1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Title Page

Title:

Effectiveness of providing university students with a mindfulness-based intervention to increase resilience to stress: one-year follow-up of a pragmatic randomised controlled trial

Authors:

1. Julieta Galante, PhD (**corresponding author**), NIHR Postdoctoral Fellow, Department of Psychiatry, University of Cambridge, Douglas House, 18b Trumpington Road, Cambridge, CB2 8AH, United Kingdom (second affiliation: National Institute for Health Research Applied Research Collaboration East of England). Email: mjg231@cam.ac.uk, phone (+44) 01223 465192

2. Jan Stochl, PhD, Senior Research Associate, Department of Psychiatry, University of Cambridge, Cambridge Biomedical Campus, Box 189, Cambridge, CB2 0QQ, United Kingdom (second affiliation: Department of Kinanthropology, Charles University, Jose Martiho 31, 162 52 Prague, Czech Republic; third affiliation: National Institute for Health Research Applied Research Collaboration East of England).

3. Géraldine Dufour, MA, Head of Counselling, University Counselling Service, University of Cambridge, Student Services Centre, Bene't Street, Cambridge, CB2 3PT, United Kingdom (second affiliation: Executive Member, British Association for Counselling & Psychotherapy: Universities and Colleges Division).

4. Maris Vainre, MA, PhD Student, MRC Cognition and Brain Sciences Unit, University of Cambridge, 15 Chaucer Rd, Cambridge, CB2 7EF, United Kingdom (former affiliation when doing this work: Research Assistant, National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care East of England, Douglas House, 18b Trumpington Road, Cambridge, CB2 8AH, United Kingdom).

5. Adam P Wagner, PhD, Senior Research Fellow, Norwich Medical School, University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ, United Kingdom (second affiliation: National Institute for Health Research Applied Research Collaboration East of England).

6. Peter B Jones, PhD, Professor of Psychiatry, Department of Psychiatry, University of Cambridge, Herchel Smith Building, Cambridge, CB2 0SZ, United Kingdom (second affiliation: National Institute for Health Research Applied Research Collaboration East of England).

Abstract

Background: There is concern that increasing demand for student mental health services reflects deteriorating student wellbeing. We designed a pragmatic, parallel, single-blinded randomised controlled trial hypothesising that providing mindfulness courses to university students would promote their resilience to stress up to a year later. Here we present one-year follow-up outcomes.

Methods (trial registration: ACTRN12615001160527): University of Cambridge students without severe mental illness or crisis were randomised (1:1, remote software-generated random numbers), to join an 8-week mindfulness course adapted for university students (MSS), or to mental health support as usual (SAU).

Results: We randomised 616 students; 53% completed the one-year follow-up questionnaire. Self-reported psychological distress and mental wellbeing improved in the MSS arm for up to one year compared to SAU (p<0.001). Effects were smaller than during the examination period. No significant differences between arms were detected in the use of University Counselling Service and other support resources, but there was a trend for MSS participants having milder needs. There were no differences in students' workload management; MSS participants made more donations. Home practice had positive dose-response effects; few participants meditated. No adverse effects related to self-harm, suicidality, or harm to others were detected.

Conclusion: Loss to follow-up is a limitation but evidence suggests beneficial effects on students' average psychological distress that last for at least a year. Effects are on average larger at stressful times, consistent with the hypothesis that this type of mindfulness training increases resilience to stress.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Summary Box

What is already known on this subject?

A recent systematic review of trials suggests that, measured shortly after their completion, mindfulness-based programmes improve university students' distress and wellbeing in comparison with passive controls (Dawson 2019). More research is needed to assess longer term effects and mental-health service use. Poor trial methodology undermines confidence in review results, highlighting the need of higher-quality trials. How long the effects of a universal intervention to increase resilience to stress last, and whether support services are affected, are key questions for policy makers to plan ahead.

What does this study add?

Our study shows that the benefits of the Mindfulness Skills for Students course on students' psychological distress and mental wellbeing last at least a year, but that students still use university mental support services at similar rates. We also show that the beneficial effects seem to be larger at stressful times, a pattern that could be interpreted as an increase in students' resilience to stress. Preventive mindfulness courses are likely to benefit the average university student, but should not be seen as a replacement of other mental health support services, for which there will continue to be demand.

Introduction

Official statistics show that the prevalence of mental health disorders among children and young people in England, emotional disorders in particular, has been increasing over time, reaching almost one in five of 17 to 19 year olds in 2017 [1]. In England now over 50% of young people enrol in higher education institutions [2] which have a golden yet under-used opportunity for prevention of mental illness in young people [3][4]. This seems particularly relevant as there are concerns that the pressure that young people experience when they transition to university can contribute to mental health issues for some of them [5]. While more research is needed [6], it is clear that the number of university students accessing counselling services has increased faster than the growth in student numbers [7].

Mindfulness, a non-stigmatising means of training the attention for the purpose of mental health promotion, has become popular in universities [8]. In this context, mindfulness practice is often defined as learning to pay attention to what is happening in the present moment in the mind, body and external environment with an attitude of curiosity and kindness [9]. There is evidence for its effectiveness in preventing psychological distress [10], and improving symptoms of common mental disorders [11].

In 2016 we completed the Mindful Student Study, a randomised controlled trial (RCT) to confirm the effectiveness of a preventative mindfulness-based programme tailored to university students called Mindfulness Skills for Students (MSS) [12]. In a recent publication we confirmed our primary hypothesis that MSS would reduce students' psychological distress during the examination period (three to six months after randomisation) compared with access to mental health support as usual (SAU) [13]. A reduction in distress under exam conditions was deemed an indicator of resilience to stress. These results are consistent with other evidence, although data on longer term effects and on use of mental health services is sparse [10].

Participants in the Mindful Student Study were followed up for a year post randomisation. Outcomes pertaining to this time point and participants' trajectories are presented herein. Consistent with the idea of resilience and prior evidence, our main hypothesis for this analysis was that MSS would have a long-term effect on psychological distress still outperforming SAU for reducing psychological distress after one year, but that this effect would be smaller than that during the examination period because students would no longer be under the examination universal stressor.

Methods

The Cambridge Psychology Research Ethics Committee approved the trial on 25/08/2015 (PRE.2015.060). This research conforms to the principles embodied in the Declaration of Helsinki. The protocol [12], was submitted to the Australian New Zealand Clinical Trials Registry on 31/08/2015, before the study began, and accepted on 30/10/2015 (trial registration: ACTRN12615001160527).

Randomisation and masking

We conducted a pragmatic RCT with two parallel arms and a one-to-one allocation ratio testing the superiority of mindfulness training provision compared with no provision. All the students at the University of Cambridge were invited to join the study. Those who responded positively were randomised via remote survey software (Qualtrics, concealed from researchers) using computer-generated random numbers (simple randomisation) to being offered the MSS course plus SAU, or to SAU alone. Participants were aware of group allocation.

We set-up an independent data monitoring and ethics committee (IDMEC), and co-produced the trial with stakeholders. Further details including sample size calculations can be found in previous publications [12] [13].

Eligibility

Eligibility criteria were assessed by participants themselves, and based on those used routinely by the University of Cambridge Counselling Service (UCS) for the MSS courses. Inclusion criteria were: (a) current undergraduate or postgraduate students at the University of Cambridge; (b) who believed they could attend at least seven sessions of the course. Exclusion criteria were: (a) currently suffering from severe periods of anxiety or depression; (b) experiencing severe mental illness such as hypomania or psychotic episodes; (c) recent bereavement or major loss; (d) experiencing any other serious mental or physical health problem that would affect their ability to engage with the course.

Two cohorts of students were recruited (October 2015 and January 2016; no main outcome differences were found between cohorts) [13]. MSS courses were free to students. A total of £11 was available to each participant as a token of appreciation for questionnaire completion.

Intervention

The MSS intervention consisted of a secular, face-to-face, group-based skills training programme based on the course book 'Mindfulness: A Practical Guide to Finding Peace in a Frantic World' [14], and adapted for university students. This course aimed to optimise wellbeing and resilience for all students, and was not specifically developed for those with distress in a clinical range. Seven MSS courses ran in parallel during university terms, with up to 30 students in each course, all delivered by an experienced and certified mindfulness teacher. The eight, weekly sessions lasted 75-90 minutes. Sessions included mindfulness meditation exercises, periods of reflection and inquiry, and interactive exercises. Students were encouraged to also practice at home, and were given reading materials. The recommended home practice time started at eight minutes, then increasing to 15-25 minutes per day. It included guided formal meditations (from here on: "formal practice") and other practices such as a mindful walk and mindful eating (from here on: "informal practice"). Students were contacted by email when they missed a session to check whether the absence related to a negative experience with mindfulness. Students were also given the opportunity to talk with the teacher in confidence outside course times. Further details can be found in previous publications [12] [13].

