Protocol for the Mindful Student Study: A randomised controlled trial of the provision of a mindfulness intervention to support university students' wellbeing and resilience to stress

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ABSTRACT

Introduction: Levels of stress in UK University students are high, with an increase in the proportion of students seeking help in recent years. Academic pressure is reported as a major trigger. Mindfulness training has been shown to reduce stress and is popular among students, but its effectiveness in this context needs to be ascertained. In this pragmatic randomised controlled trial we hypothesise that the provision of a preventative mindfulness intervention in universities could reduce students' psychological distress during the exam period (primary outcome), improve their resilience to stress up to at least one year later, reduce their use of mental health support services, and improve academic performance.

Methods and analysis: At least 550 University of Cambridge students free from active crises or severe mental illness will be randomised to joining an eight-week mindfulness course or to mental health provision as usual (one-to-one allocation rate). Psychological distress will be measured using the Clinical Outcomes in Routine Evaluation Outcome Measure at baseline, post-intervention, exam term, and one-year follow-up. Other outcomes are use of mental health services, inability to sit exams or special circumstance requests, exam grades, wellbeing, altruism, and coping measured with ecological momentary assessment.

Outcome assessment and intention-to-treat primary analysis using linear mixed models adjusted for baseline scores will be blind to intervention allocation. We will also conduct per-protocol, sub-group, and secondary outcome analyses. An Independent Data Monitoring and Ethics Committee will be set up. We will systematically monitor for, and react to, possible adverse events. An advisory reference group will comprise student representatives, members of the University Counselling Service, and other student welfare staff.

Ethics and dissemination: Approval has been obtained from Cambridge Psychology Research Ethics Committee (PRE.2015.060). Results will be published in peer-reviewed journals. A lay summary will be disseminated to a wider audience including other universities.

Registration: ACTRN12615001160527.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- One of the largest randomised controlled trials assessing mindfulness interventions and the largest involving students, to date
- A pragmatic design evaluating the provision of a service, intended to inform university student welfare policies in the global context of massively increasing participation in higher education
- Interdisciplinary team and horizontal co-production of research question and study design between researchers and stakeholders
- Study design assesses the effectiveness of mindfulness (i.e. whether it produces the expected results under 'real world' settings), but does not test its efficacy (i.e. whether mindfulness produces the expected results under ideal circumstances, such as perfect course attendance), or determine its specific effects

ADMINISTRATIVE INFORMATION

Twenty elements of the WHO Trial Registration Data Set:

Main

Register:	ANZCTR
Main ID:	ACTRN12615001160527
Date of registration:	30/10/2015
Primary sponsor:	University of Cambridge
Public title:	Mindful Student Study: An evaluation of the provision of mindfulness training to support university students' wellbeing and resilience to stress
Scientific title:	A randomised controlled evaluation of the provision of mindfulness training to support university students' wellbeing and resilience to stress
Date of first enrolment:	28/09/2015
Target sample size:	550
Recruitment status:	Active, not recruiting
URL:	http://www.anzctr.org.au/ACTRN12615001160527.aspx
Study type:	Interventional
Study design:	Randomised controlled trial Parallel
Phase:	Not Applicable

Countries of recruitment

United Kingdom

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Key inclusion & exclusion criteria

Inclusion criteria:
(a) Undergraduate and graduate University of Cambridge students;
(b) Who consider they can realistically attend at least seven sessions of the course (courses timetables will be available for potential participants to assess availability).

Exclusion criteria:
(a) Currently suffering from severe periods of anxiety or depression;
(b) Experiencing severe mental illness such as hypomania or psychotic episodes;

(c) Following recent bereavement or major loss;
(d) Experiencing any other serious mental or physical health issue that would impact on their ability to engage with the course.

Age minimum: 18 Years
Age maximum:
Gender: Both males and females

Health Condition(s) or Problem(s) studied

Academic performance

Psychological distress

Use of mental health services

Wellbeing

Intervention(s)

