a consent form.

For pupils under the age of 16, schools will send letters home to pupils' parents/guardians, and those that are happy for their young people to take part will be required to sign a consent form. Prior to focus groups taking place, pupils will be required to read an information sheet and tick an assent form stating that they are happy to take part. Those who do not assent will not take part.

*Observations*: As no individual or personal data will be collected for observations, consent/assent will not be required.

Monitoring of adverse events: Adverse events (AEs), defined as a negative, emotional and behavioural occurrence, or sustained deterioration in a research participant, will be captured as part of the study. This includes serious adverse events (SAEs) which are a threat to life: suicidal ideation, suicidal intent, hospitalisation due to psychiatric of use of substances and death including suicide. Other adverse events: violent behaviour, self-harm or any other event that an individual feels it is important to report, will also be captured. School safeguarding leads will judge whether they believe the AE is likely related to the intervention.

The ongoing conduct and progress of this study are monitored by an independently chaired Data monitoring committee (DMC). On becoming aware of SAEs, the chief investigator/trials manager will report all SAEs, or AEs which are likely to be related to the intervention or research, to the DMC within two working days. AEs thought to be unlikely related to the intervention or research should be reported within five working days and will be collated and reported quarterly to the DMC. The UCL Research Ethics Committee will also be informed of AEs and SAEs using the same mechanisms. School and research safeguarding protocols will be followed as standard in addition to the reporting and documenting of AEs. The DMC is responsible for making recommendations to the Department for Education regarding the stopping or continuing of the trial.

Trial sponsor: The trial is sponsored by University College London.

**Competing interests**

The authors declare that they have no competing interests.

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## Publisher's Note