SAU consisted of access to comprehensive centralised support at the UCS in addition to support available from the university and its colleges, and from health services including the National Health Service, external to the University. Participants randomised to SAU were guaranteed a space in the following year's mindfulness courses and were requested to inform the team if they decided to learn mindfulness elsewhere during the follow-up period.

Measures

Self-reported data were collected using online questionnaires accessed by participants via a unique link. The examination period as defined by the Student Registry spanned 16 May 2016 to 10 June 2016, the most stressful weeks of the academic year for most students (not all have exams, approximately 14% did not in our sample), approximately six-months after randomisation for Cohort 1, and three-months after randomisation) for Cohort 2. Supplemental Table 1 lists all trial outcome measures and data collection time points.

Self-reported mental health

Psychological distress was measured with the Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM), a 34-item scale that has been widely used with UK university students [15].

Higher scores mean more distress. The total mean score (range 0-4) is obtained by dividing the total score by the number of completed items (as long as no more than three items have been missed) [16]. This measure also contains four sub-scales: subjective wellbeing (4 items), problems/symptoms (12 items), life functioning (12 items), and risk/harm (6 items). We have primarily used the full-scale total mean score, but also explored the sub-scale mean scores to see whether the effect of mindfulness would focus on specific dimensions of distress.

Mental wellbeing was assessed with the 14-item Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) [17]. The total score is calculated by adding the response values of all items (range 14-70, higher scores indicate greater wellbeing).

Use of mental health support resources

Following confidentiality protocols, the UCS provided the research team with information about which participants used their services, what type of services they used, and how frequently they were used. The UCS offers a variety of support services for students depending on their needs and ranging from workshops or therapy groups, to attending a consultation with a Counsellor, CBT therapist, Mental Health Advisor or Sexual Assault & Harassment Advisor. We assessed usage of the services from the moment each participant was randomised up to a year after that, and usage during the examination period specifically. We also assessed UCS services according to the intensity of support. For this, blind to any data and before analysis, Géraldine Dufour (accredited senior psychotherapist and Head of service) and three accredited senior counsellors categorised services according to the intensity of the support they provide into low, medium or high, reflecting the severity of the mental health problems that they are intended to address (Supplemental Table 2). Then, these categories were uniformly applied to the type of service variable in the dataset provided by the UCS.

To assess use of the wider range of mental health support resources, participants were asked "Have you turned to any of the following resources to discuss your mental health during the past year?", and a list of available resources was presented to them. They could choose multiple items and there was an "other resources" option with a text box to specify any unlisted resources. We analysed usage of resources overall and by type.

Other outcomes compared between arms

Mindfulness aims to cultivate a general attitude of care and kindness, prompting claims, and some evidence, that it may also increase altruistic behaviour [18]. We therefore incorporated an opportunistic measure of altruism, based on offering high street shopping vouchers to participants upon questionnaire completion (equivalent to £3 at post-intervention and one-year follow-up, and £5 during the examination period) with a choice to donate them to a named charity.

We have also measured perceived university course workload. This was assessed by asking participants to indicate agreement on a five-point Likert scale with the statement "The workload on my course was manageable during the past year".

We report the number of adverse scores recorded at the one-year follow-up (identified by CORE-OM risk sub-scales above standard thresholds). Such ratings were defined as adverse events not

necessarily caused by the intervention (as opposed to adverse effects, which would be). For further detail, see the trial protocol [12].

Mindfulness practice effects

In order to assess mindfulness practice dose-response effects, we monitored participants' practice throughout the follow-up. Within the MSS arm, formal and informal practice were self-reported via two questions asked at each time point except for baseline (e.g. "During the mindfulness course did you practice mindfulness informally at home (e.g. mindful living, mindful walks, mindful pauses, mindful attitudes)?", "Have you been practising mindfulness formally (meditation practice) since you finished your mindfulness course?"). Attendance at mindfulness courses was registered. Also, at each time point SAU participants were asked whether they had practised meditation elsewhere (e.g. "About how many hours have you spent meditating in total since May, when we last sent you a questionnaire?") and the type of meditation practiced.

Statistical methods

All analyses were conducted according to intention-to-treat at an alpha level of p=0.05 (two-sided). Logistic regression was employed to assess baseline predictors of outcome completeness using R version 3.4.4 [19].

The expected average trajectory for each arm over time on psychological distress and wellbeing was estimated using latent growth curve modelling [20 21], controlling for cohort, gender and age (variables controlled for in the primary outcome analysis as pre-specified in the protocol) [12 13]. Multiple imputation was not employed.

For comparing differences between arms in the proportion of users of UCS and other support resources we used chi-squared tests. Differences in the number of UCS contacts per user, or number of support resources, were compared using quasi-Poisson regression.

We used a hierarchical multinomial logit model in MPlus to compare differences between arms in terms of intensity of service use provision [22]. This accounts for the hierarchical nature of the data structure, as any one student can use any particular service one or more times, and services belong to different levels of intensity. We expressed results as odds ratios. We also used chi-squared, quasi-Poisson regression and odds ratios to compare altruism and workload by arm.

To assess dose-response effects of mindfulness practice on psychological distress (the trial's main outcome), the basic growth model mentioned above was extended with time-varying covariates representing mindfulness practice and distress reported at each time point. One model was created to assess formal mindfulness meditation, and another to assess informal mindfulness practice. These models also controlled for cohort, gender and age. Mindfulness practice data required pre-processing to include within the models (see Supplementary Materials for detail).

Results

One-year follow-up questionnaire data were collected between 26/09/2016 and 11/10/2016 for Cohort 1, and between 10/01/2017 and 23/01/2017 for Cohort 2. Out of the 616 randomised participants (MSS=309, SAU=307), 326 (53%) completed the one-year follow-up questionnaire (MSS=161, 52%, SAU=165, 54%, Supplemental Figure 1). No reasons were given for non-completion. There were no significant baseline differences between completers and non-completers, except that completers were less likely to be final year students. This may be explained by the fact that those

who were in their final year at the beginning of the study may no longer have had the university email account used to contact them one year later (nor was a non-university address shared when requested ahead of their departure). Leaving university might have also reduced investment in the study.

Self-reported mental health

Table 1 shows CORE-OM total mean scores and sub-scale mean scores, overall and by arm measured at one-year follow-up. Average distress levels were lower at this time point than at any previous ones [13]. To evaluate the long-term effect of mindfulness training we have parameterized the growth model (Supplemental Figure 2) such that the slope estimate can be interpreted as the difference in

CORE-OM total mean scores between arm trajectories at the one-year follow-up adjusted for our a-priori set of baseline covariates. This slope takes the value of -0.22 (SE=0.05, p<0.001) suggesting that the MSS course reduces psychological distress for at least one year compared to SAU. This reduction is slightly smaller than that during the examination period (-0.25 points) [13].

Figure 1 shows the estimated trajectory by arm including CORE-OM sub-scales. The trajectory of the MSS group CORE-OM total mean score is an inverted U-shaped curve: the differences with the SAU group are larger at mid-follow-up time points. Sub-scales show very similar patterns to the total mean score.

Table 1 shows WEMWBS total scores overall and by arm measured at one-year follow-up. Average wellbeing levels were higher at this time point than at any previous ones [13]. The latent growth model, built in the same way as that for CORE-OM, shows that the difference in total WEMWBS scores between SAU and MSS was 2.73 (SE=1.03, p=0.008). This suggests that the MSS course improves wellbeing for at least one year compared to SAU, although the difference with SAU lies slightly below the 'minimum detectable change' for this instrument (defined as 3 points [23]). Figure 2 shows the modelled trajectory by arm.