The delivery of a mindfulness course called 'Mindfulness Skills for Students', a secular, manualised, group-based skills training programme based on the course book 'Mindfulness: A Practical Guide to Finding Peace in a Frantic World', by Mark Williams and Danny Penman, and adapted for university students. The course is free but students need to buy the course book.
The sessions last for 90 minutes for the first session, and 75 minutes for the remaining sessions. There are eight weekly sessions. The sessions are run by Dr Elizabeth English, a certified Mindfulness trainer with over 30 years' experience of practising and teaching meditation. The sessions include two mindfulness meditations, the first embedding the meditation that the students have practised at home throughout the week; the second, introducing them to the new meditation that they will practice at home in the coming week. There are also periods of reflection and inquiry, helping the students to understand the nature of mindfulness, to deepen their learning and embed it into their everyday lives. A few simple models are used and developed throughout the course, to give the students some theoretical understanding of the points developed experientially. Each session also includes interactive exercises, so that the students share their experience and get to know each other throughout the course, building a sense of safety and community. Before and after each class, students receive an email from the Mindfulness teacher. This reminds them of the themes covered in the previous class, and lets them know the topics coming up in the next class. These emails also include handy tips, poems and video clips. There is also a course handout available in hard copy at each class, which describes the home practice for the coming week (this handout is also available as a download in the post class email, and the home practice is also described in the course book.) The home practice time varies through the course, starting at eight minutes, and increasing to about 15-25 minutes per week, plus ongoing reflection through the day. More practice is possible for those who want it, and students are encouraged not to miss a day, and therefore to consider doing less on days when they are very busy, rather than missing the practice altogether. The home practice includes meditations from the CD by Mark Williams, as described in the course book above. Other mindfulness practices are recommended by the authors of the course book, such as a mindful walk, mindful eating, habit breakers, and so on.
Seven courses are offered to students each term, two terms a year (Michaelmas, which runs from October to December, and Lent, which runs from January to March). Courses are not offered during the exam period (Easter term, which runs from April to June).
The following process measures will assess how the course is being delivered: (a) Registering attendance to mindfulness courses and asking why sessions were missed; (b) Asking students about their compliance with their mindfulness homework.

Primary Outcome(s)

Psychological distress with CORE-OM

Secondary Outcome(s)

Exam grades (data linkage)

Helping behaviour (donations)

Interference with academic life: special circumstances requests for exams, intermissions, deferments and degrading (data linkage)

Mental health services use during exam period (single question)

Perceived impact of students' problems on their academic performance (bespoke questionnaire)

Physical activity and sleep patterns (sensor-assisted data collection)

Stress and coping level (ecological momentary assessment)

Use of the University Counselling Service (data linkage)

Wellbeing with Warwick-Edinburgh Mental Wellbeing Scale

Secondary ID(s)

None

Source(s) of Monetary Support

Collaboration for Leadership in Applied Health Research & Care (CLAHRC) East of England

University Counselling Service, University of Cambridge

Vice-Chancellor’s Endowment Fund, University of Cambridge

Secondary Sponsor(s)

Geraldine Dufour

Julieta Galante

Peter B Jones

INTRODUCTION

Background and rationale

University students show elevated levels of stress. Although mental illness rates among first year students appear to be lower than those of the general population, they surpass general population rates when undergraduates get to their second year [1]. Students report academic pressure as the biggest trigger of their mental health problems [2]. University counselling services in the UK have noted the constant increase in the proportion of students seeking help in recent years [3 4]. At the University of Cambridge, 8.5% of the students required access to counselling in 2014. An effective preventative intervention is needed to help students cope better with academic life and develop resilience.

Mindfulness interventions have been shown to reduce stress and prevent depression in clinical and non-clinical populations [5 6]. Secular mindfulness training involves paying attention to the present moment on purpose and non-judgmentally [7]. It is popular among students and increasingly used to support them in the UK [8]. However, there is little evidence on the effectiveness of offering mindfulness training to this population or of any adverse effects. Previous randomised trials assessing mindfulness for supporting university students generally suffer from small sample sizes, lack of follow-up, low methodological quality, and poor reporting [9]. The largest good-quality study randomised 288 medical and psychology Norwegian students to Mindfulness-based Stress Reduction or a waitlist and found moderate post-intervention effects on psychological distress and subjective well-being [10]. A recent systematic review which meta-analysed nine randomised and non-randomised studies found that mindfulness significantly reduced anxiety among university students (d = 0.73; 95% CI 1.00 to 0.45) [11]. A good-quality and adequately powered randomised evaluation including the wider spectrum of university students is needed to confirm previous findings, extend the follow-up period and provide a more complete view of the potential impact (positive and negative) of the provision of mindfulness training on university student life. The University of Cambridge Vice-Chancellor's Endowment Fund is supporting such evaluation for use by services, funders and policy makers, as well as to inform the University's own decisions about the provision of mindfulness for students.