Use of mental health support resources

Table 2 shows UCS service usage overall and by arm. Overall, 20% of all the study participants (122 of 616) used (i.e. attended) at least one of the services offered by the UCS during the full follow-up year, 5% during the examination period. Many UCS users had more than one contact with the UCS (median of three contacts among those who used the UCS). Sixteen participants booked UCS services but did not attend. No significant differences between arms were detected in the proportion of UCS users (chi-squared=0.56, df =1, p-value=0.46) or in the number of contacts per user (quasi-Poisson regression coefficient= -0.17, p-value=0.46). Restricting observations to the main examination period yielded similar results (data not reported).

Regarding differences in the type of support provided by arm (Supplemental Table 3), MSS participants had 13% the odds of SAU participants of using high-intensity UCS support compared with low-intensity support (OR 0.13, 95%CI 0.02-0.72, p=0.02), and 22% the odds compared with mid-intensity support (OR 0.22, 95%CI 0.05- 1.00, p=0.05). There were no statistically significant differences between use of low- and middle-intensity support (OR 1.71, 95%CI 0.70-4.20, p=0.24).

Table 2 shows the self-reported use of mental health resources overall and by arm. Overall, 51% of the students who completed this question reported using at least one of these resources, with many students using more than one resource (median of two resources among those who used them). In both arms, the most frequently used resource was seeing their college supervisor, tutor of director of studies (27% of those who responded the question). Those who chose the category "other

resources" had the chance to explain further. Out of 16 people who chose this category, 13 (MSS=9, SAU=4) mentioned friends, family or loved ones. There are no significant differences between the arms in whether participants used any resources or not (chi-squared=0.36, df=1, p-value=0.55), the number of resources used (quasi-Poisson regression coefficient=0.03, p-value=0.87), or in the usage by type of resource (all p-values >0.3).

Other outcomes comparing arms

Table 2 shows the number of participants donating the vouchers offered to recompense them for completion of the one-year follow-up questionnaires, and the cumulative count of donations throughout the follow-up period). Significantly more MSS participants donated at the one-year follow-up time point, compared to SAU participants (odds ratio=1.91, 95%CI 1.21-3.04, chi-squared=7.88, df=1, p-value=0.005). Over the course of the year, 101 participants donated once, 106 donated twice and 122 donated 3 times. MSS participants donated more times than SAU participants (quasi-Poisson regression coefficient=0.37, p<0.0001).

Table 2 shows participants' degree of agreement with the statement that their course workload during the past year had been manageable. There were no significant differences between trial arms in whether participants viewed their academic workload as manageable (chi-squared = 4.65, df = 4, p-value=0.33).

Table 2 presents the number of adverse events counted at the one-year follow-up, and the cumulative count of adverse events throughout the follow-up period. There were fewer adverse events in the MSS arm than in the SAU arm. All of the adverse events in the period between the examination period time point and the one year follow-up time point were generated by the monitoring of the CORE-OM risk sub-scales [12], and none of them was considered by the IDMEC as an adverse effect deriving from mindfulness practice. Overall, four people experienced more than one adverse event in the year, and they were all SAU.

Mindfulness practice effects

Figure 3 shows the frequency of formal mindfulness meditation and informal mindfulness exercises respectively at each time point for the MSS participants who answered these questions. Most participants (33%) meditated at home between one and three hours per week during the MSS course, but meditation dropped sharply later with 38% not having meditated at all between course completion and the exam period, and 46% not having done so after the examination period. However, doing informal mindfulness exercises was more stable, with most participants reporting doing them "sometimes" (35%, 33% and 33% at post intervention, exam period and one-year follow-up respectively). After one year, at least 33 (11%) SAU participants had practised more than 10 hours of any type of meditation (all of them either mindfulness or Vipassana [24]) or done an 8-week mindfulness course.

Having practiced formal mindfulness meditation significantly reduced psychological distress at all time points at post-intervention (post intervention estimate= -0.01, p-value <0.001; examination period estimate= -0.005, p-value=0.03; one-year follow-up estimate= -0.005, p-value= 0.003; model in Supplemental Figure 3). Having practiced informal mindfulness exercises significantly reduced distress at all time points and with larger effect sizes (post-intervention estimate= -0.08, examination period estimate = -0.09, one-year follow-up estimate = -0.09, all p-values <0.001, model in Supplemental Figure 4). Having practiced formal or informal mindfulness exercises improved wellbeing at all time points (Formal practice: post intervention estimate= 0.17, p-value< 0.001; examination period estimate= 0.12, p-value=0.001; one-year follow-up estimate= 0.09, p-

value=0.004. Informal practice: post intervention estimate= 1.80, p-value <0.001; examination period estimate= 1.82, p-value <0.001, one-year follow-up estimate= 1.26, p-value=0.01).

Discussion

After one year, average distress and wellbeing levels improved in both trial arms. Multiple factors could account for this: regression to the mean, increasing familiarity with the university environment, recent return from summer holidays, or even graduation. Our evidence supports an average beneficial effect of the MSS course on students' psychological distress and mental wellbeing that lasts at least a year. The effect seems to be larger at stressful times: the CORE-OM difference between the MSS and the SAU participants corresponded to a moderate effect size during the examination period according to Cohen's rules of thumb [13][25], while after a year this difference was slightly smaller (-0.25 versus -0.22 CORE-OM points). This pattern is consistent with the hypothesis that mindfulness training increases resilience to stress. It also may explain why mindfulness-based programmes are being used in clinical settings, or as indicative preventative interventions for those with sub-clinical symptoms. Still, universal interventions not explicitly addressing mental health may appeal to those who would otherwise not seek help, as they are less stigmatising [13]. Small to moderate effect sizes are typical of this type of interventions [26], which aim to impact by producing small changes in broad sections of the population. The MSS group format makes such large-scale implementation easier and impact swifter. In any case, we only provide evidence on a voluntary student course. Appropriateness, acceptability and effectiveness of incorporating mindfulness training into students' compulsory curricula are still unclear [27][28]. Mindfulness courses may not be suitable or engaging for some groups of people. We favour the implementation of the MSS to be offered along with other preventative interventions as part of a wider student wellbeing strategy.

The MSS course may not impact the subjective experience of managing academic workloads also see [29], or the frequency of use of mental health support services. However, it may impact the type of mental health support needed in a desirable direction: SAU participants needed more intensive types of UCS support that indicated more severe circumstances, while MSS participants needed types of UCS support that indicated milder severity. MSS participants may have experienced less severe problems, and/or they were more pro-active at asking help. This finding was not evident in the self-reported use of mental health resources - although the latter was only available from approximately half of participants and questions lacked sensitivity in determining support intensity.

Economic implications of these results for the UCS are being explored in an economic evaluation currently being conducted.

Participants randomised to the MSS arm have consistently donated more than those allocated to SAU. This may partly be a specific effect of mindfulness training, but it is possible that MSS participants felt more predisposed to donate than SAU participants because they were offered the MSS course, while those in the SAU arm were offered nothing. Therefore, the extra donations may have worked more as a "payment for a service", so more related to a sense of justice than altruism.

Despite MSS course teacher's advice, very few students continued practising formal mindfulness meditation after the course, although they reported continuing practising mindfulness informally in their everyday life. Formal practice requires dedicated time, while informal practice (e.g. washing dishes mindfully) does not; this may explain our results. Our dose-response analyses suggest that mindfulness practice matters: the more participants practiced, formally or informally, the more benefit they got. This makes informal practice especially relevant: adherence is good and it still has desirable effects.

Comparison with existing evidence

Our study confirms previous evidence, derived from smaller and/or lower-quality trials conducted in different settings and countries, that mindfulness courses reduce distress among university students [10]. Very few studies have looked at longer term effects among students. One trial followed 288 students up for six years and found increased wellbeing compared with a no-intervention control although only a third of the sample were responsive by then [30].

Similarly to our findings, Bondolfi et al found that following course completion, frequency of informal mindfulness practice remained unchanged over 14 months, whereas the use of formal meditation decreased over time [31]. A recent systematic review found that participants do on average 64% of the formal practice amount requested during the course, with high variability [32]. We are unable to calculate such a figure with our data regarding adherence to formal practice during the course, but our results are roughly aligned with it.

We have found beneficial effects to be correlated with mindfulness practice. Agreeing with our findings, a recent systematic review found a small but significant association between formal mindfulness practice during the course and post-intervention outcomes [32]. Analyses of associations between formal practice after the course and follow-up outcomes are scarce and inconsistent [33][34][35].

Very few studies have assessed the frequency and effects of informal mindfulness practice [33], in part because of the difficulties in measuring it [36]. A recent dose-response analysis found that informal practice was associated with improved positive emotions with no association with negative emotions [37]. Other studies have not found associations [38][39]. Our finding that those who practice more get more benefit only apply to contexts where beginner mindfulness practitioners practice in their everyday lives, and do not inform about dose-response effects in intensive practice contexts such as meditation retreats. Similarly, they do not inform the quality of the practice (i.e. what/how participants practice). Quality could be a critical factor in determining practice effects [33], particularly given the generally low level of support offered to participants once mindfulness courses have concluded.

Recent systematic reviews indicate an effect of mindfulness training on prosocial behaviours, although this may only be true in studies where the meditation teacher was a co-author and the control group was passive [18][40]. When a meditation course aiming to cultivate empathy was compared with an active control (stretching), the intervention failed to show clear evidence of increased altruism despite increased prosocial reflection [41]. These support the idea that SAU participants in our trial donated less because of not receiving an intervention.

Our active monitoring system has found no evidence of adverse effects related to self-harm, harm to others or suicidality among MSS participants. However, there are suggestions that subtler adverse effects may go underreported unless asked about specifically [42] - further research is needed.

Strengths and limitations

This RCT is the largest, to our knowledge, assessing mindfulness training for university students. Its careful design and analysis were pre-specified in a publicly registered protocol, which minimises reporting biases. However, it lacked an active control intervention beyond the standard support on offer to students. Therefore, it is not possible from our data to find out to what extent results are influenced by participants' expectations, peer and teacher support, and other factors unspecific to mindfulness training. However, there are reasons to think that at least part of the effect seen in this trial is specific to mindfulness [11]. Outcomes were self-reported and participants were not blind to

trial arm, meaning that responses may have been indeed influenced by their expectations. Loss to follow-up was considerable, and despite our efforts to collect data, reasons for loss to follow-up are unknown to us. Requesting personal, as well as institutional, email addresses at the start of the study might have helped to mitigate this.

UCS data had no loss to follow-up and was collected from the UCS directly rather than self-reported, making these results highly reliable. However, this was planned as a secondary outcome, and the service intensity subgroup analyses are subject to multiple testing bias.

In contrast to most studies, we measured formal and informal practice. Our analyses of the impact of practice on mental health discard reverse-causality and take into account contamination in the control group. However, they did not compare randomly allocated groups, so they may be subject to residual confounding (e.g. those with more time to spare may meditate more and also feel less distressed). In addition, we treated nominal variables as continuous which may contribute bias.

Licence for Publication

The Corresponding Author has the right to grant on behalf of all authors and does grant on behalf of all authors, an exclusive licence on a worldwide basis to the BMJ Publishing Group Ltd to permit this article to be published in JECH and any other BMJPGL products and sublicences such use and exploit all subsidiary rights, as set out in our licence(http://group.bmj.com/products/journals/instructions-for-authors/licence-forms).

Competing interest

None declared.

Acknowledgements

Data Sharing

Deidentified individual participant data and dictionary are available for researchers upon request from the corresponding author after approval of a proposal, with a signed data access agreement.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Contributors

GD conceived the intervention pilot. PBJ and GD applied for research funding. All authors planned the study. JG, GD, MV, and PBJ did the study. JG, JS, and APW did the analysis. JG wrote a manuscript that was revised through discussion with all the authors.

References

1. NHS Digital. Mental Health of Children and Young People in England. 22 Nov 2018 ed, 2018.

2. UK Department for Education. Participation Rates in Higher Education: Academic Years 2006/2007 – 2017/2018 (Provisional). 2019. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/843542/Publication_HEIPR1718.pdf.

3. Faculty of Public Health and Mental Health Foundation. *Better Mental Health For All: A public health approach to mental health improvement*. London, 2016.

4. Auerbach RP, Mortier P, Bruffaerts R, et al. WHO world mental health surveys international college student project: Prevalence and distribution of mental disorders. J Abnorm Psychol 2018.

5. Bewick B, Koutsopoulou G, Miles J, et al. Changes in undergraduate students' psychological well-being as they progress through university. Studies in Higher Education 2010;**35**(6):633-45.

6. Barkham M, Broglia E, Dufour G, et al. Towards an evidence-base for student wellbeing and mental health: Definitions, developmental transitions and data sets. Counselling and Psychotherapy Research 2019;**19**(4):351-57.

7. Thorley C. Not By Degrees: Improving student mental health in the UK's Universities. 2017. https://www.ippr.org/research/publications/not-by-degrees.

8. Barnes N, Hattan P, Black DS, et al. An Examination of Mindfulness-Based Programs in US Medical Schools. Mindfulness 2017;**8**(2): 489–94.

9. Mindfulness All-Party Parliamentary Group. Mindful Nation UK Report. The Mindfulness Initiative; 2015 [accessed 10/07/2017]. Available from: http://themindfulnessinitiative.org.uk/images/reports/Mindfulness-APPG-Report_Mindful-Nation-UK_Oct2015.pdf.

10. Dawson AF, Brown WW, Anderson J, et al. Mindfulness-based Interventions for University Students: A Systematic Review and Meta-analysis of Randomized Controlled Trials. Applied Psychology: Health and Well-Being 2019;**Epub ahead of print**.

11. Goyal M, Singh S, Sibinga EMS, et al. Meditation programs for psychological stress and well-being: a systematic review and meta-analysis. JAMA Intern Med 2014;**174**(3):357-68.

12. Galante J, Dufour G, Benton A, et al. Protocol for the Mindful Student Study: a randomised controlled trial of the provision of a mindfulness intervention to support university students' well-being and resilience to stress. BMJ Open 2016; 6. http://dx.doi.org/10.1136/bmjopen-2016-012300.

13. Galante J, Dufour G, Vainre M, et al. A mindfulness-based intervention to increase resilience to stress in university students (the Mindful Student Study): a pragmatic randomised controlled trial. The Lancet Public Health 2018;**3**(2):e72-e81.

14. Williams M, Penman D. *Mindfulness: a practical guide to finding peace in a frantic world*. London: Hachette UK, 2011.

15. Connell J, Barkham M, Mellor-Clark J. The effectiveness of UK student counselling services: an analysis using the CORE System. British Journal of Guidance & Counselling 2008;**36**(1):1-18.

16. Core System Group. CORE system user manual. (15/09/2015). http://www.coreims.co.uk/index.html.

17. Stewart-Brown S, Janmohamed K. Warwick-Edinburgh mental well-being scale user guide. University of Warwick 2008 [accessed 10/07/2017]. Version 1 [Available from: http://www.mentalhealthpromotion.net/resources/user-guide.pdf].

18. Donald JN, Sahdra BK, Van Zanden B, et al. Does your mindfulness benefit others? A systematic review and meta-analysis of the link between mindfulness and prosocial behaviour. Br J Psychol 2018.

19. R Core Team. R: A language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing; 2017. Available from: http://www.R-project.org/.

20. Byrne BM. *Structural Equation Modeling with AMOS*. London: Routledge, 2010.

21. Mirman D. *Growth Curve Analysis and Visualization Using R*. Florida: CRC Press, 2014.

22. Muthén lK, Muthén BO. *Mplus User's Guide*. 8th ed. Los Angeles, CA: Muthén & Muthén, 1998-2019.

23. Warwick Medical School. WEMWBS: 14-item vs 7-item scale. 2019 [accessed 11/12/2019]. Available from: https://warwick.ac.uk/fac/sci/med/research/platform/wemwbs/about/wemwbsvsswemwbs/.

24. Chiesa A. Vipassana meditation: Systematic review of current evidence. Journal of Alternative and Complementary Medicine 2010;**16**(1):37-46.

25. Cohen J. *Statistical power analysis for the behavioral sciences*. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates, 1988.

26. Public Health England. Decision making in public health: using Number Needed to Treat (NNT) to determine intervention effectiveness. 2014 [accessed 10/07/2017]. Available from: http://www.nwph.net/Publications/NNT_FINAL.pdf.

27. Stewart-Brown S, Cader M, Walker T, et al. Experiences with a universal mindfulness and well-being programme at a UK medical school. Health Education 2018;**118**(4):304-19.

28. Brown CG. *Debating Yoga and Mindfulness in Public Schools Reforming Secular Education or Reestablishing Religion?* Chapel Hill: The University of North Carolina Press, 2019.