Objectives

The proposed study aims to evaluate whether the provision of a mindfulness course to higher education students:

- Helps them to manage stress during the examination period
- Improves their mental wellbeing and resilience to stress up to one year later
- Reduces their use of mental health treatment and support services
- Improves their engagement with student life, including their academic performance

Our main hypothesis is that the provision of mindfulness training will reduce students' psychological distress during the exam period in comparison with students who have not been offered this provision.

Trial design

The study will be a pragmatic randomised controlled evaluation with two parallel arms and a one-to-one allocation rate testing the superiority of mindfulness training provision to no provision. University of Cambridge students will be randomised to joining a mindfulness course during the term they are starting plus mental health provision as usual (PAU), or to PAU alone. PAU comprises access

to individual counsellors, mental health advisors and psychiatrists at the University of Cambridge Counselling Service (UCS), as well as access to welfare staff in the University colleges (this provision varies across colleges, but can include: college nurse, counsellor, welfare officer or tutor) and NHS services. Those allocated to PAU alone will be offered a mindfulness course one year later, providing they are still students at the University.

The mindfulness intervention was offered for two terms before study commencement; this allowed the intervention to become established before evaluating it, and provided feasibility and acceptability data. The present proposal is partly based on the experience during those two terms. Interest in the courses doubled teaching capacity. An opportunistic randomised evaluation was therefore considered reasonable.

METHODS

This protocol was prepared in accordance with SPIRIT 2013 statement [12]. The SPIRIT checklist is available as a supplementary file online. The trial registration process (ACTRN12615001160527) needs clarification. The protocol was submitted to the trial registry in time for prospective registration but an unforeseen delay at their fault led to a final retrospective registration date. This problem was acknowledged by the trial registry and did not increase risk of bias compared with routine prospective registration.

Eligibility criteria

Participant eligibility criteria for this study are unchanged from those used routinely by the UCS for mindfulness courses. They are all self-reported. The inclusion criteria are as follows:

(a) Undergraduate and postgraduate University of Cambridge students in any year or course;
(b) Who consider they can realistically attend at least seven sessions of the course.

The exclusion criteria are as follows:

(a) Currently suffering from severe periods of anxiety or depression;
(b) Experiencing severe mental illness such as hypomania or psychotic episodes;
(c) Following recent bereavement or major loss;
(d) Experiencing any other serious mental or physical health issue that would impact on their ability to engage with the course.

Students will be advised to contact the study team if they are unsure about their eligibility.

Intervention

The eight-week mindfulness course is called ‘Mindfulness Skills for Students’. It consists of a secular, group-based skills training programme based on the course book ‘Mindfulness: A Practical Guide to Finding Peace in a Frantic World’ [13], and adapted for university students. This intervention aims to optimise experiences across a range of students and is not specifically developed for those students in the clinical range.

The sessions last for 90 minutes for the first session, and 75 minutes for the remaining sessions. There are eight weekly sessions, all run by Dr Elizabeth English, an experienced and certified mindfulness teacher. Each session includes two mindfulness meditations, the first embedding the meditation that the students have practised at home throughout the week; the second, introducing them to the new meditation that they will practice at home in the coming week. There are also periods of reflection and inquiry, helping the students to understand the nature of mindfulness, to deepen their learning and embed it into their everyday lives. A few simple models are used and

developed throughout the course, to give the students some theoretical understanding of the concepts developed experientially. As is usual in mindfulness programmes, each session also includes interactive exercises, so that the students share their experience and get to know each other throughout the course, building a sense of safety and community.

Before and after each class, students receive an email from the mindfulness teacher. This reminds them of the themes covered in the previous class, and lets them know the topics coming up in the next class. These emails also include handy tips, poems and video clips. There is also a course handout available in hardcopy at each class that can also be downloaded via a link in the post-class email, which describes the home practice for the coming week. The home practice time varies through the course, starting at eight minutes, and increasing to about 15-25 minutes per week plus ongoing reflection through the day. It includes meditations from the course book's compact disc and other mindfulness practices such as a mindful walk, mindful eating, habit breakers, and so on. More practice is possible for those who want it, and students are encouraged not to miss a day, but to rather consider doing less on days when they are busy. A detailed intervention manual is available upon request from the corresponding author.

Seven Mindfulness Skills for Students courses run in parallel each term (which only lasts 9 weeks in Cambridge) with up to 30 students each. Students need to choose a session time and day to attend each week but are encouraged to attend as many sessions as they can, so if they cannot make their usual session, they can attend an alternative session within the same week ('session hopping'). Students are contacted by email when they miss a session to check whether the absence is related to a negative experience with mindfulness and, subsequently, to offer support.