29. Bóo SJM, Childs-Fegredo J, Cooney S, et al. A follow-up study to a randomised control trial to investigate the perceived impact of mindfulness on academic performance in university students. Couns Psychother Res 2019;**20**(2):286-301.

30. de Vibe M, Solhaug I, Rosenvinge JH, et al. Six-year positive effects of a mindfulness-based intervention on mindfulness, coping and well-being in medical and psychology students; Results from a randomized controlled trial. PLoS One 2018;**13**(4):e0196053.

31. Bondolfi G, Jermann F, der Linden MV, et al. Depression relapse prophylaxis with Mindfulness-Based Cognitive Therapy: replication and extension in the Swiss health care system. J Affect Disord 2010;**122**(3):224-31.

32. Parsons CE, Crane C, Parsons LJ, et al. Home practice in Mindfulness-Based Cognitive Therapy and Mindfulness-Based Stress Reduction: A systematic review and meta-analysis of participants' mindfulness practice and its association with outcomes. Behav Res Ther 2017;**95**:29-41.

33. Lloyd A, White R, Eames C, et al. The Utility of Home-Practice in Mindfulness-Based Group Interventions: A Systematic Review. Mindfulness 2018;**9**(3):673-92.

34. Solhaug I, de Vibe M, Friborg O, et al. Long-term Mental Health Effects of Mindfulness Training: a 4-Year Follow-up Study. Mindfulness 2019;**10**(8):1661-72.

35. Madson L, Klug B, Stimatze T, et al. Effectiveness of mindfulness-based stress reduction in a community sample over 2 years. Ann Clin Psychiatry 2018;**30**(1):52-60.

36. Segal Z, Dimidjian S, Vanderkruik R, et al. A maturing mindfulness-based cognitive therapy reflects on two critical issues. Curr Opin Psychol 2019;**28**:218-22.

37. Fredrickson BL, Arizmendi C, Van Cappellen P, et al. Do Contemplative Moments Matter? Effects of Informal Meditation on Emotions and Perceived Social Integration. Mindfulness 2019;**10**(9):1915-25.

38. Crane C, Crane RS, Eames C, et al. The effects of amount of home meditation practice in Mindfulness Based Cognitive Therapy on hazard of relapse to depression in the Staying Well after Depression Trial. Behav Res Ther 2014;**63**:17-24.

39. Hawley LL, Schwartz D, Bieling PJ, et al. Mindfulness Practice, Rumination and Clinical Outcome in Mindfulness-Based Treatment. Cognitive Therapy and Research 2014;**38**(1):1-9.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

40. Kreplin U, Farias M, Brazil IA. The limited prosocial effects of meditation: A systematic review and meta-analysis. Sci Rep 2018;**8**(1):2403.

41. Galante J, Bekkers MJ, Mitchell C, et al. Loving-Kindness Meditation Effects on Well-Being and Altruism: A Mixed-Methods Online RCT. Appl Psychol Health Well Being 2016;**8**(3):322-50.

42. Van Dam NT, van Vugt MK, Vago DR, et al. Mind the Hype: A Critical Evaluation and Prescriptive Agenda for Research on Mindfulness and Meditation. Perspect Psychol Sci 2017:1745691617709589.

Journal of Epidemiology & Community Health

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Tables

Table 1. One year follow-up psychological distress (CORE-OM and its sub-scales) and wellbeing (WEMWBS) outcomes.

		All	MSS	SAU
CORE-OM total mean score	N	338	169	169
	Mean	0.86	0.80	0.93
	SD	0.52	0.49	0.55
	Median	0.74	0.68	0.82
	Min-Max	0-2.76	0-2.76	0-2.68
CORE-OM wellbeing sub-scale mean score	N	338	169	169
	Mean	1.04	0.98	1.10
	SD	0.74	0.73	0.75
	Median	1	0.75	1
	Min-Max	0-3.50	0-3.50	0-3.50
CORE-OM symptoms sub-scale mean score	N	337	168	169
	Mean	1.13	1.06	1.20
	SD	0.71	0.68	0.75
	Median	1	0.92	1.08
	Min-Max	0-3.58	0-3.33	0-3.58
CORE-OM functioning sub-scale mean score	N	335	168	167
	Mean	0.92	0.85	0.99
	SD	0.57	0.55	0.59
	Median	0.83	0.75	0.92
	Min-Max	0-3.17	0-3.17	0-2.83
CORE-OM risk sub-scale mean score	N	339	179	169
	Mean	0.08	0.06	0.10
	SD	0.21	0.17	0.25
	Median	0	0	0
	Min-Max	0-1.17	0-1.17	0-1.17
WEMWBS total score	N	335	168	167
	Mean	49.92	51.06	48.77
	SD	9.31	9.58	8.92
	Median	51	52	50
	Min-Max	17-70	17-70	25-70

Abbreviations: CORE-OM=Clinical Outcomes in Routine Evaluation Outcome Measure; MSS=mindfulness skills for students; Min-Max=Minimum and maximum values; SAU=support as usual; SD=standard deviation; WEMWBS=Warwick-Edinburgh Mental Wellbeing Scale.

Table 2. One year follow-up and cumulative results for various outcome measures.

		All		MSS		SAU	
Use of UCS services	Participants who used the UCS during the full follow-up period	122	20%	57	18%	65	21%
(nMSS=309 , nSAU=307)	Total number of contacts	517		238		279	
	Number of contacts per user among users (median range)	3	19	3	17	3	19
	Participants who used the UCS during the exam period	32	5%	13	4%	19	6%
Severity of UCS contacts	Total number of low severity contacts	49	9%	29	12%	20	7%
(nMSS=309 , nSAU=307)	Total number of medium severity contacts	449	87%	206	87%	243	87%
	Total number of high severity contacts	19	4%	3	1%	16	6%
Mental health resources used (self-report)	None	162	49%	78	47%	84	51%
(nMSS=166 , nSAU=165)	Supervisor/director of studies/tutor	91	27%	44	27%	47	28%
	UCS counsellor/mental health advisor	66	20%	31	19%	35	21%
	College nurse/counsellor"	60	18%	34	20%	26	16%
	GP	57	17%	26	16%	31	19%
	External professional counsellor/psychotherapist/psychologist	40	12%	22	13%	18	11%
	Psychiatrist	19	6%	10	6%	9	5%
	Other	16	5%	12	7%	4	2%
	Chaplain	15	5%	8	5%	7	4%
	Complementary medicine	14	4%	5	3%	9	5%
	Helpline, nightline, Samaritans	7	2%	4	2%	3	2%
	Emergency services	3	1%	1	1%	2	1%
	Used any resource	169	51%	88	53%	81	49%
	Number of resources per user among users (median range)	2	8	2	8	2	7
Workload perceived as manageable	Definitely agree	51	15%	30	18%	21	13%
(nMSS=165 , nSAU=166)	Mostly agree	136	41%	66	40%	70	42%
	Neither Agree nor Disagree	51	15%	20	12%	31	19%
	Mostly Disagree	68	21%	37	22%	31	19%
	Definitely Disagree	25	8%	12	7%	13	8%

39	(nMSS=179 , nSAU=169)	One-year cumulative count of adverse events	60	28	32
40					
41					
42					
43					
44					
45					
46					

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

Altruism	Participants donating at one-year follow-up	191	57%	109	65%	82	49%
(nMSS=168, nSAU=167)	One-year cumulative count of donations	679		403		276	