As this will be a pragmatic study, care will be taken not to interfere with or modify routine practices for intervention delivery. Therefore, there will be no ad hoc adherence optimization procedures. Participants in the control group will be guaranteed a space in the following year's mindfulness course and will be requested to inform the research team should they decide to learn mindfulness elsewhere during the follow-up period.

Outcomes & data collection

Several outcomes will be measured and compared between mindfulness and control groups to assess the effects of the course. The primary outcome will be a self-reported global measure of psychological distress assessed during the exam term, the most stressful period of Cambridge students' academic year. Secondary outcomes are exploratory assessments that may help to describe mindfulness' effects in more focused ways. Outcomes are listed in Table 1.

Psychological distress will be measured using the Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM), a 34-item generic questionnaire which was designed to assess efficacy and effectiveness across multiple disciplines offering psychological therapies, and has been widely used with UK university students. It is scored on a 5-point scale ranging from 0 (not at all) to 4 (most or all the time). The total score range is 0-136, this is usually divided by number of completed items to form a total mean score. CORE-OM has good convergent validity, internal and test-retest reliability and sensitivity to change [14].

Students' subjective wellbeing will be assessed using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS), a questionnaire that captures a broad conception of wellbeing. It consists of 14 items, each scored on a five-point scale ranging from 1 (none of the time) to 5 (all of the time). The WEMWBS has good validity, internal consistency and test-retest reliability with a sample of UK students (n = 354) and general population (n = 2075) [15].

Mental health services use will be assessed by asking students whether during the exam term they have requested help with mental health issues and stress from a range of resources (e.g., psychiatrist, Samaritans). Participants will also be asked to what extent such problems may have impacted on their academic performance (e.g., 'To what extent do you have problems affecting your study?') and whether in their view their academic course workload was manageable. Data on inability to sit exams will be provided by the Student Registry. The UCS will provide the research team with information about which participants used their services and how frequently they were used.

Day-to-day coping during the exam period will be assessed by applying ecological momentary assessment based on the cognitive appraisal theory of coping [16]. Every morning for two weeks, six questions will be asked about coping with academic stress on the previous day. These data will also be collected for a week at baseline from the participants recruited in January 2016. Motivational relevance ('How motivated did you feel by academic matters yesterday?', 'How stressed did you feel by academic matters yesterday?'), problem-focused coping potential ('Did you study as much as you had planned yesterday?', 'Did you take as many breaks from study as you had planned yesterday?') and emotion-focused coping potential ('How satisfied with yourself are you about the amount you studied yesterday?', 'How satisfied with yourself are you about the breaks from study you took yesterday?') will be assessed. Participants with an Android smartphone will be able to install a free application ('EasyM', developed by the University of Cambridge Computer Laboratory[17]) that will send notifications and display the questions. Other participants will receive a text message notification with a link to an online survey. In order to see how disrupted students' healthy routines become during the exam period, physical activity and sleep pattern data will be passively collected from Android users by the EasyM app using movement sensors (built-in accelerometer) for two weeks.

In view of evidence that mindfulness may stimulate altruism[18], and that altruistic actions are associated with increased well-being[19], we are exploring altruistic behaviour differences between groups. A sum of money in the form of Amazon vouchers will be offered to participants after completing each questionnaire (£3 for post-intervention and one-year follow-up questionnaires, £5 for the exam term questionnaire which will measure the primary outcome). A choice will be given as to whether to keep the token or to donate it to a local mental health charity. This will constitute an objective measure of altruism.

Process measures will involve: (a) Registering attendance at mindfulness courses (register taken) and asking why sessions were missed (routine practice for UCS); (b) Asking students whether they did their mindfulness homework during the course and how much they have practised after the course, including whether they became members of the Mindfulness Society; (c) For students who abandon the study (i.e. fail to complete questionnaires or contact us saying they wish to quit the study), information on why they have done so will be requested; (d) Participants in the control group will be asked whether they have practised mindfulness elsewhere during the follow-up period.

Apart from the baseline measurements outlined in Table 1, the following baseline data will be collected in order to compare the sample with the student population, and to run sub-group analyses: (a) Students' prior experience with meditation and mindfulness; (b) Demographic data provided by the student registry (e.g., disability, ethnicity, socio-economic classification). All baseline data will be collected before randomisation.

Questionnaires will be web-based. Privacy issues related to accessing student records and collecting data from smartphone sensors were explored in a focus group with students who completed mindfulness courses taught before the trial. Students felt these methods were acceptable.

Table 1. MSS study outcomes

Outcome	Source / measure	Variable type	Collection points
Use of mental health services	Self-reported	Nominal	One-year follow-up
Use of University Counselling Service	Routinely collected	Nominal	Baseline, one-year follow-up
Perceived impact of problems on academic performance	Self-reported	Ordinal	Exam term
Exam grades and rankings	Routinely collected	Ordinal	Exam term
Special circumstances requests for exams	Routinely collected	Nominal	Exam term
Inability to sit exams (intermissions & degrading)	Routinely collected	Nominal	Exam term
Psychological distress	Self-reported: CORE-OM	Treated as interval	Baseline, post-intervention, exam term, one-year follow-up
Wellbeing	Self-reported: WEMWBS	Treated as interval	Baseline, post-intervention, exam term, one-year follow-up
Altruism	Behavioural	Ordinal	Post-intervention, exam term, one-year follow-up
Coping	Self-reported	Ordinal	Baseline (Lent), Exam term
Physical activity	Behavioural (sensor)	Ratio	Baseline (Lent), Exam term
Sleep times	Behavioural (sensor)	Ratio	Baseline (Lent), Exam term

Abbreviations: CORE-OM: Clinical Outcomes in Routine Evaluation Outcome Measure; WEMWBS: Warwick-Edinburgh Mental Wellbeing Scale.

Sample size

The minimum sample size required was calculated to detect a 0.3 standard deviation change in psychological distress with CORE-OM, the primary outcome. This change constitutes a small difference, but is reasonable for a relatively short mindfulness course, and attractive if this shift happens at a community rather than a clinical level [20].

A study of a non-clinical sample (746 students from two UK universities plus a community sample of 360 people) found a mean total score of 0.76 points and a standard deviation of 0.59 points [21]. To detect a change of 0.3 standard deviations at $p<0.05$ with 90% power, 550 students (275 per arm) are estimated to be needed, allowing for 20% loss to follow-up as informed by previous studies (e.g., Warnecke 2011[22]).

Recruitment

Students will be recruited in two waves, in October 2015 (beginning of Michaelmas term) and January 2016 (beginning of Lent term). Figure 1 shows the participant timeline.

The evaluation will be advertised widely in the student community at the University of Cambridge. Posters will be put up in University buildings. Facebook and Twitter study accounts will be utilised. Colleges will circulate an email presenting the study and inviting students to attend the information sessions at the beginning of both terms. The students' Mindfulness Society has agreed to direct

students who approach them with an interest in learning mindfulness to the information sessions. All materials will display a dedicated email address for contacting the study team.

Advertising will focus on letting students know about the study and directing them to a dedicated website or to information sessions that will take place in the first weeks of each term. Both the website and the information sessions will provide prospective participants with detailed information about the study and consent procedures.

Blinding and randomisation procedures

After agreeing to take part, students will be emailed with a link to the online baseline questionnaire. Only those who complete the baseline questionnaire will be randomised. Simple randomisation will be done remotely by the survey software (Qualtrics) using computer generated random numbers. Participants will be informed of their allocation automatically after completing the baseline questionnaire. This way the allocation process will be concealed from researchers.

Participants randomised to the intervention group will be requested to state which of the seven mindfulness session times on offer they would be able to attend. Then, to minimise attrition, an allocation optimisation programme will be run with these data to assign as many students as possible to one of their preferred course times.

Participants cannot be blind to allocation because of the nature of the intervention. However, outcome assessment will be blind because data collection is done remotely and automatically. The primary analysis will be carried out by a statistician blind to which arm is the intervention, and other variables/information which could be used to identify intervention arm data. Mindfulness courses will include participants who are not part of the trial (consisting of up to 60 interested students distributed evenly across courses so that 4-5 students out of 30 per course are not part of the study), and the mindfulness teacher will not be told who is and who is not a participant in the study.

Inducements for participation

There will be no inducements for completing the mindfulness courses. However, to promote participant retention and as a token of appreciation for completing all the study questionnaires, a total of £11 will be available to each student across the study in the form of Amazon vouchers as explained above. In addition, there will be a prize draw of 5 x £100 Amazon vouchers among those who complete 50% or more smartphone questions plus all the questionnaires. Students who complete 50% or more smartphone notifications will be offered individual feedback on their coping, sleep and physical activity patterns after the study ends.

Public engagement

Involving stakeholders in the choice of question and design of the research is important to ensure relevance[23]. The study plans presented here were reviewed by a group comprising representatives from the UCS, the Academic Division, student representatives and college tutors. A focus group with students who completed mindfulness courses taught before the trial was consulted about the study plans before submission to the Ethics Committee for approval.