Showing n(%) unless otherwise stated. Abbreviations: GP= general practitioner; MSS=mindfulness skills for students; SAU=support as usual; UCS=University Counselling Service.
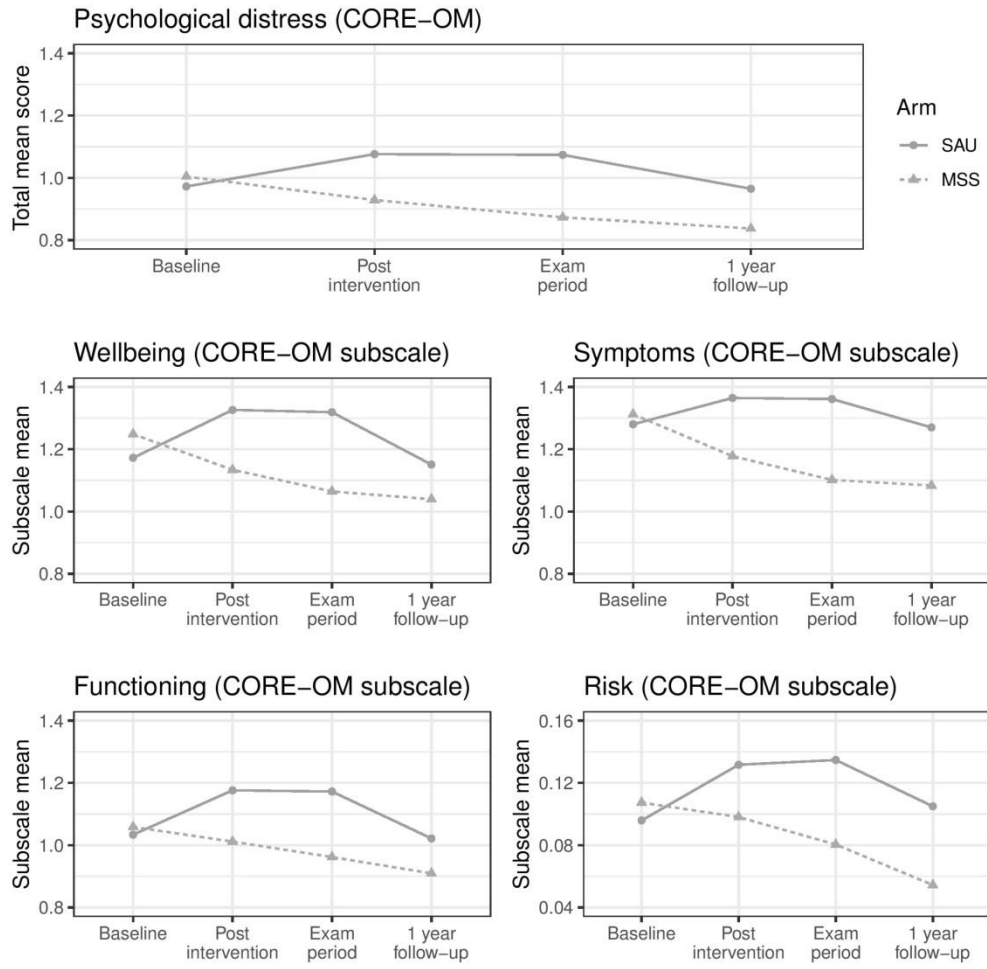
Figure legends

Figure 1. Multiple group growth model trajectories for psychological distress outcome (CORE-OM total mean and its sub-scales: Wellbeing, Symptoms, Functioning, and Risk).

Figure 2. Multiple group growth model trajectories for wellbeing outcome (WEMWBS).

Figure 3. Frequency of formal (top) and informal (bottom) mindfulness practice at home at each time point.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1. Multiple group growth model trajectories for psychological distress outcome (CORE-OM total mean and its sub-scales: Wellbeing, Symptoms, Functioning, and Risk).

177x177mm (300 x 300 DPI)
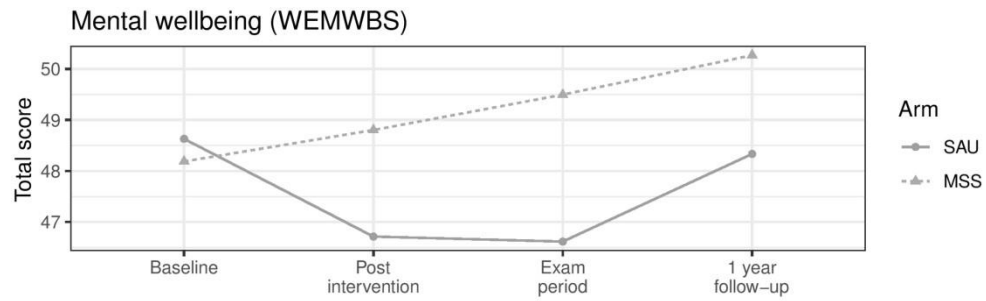
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 2. Multiple group growth model trajectories for wellbeing outcome (WEMWBS).
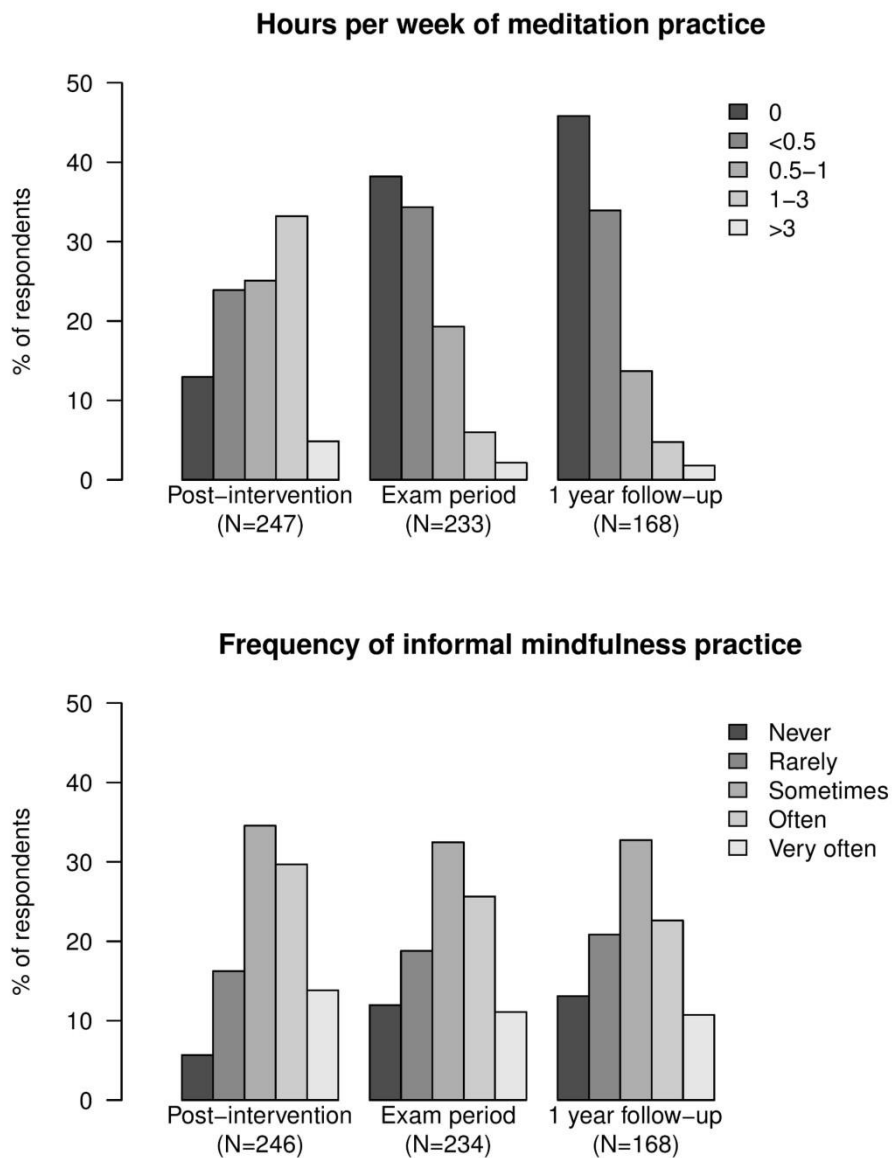177x59mm (300 x 300 DPI)

Figure 3. Frequency of formal (top) and informal (bottom) mindfulness practice at home at each time point.

157x210mm (300 x 300 DPI)

Effectiveness of providing university students with a mindfulness-based intervention to increase resilience to stress: one-year follow-up of a pragmatic randomised controlled trial

Julieta Galante, Jan Stochl, Géraldine Dufour, Maris Vainre, Adam P Wagner, Peter B Jones

Supplementary Materials

Supplementary Methods: Pre-processing practice data

Mindfulness practice data required pre-processing for inclusion within models. Questions had frequency Likert scales transformed to numeric values. For formal meditation practice, the MSS group was asked how much they had practiced in an average week, while the SAU group was asked about the total amount of meditation within the specified period. Response items consisted of hour ranges (e.g. "Between 0.5 and 1h per week"). In order to estimate a figure representing hours of practice we took a mid-value of the range for control and intervention options, then for the intervention participants who were asked how much they had practiced on an average week, we multiplied the weekly value by the number of weeks in the period. For the post-intervention meditation practice calculation in the intervention group, we also added half an hour of meditation for each course session attended (only added in the dose-response models).