An advisory Reference Group will be put together comprising student representatives, members of the University Counselling Service, and other student welfare staff. They will meet three times a year. Study researchers will attend these meetings and present updates. Reference Group terms of reference will be available upon request.

Statistical methods

The primary analysis will consist of an intention-to-treat analysis comparing the primary outcome, CORE-OM during the exam period, between arms adjusted for baseline scores, routine demographics and timing of receipt of intervention relative to exams (as some will have done the course during Michaelmas 2015 and others during Lent 2016). Multiple imputation will be used as long as there is less than 40% missing data in the corresponding variable to ensure validity of imputations and will be applied only to variables with expected missing completely at random and missing at random patterns (i.e. when there are no reasons to think that the pattern may be missing not at random). This imputation will take account of other CORE-OM data points and routinely collected demographics. We will also conduct a per protocol analysis (minimum dose assumed to be 50% attendance of sessions[24]) excluding individuals in the control group who have engaged in meditation elsewhere during the follow-up period preceding outcome measurement.

Outcomes measured at three time points (CORE-OM, WEMWBS and altruism, measured at post-intervention, exam period and one-year follow-up) will be analysed using a repeated measures design with a treatment by time interaction term to study their trajectories through the academic year and to determine whether differences (i.e. intervention effects) were consistent over time. Repeated measures analyses will also be performed with ecological momentary assessment data to study outcome trajectories, pattern changes during the exam period and differences between arms.

CORE-OM and WEMWBS data will be combined to explore the broader spectrum of distress/wellbeing if taken as a continuum [25]. Subscales of the CORE-OM (subjective-well-being, problems-symptoms, functioning, risk/harm) will also be explored as secondary outcomes, and results reported with and without correction for multiple testing. Multilevel models will be used to assess academic degrees and academic rankings as any student may sit more than one exam.

The following predefined subgroup analyses will be conducted on the primary outcome by using interaction tests [26]:

- By degree, as most have exams during the exam term but some do not
- By year of study, to explore whether results differ for last year students, a different sub-population as control group final year students will not be offered mindfulness a year later
- By baseline CORE-OM: Those initially worse may drive change
- By gender: There is evidence of differential impact [10]
- By amount of home practice during and after course in intervention group participants
- By prior meditation experience (prior 8-week course or +50 hours spent meditating in the past – an 8-week course translates into 10-50 hours) as only novices may experience a change.

In order to assess how our sample compares against the student population in the UK, demographic and normative wellbeing/distress data will be obtained from the literature and compared with baseline values in our sample. A comparison of our baseline data with the profile of students attending the University Counselling Service will also be performed where possible to evaluate where our sample lies in the range between community and clinical student samples.

All statistical analyses will be conducted at an alpha level of p=0.05 (two-sided). Linear mixed models will be used for the analyses. Assumptions will be tested and diagnostic plots will be explored to assess model fit. Descriptive statistics for continuous variables will be summarised using mean/standard deviation and median/interquartile range. Discrete variables will be summarised by proportions.

It is expected that the clustering effect will be negligible: although this is a group intervention, the work is highly personal, all the courses are taught by the same teacher, each course includes students from different colleges and courses, and the 'session hopping' option introduces variability. However, we will compute intra-class correlation by analysing session attendance patterns to see whether there is any clustering effect. If there is one, we will adjust for it using multilevel techniques.

Data monitoring and adverse events

An Independent Data Monitoring and Ethics Committee (IDMEC) will be set up comprising an independent chair familiar with student welfare issues, an independent researcher, a representative from the student body and a representative from the colleges that make up the University. Its role will be to safeguard the interests of trial participants, assess the safety and efficacy of the intervention during the trial, and monitor the overall conduct of the trial. The IDMEC will meet three times a year and make recommendations to the researchers; its terms of reference are available upon request and include provision for terminating the trial early. There are no plans for interim analyses, although the IDMEC could request them.