In the model assessing the effect of formal mindfulness practice, we included all trial participants because we have meditation data for the control group as well as the intervention group. The model assessing informal mindfulness practice only included intervention participants since there is no data collected on this in the SAU group.

Supplementary Tables

Supplemental Table 1. Outcome measures reported in this publication with the time points at which data for each was collected.

Type of data collected	Baseline	Post-intervention	Exam period	One-year follow-up
Demographics & prior meditation	X			
Attendance at mindfulness courses (MSS arm)		X		
Mindfulness course homework (MSS arm)		X		
Practised after the course (MSS arm)			X	X
Practised meditation elsewhere (SAU arm)		X	X	X
Psychological distress	X	X	X	X
Wellbeing	X	X	X	X
Donations		X	X	X
Use of mental health services				X
Use of University Counselling Service				X
Workload manageable				X

Abbreviations: MSS=mindfulness skills for students; SAU=support as usual

2

**Supplemental Table 2. UCS services according to the intensity of the support they provide**

Intensity level	UCS resource
1	Assertiveness Group
	MPhil Group
	Returners Group
	Returners - Anxiety
	Returners - Self Compassion
	Returners - Time Management
	Workshop - Anxiety
	Workshop - CBT for self-help
	Workshop - Exam Preparation
	Workshop - Food and mood
	Workshop - Panic attacks
	Workshop - Procrastination
	Workshop - Self-compassion
	Workshop - Sleep
	Workshop - Social anxiety
2	Counselling
	Assessment
	Bereavement Group
	Client Contact by Phone or Email
	Managing Mood Group
	Perfectionism Group
	Postgraduate Group
	Self-esteem Group
	Undergraduate Group
3	Mental Health Advisor - Assessment
	Mental Health Advisor - Ongoing

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Supplemental Table 3. Use of University Counselling Service: differences between intervention and control groups by levels of support (hierarchical multinomial logit model).

UCS support type	Estimate	SE	P value	OR	OR 95%CI
High vs low	-2.05	0.87	0.02	0.13	0.02 to 0.72
High vs middle	-1.51	0.77	0.05	0.22	0.05 to 1.00
Low vs middle	0.54	0.46	0.24	1.71	0.70 to 4.20

Abbreviations: 95%CI= 95% confidence interval; OR=odds ratio; UCS= University Counselling Service.
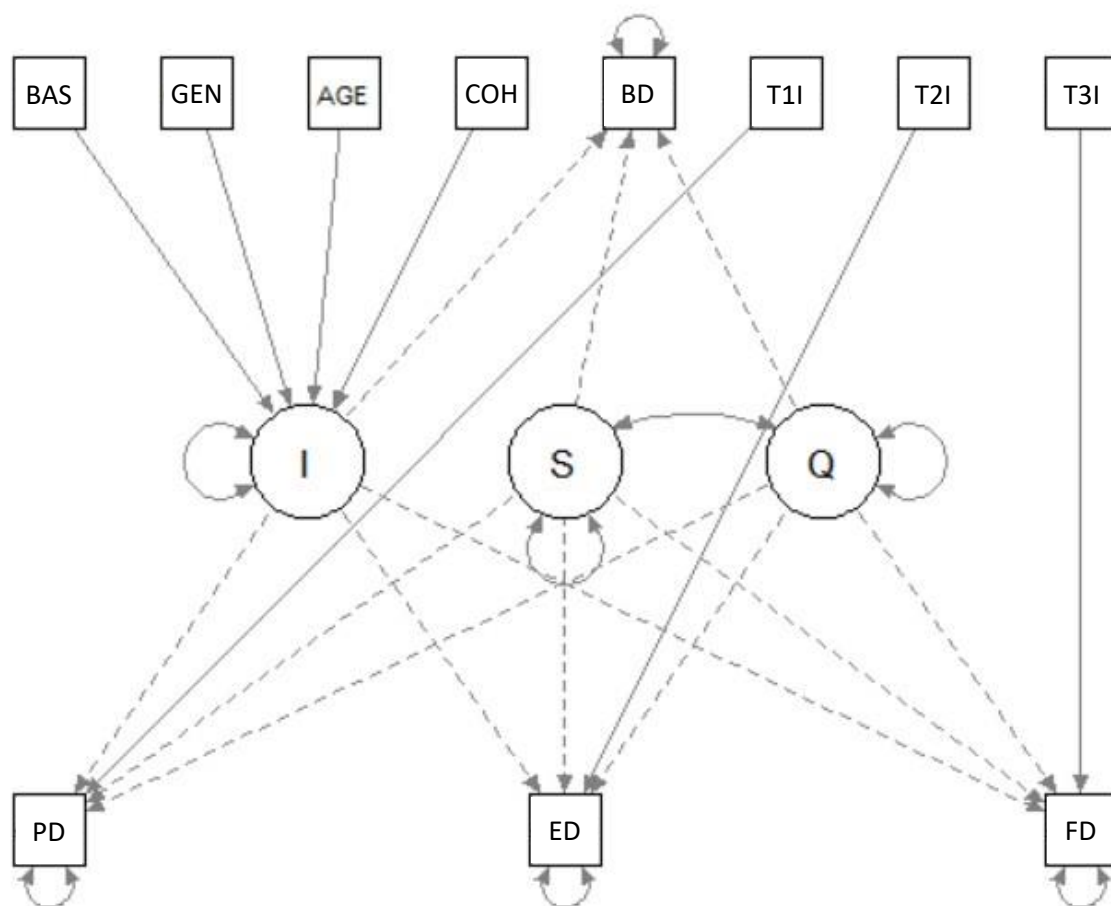
Supplementary Figures
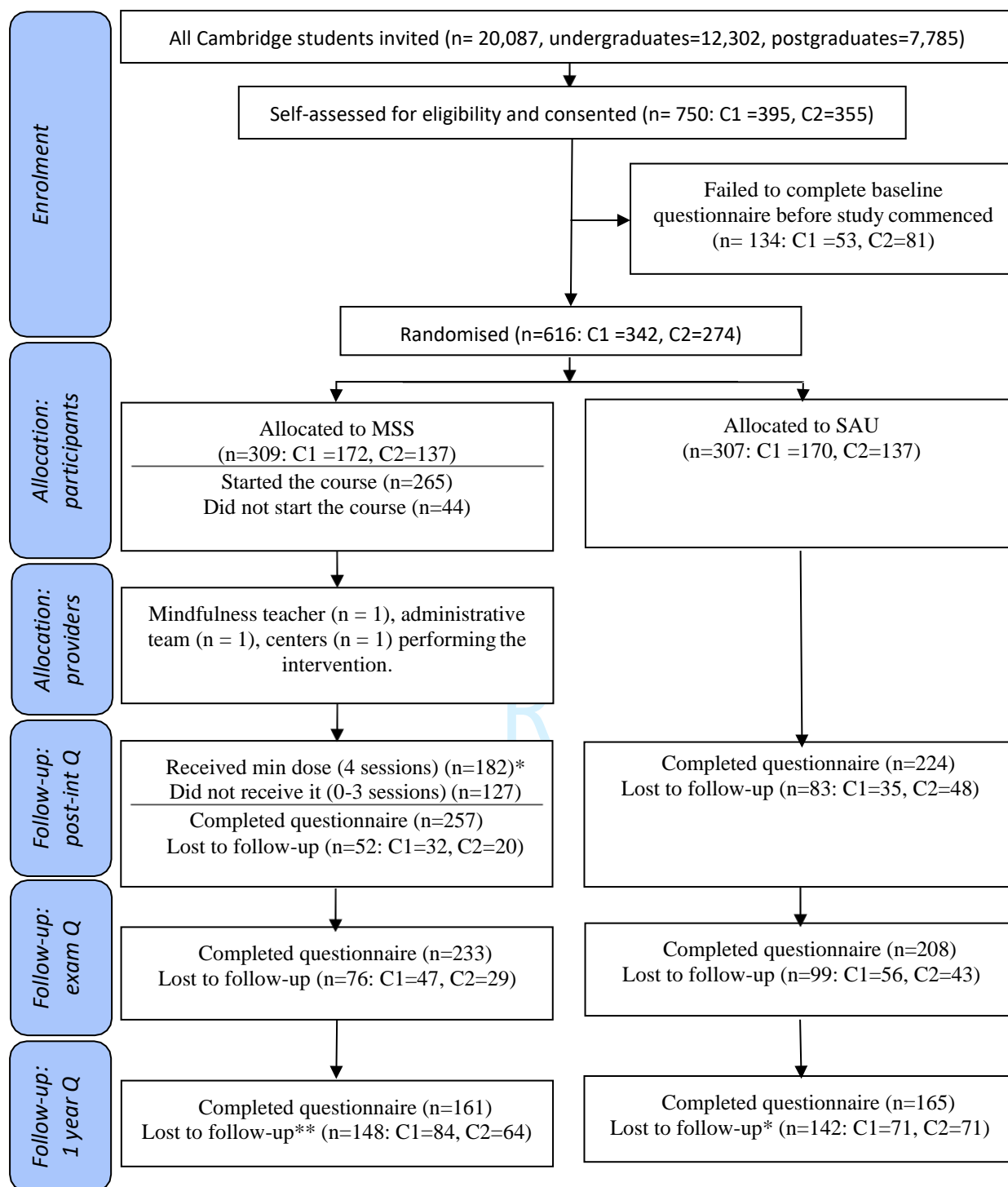
Supplemental Figure 1. CONSORT 2010 flow diagram. See text and tables for number of participants included in each analysis. * A minimum dose of four sessions is typically suggested in mindfulness research (Gu et al. 2015). ** No reasons were given for non-completion. Abbreviations: C1= study cohort 1; C2= study cohort 2; min= minimum; Q= questionnaire; post-int= post intervention, MSS=mindfulness skills for students; SAU=support as usual.
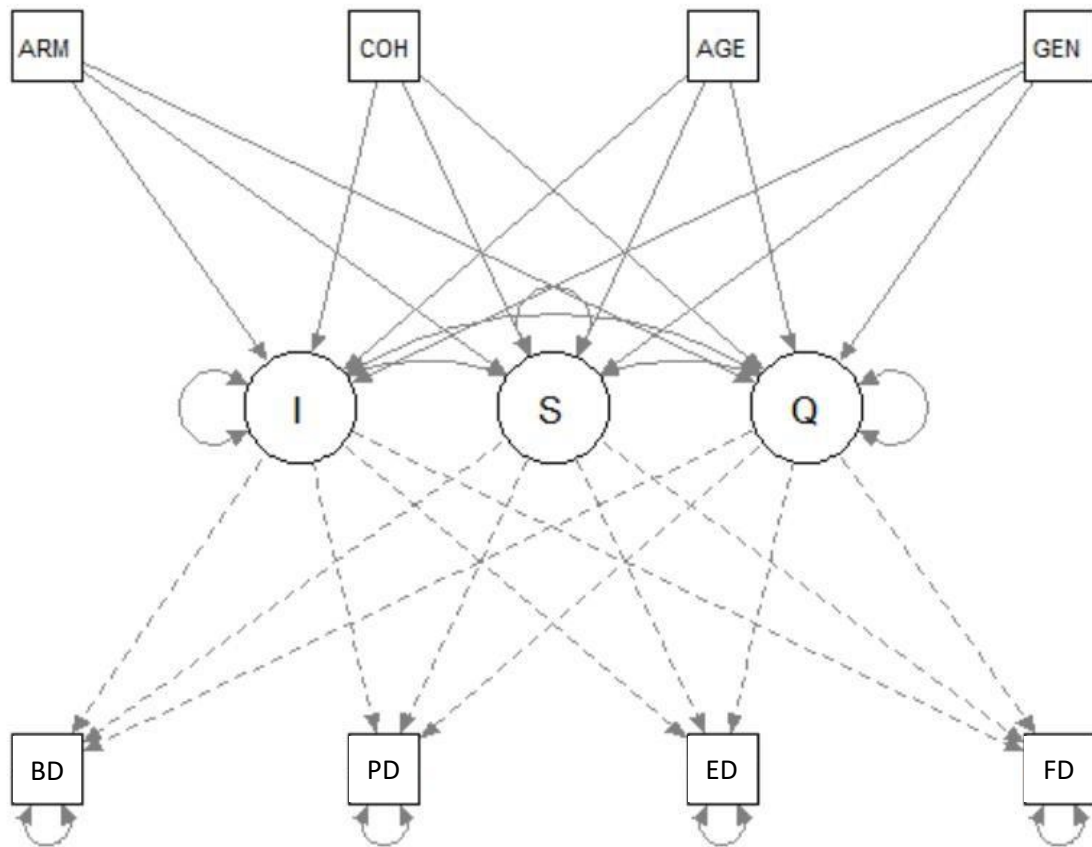
Supplemental Figure 2. Growth mixture model conceptual path diagram for outcome psychological distress. Dashed lines are fixed parameters whereas solid lines are estimated in the model. See Byrne 2010 or Mirman 2014 (references in the main text) for further detail on such models. Abbreviations: COH=cohort; GEN=gender; I=intercept; S=slope; Q= quadratic term; BD=baseline distress (CORE-OM); PD=post-intervention distress (CORE-OM); ED=exam-term distress (CORE-OM); FD=follow-up distress (CORE-OM).