Introductory, eight-week mindfulness courses for people who meet our selection criteria are not known to be associated with adverse events. However, we will systematically monitor for such events and have a duty of care to react when there is an indication of extreme distress or risk in a student. Participants will be encouraged upon enrolment to look for signs of their mental or physical health deteriorating, whether or not it is related to the mindfulness course. Emergence of such symptoms will be considered adverse events. Subsequently, during the study, there will be three ways of identifying adverse events:

1. There may be uncomfortable moments during the mindfulness course as participants are requested to turn their attention to whatever thoughts are coming into their minds. They will be taught how to safely deal with these thoughts, but initial experiences can be somewhat distressing. Participants are frequently encouraged to approach the course teacher to discuss any concerns.
2. All participants will complete the CORE-OM questionnaire at baseline, post intervention, during the exam term and at one-year follow-up. The study team will monitor the risk subscales of CORE-OM each time participants complete it (as stated in the participant information sheet). Studies support using the following cut-off scores as markers of significant risk: 3 or more for the self-harm risk subscale, 3 or more for the harm to others risk subscale, or 5 or more for the suicide risk subscale [27] [28]. Scores of 7 or more points in any subscale will be prioritised.
3. All the trial participants will be requested to let the study team know if and why they are planning to leave the study.

In the event of any adverse events emerging, participants will be contacted, strongly encouraged to seek additional help and directed to relevant health services. If a participant fails to respond or refuses to access help without reasonable justification, they will be informed that the research team will try to contact support services (e.g., college nurse) without their consent (as stated in the participant information sheet). Events will be recorded on a structured form sent to the IDMEC Chair who will determine whether they could be related to the intervention (i.e. adverse reactions[29]) and how to proceed (e.g., stopping the trial early).

ETHICS AND DISSEMINATION

Approval was obtained from Cambridge Psychology Research Ethics Committee on 25/08/2015 (PRE.2015.060). Protocol amendments will be prepared by the study researchers in consultation with the IDMEC and the Reference Group. Ethical approval will be sought. The Trial Registry and the Research Governance Office will be informed.

Consent

After reading the participant information sheet, students will be able to consent online or in person (a copy of the consent form is available as a supplementary file online). The electronic and paper-based information sheets and consent forms will have the same content. They will clearly state eligibility criteria and request students to self-assess whether they meet them. They will also list other mental health support resources (e.g., University Counselling Service) within and outside the University for those who do not wish or cannot take part in this study.

Information sessions will be set up in central locations on different days where a member of the research team will distribute participant information sheets. They will give plenty of time for students to read them and ask all the questions they need. They will also be able to take the information sheet with them and come back later or use the website to consent. The mindfulness teacher will be either present at the sessions or reachable by phone and email for students to ask questions about the course.

The online consent will be programmed in Qualtrics and participants' consents will be recorded in a secure database. An 'I agree' button will allow participants to continue answering baseline questionnaires, those who do not consent will not be able to continue answering so no personal information about them will be recorded online before they consent. If a student reads the participant information on the website and has questions, they will be able to phone and email the research team, or attend the information sessions. They will be emailed a copy of the consent for their records.

Students in their final year have a 50% chance of assignment to the control group and may not be able to receive the mindfulness course in the following year unless they stay on for another degree. This issue was explored in the focus group with students and it did not raise any significant concerns. However, this circumstance will be made clear in the participant information sheet for last year students to make an informed decision on whether to take part in the study. In any case, participants randomised to the control group will not be requested to avoid learning mindfulness elsewhere, and a list of resources to do so will be offered in the study website.

Data management

Identifiable research data will be stored at the Clinical School's Secure Data Hosting Service, only accessible by the data manager (AW), the principal investigator (PJ) and the trial manager (JG). From here, an anonymised copy blind to which arm will be the intervention arm will be made to be used for the independent statistician (JS) who will conduct the primary analysis. During the conduct of the trial the independent statistician will be excluded from any information that would help identify the arms.

Adverse event reports will be personally identifiable but kept strictly confidential. Only some members of the research team (GD, PJ, MV, JG, AW), the mindfulness teacher and the IDMEC chair will have access to them.

Dissemination policy

Findings will be submitted to high impact peer-review journals. Publication authorship will be based on the International Committee of Medical Journal Editors' criteria.

We will also send a briefing to other universities and a lay summary to participating students. Further dissemination will take place by developing an online interactive social media presence, taking part in public engagement events, and using media channels.

AUTHORS' CONTRIBUTIONS

GD and AB had the idea for a mindfulness intervention pilot; PBJ, AB and GD applied for funding for a randomised evaluation; JG and PBJ produced an initial draft of the protocol that was revised through discussion with TJC, GD, AB, EH, and MV; the analysis plan was devised by JG, PBJ, JS and AW. JG is the lead researcher; PBJ is guarantor of the study.

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COMPETING INTERESTS STATEMENT

The authors declare no competing interests.

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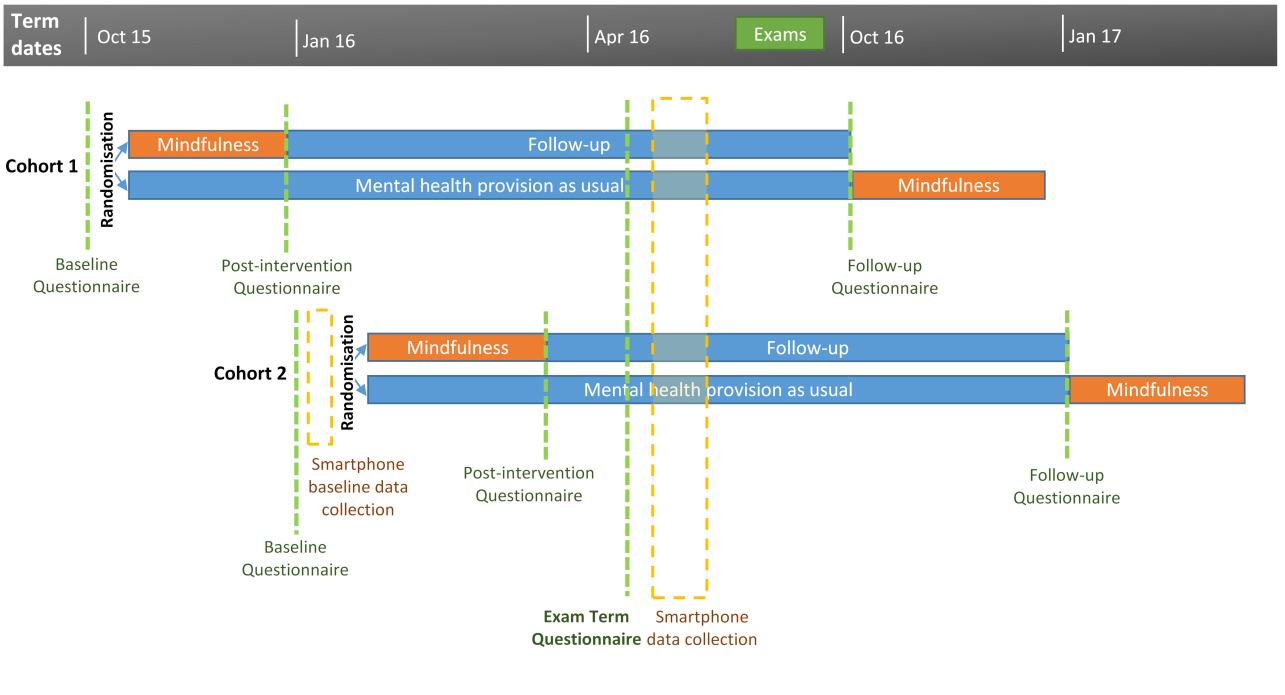
Term dates
Oct 15
Jan 16
Apr 16
Exams
Oct 16
Jan 17
Cohort 1
Randomisation
Mindfulness
Follow-up
Mental health provision as usual
Mindfulness
Baseline Questionnaire
Post-intervention Questionnaire
Follow-up Questionnaire
Cohort 2
Randomisation
Mindfulness
Follow-up
Mental health provision as usual
Mindfulness
Smartphone baseline data collection
Baseline Questionnaire
Post-intervention Questionnaire
Follow-up Questionnaire
Exam Term Questionnaire
Smartphone data collection

The Mindful Student Study

Consent form

By agreeing to take part you **declare** that:

Tick box to confirm you have read each statement:

• You have read and understand the **Participant Information Sheet**	
• You have had the opportunity to **ask questions** and had them answered	
• You understand that personal details will remain strictly **confidential** and will be separated from all other information so that researchers work with anonymous data.	
• You understand that your participation is voluntary and that you are **free to withdraw** at any time without giving a reason.	
• You are a **student** at the University of Cambridge	
• You are able to attend at least **seven sessions** of the 8-session mindfulness course	
• **You are NOT**: o Currently suffering from severe periods of anxiety or depression; or o Experiencing severe mental illness such as hypomania or psychotic episodes; or o Recently bereaved or have suffered a major loss (of about six months to a year); or o Experiencing any other serious mental or physical health issue that would impact on your ability to engage with the course.	

By giving the details below you agree to take part in this study:

Name……..

CRSID……..

Signature……..

Date…….

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page in submitted manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	3-5
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1,14
	5b	Name and contact information for the trial sponsor	3
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	12,13
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6
	6b	Explanation for choice of comparators	6,7
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7,8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11,12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11,12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	12,13

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	13
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	14
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	-

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	14
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	-
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	yes
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	-

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.