Galante et al. – Supplementary Materials
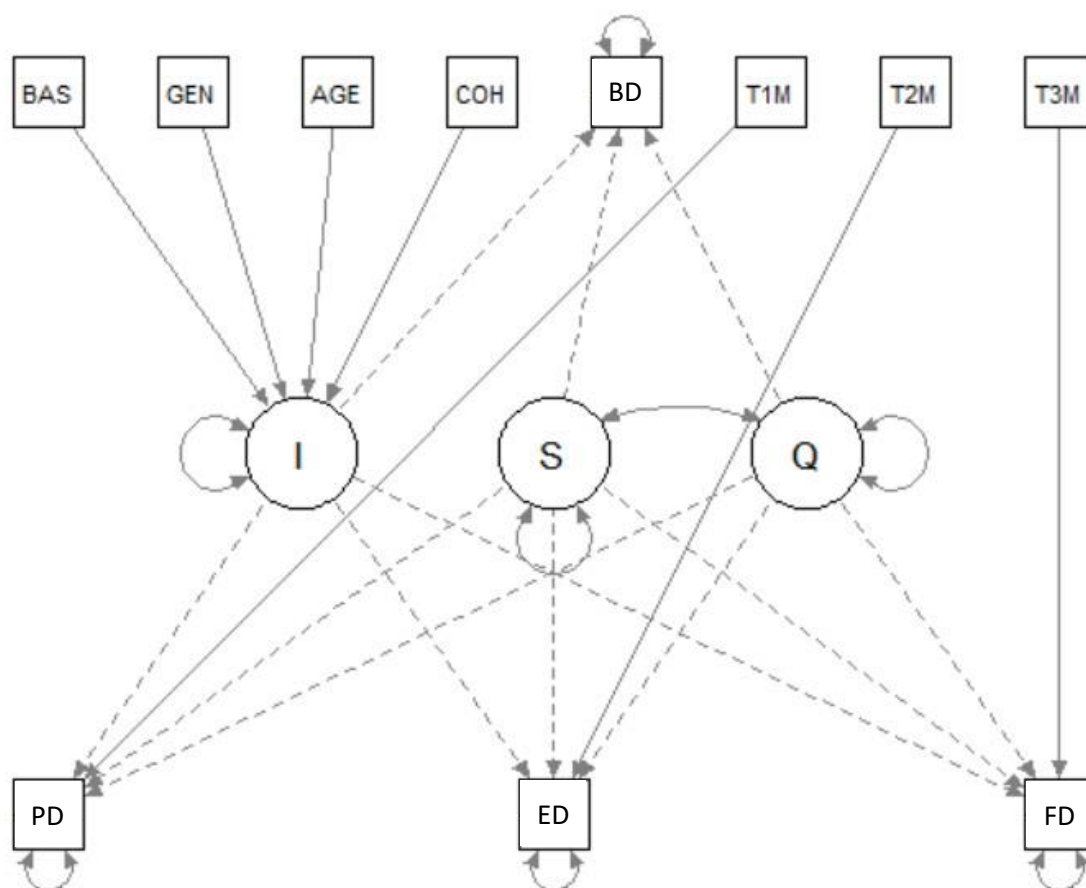
Supplemental Figure 3. Growth mixture model conceptual path diagram testing the influence of meditation practice (time-varying co-variates) on psychological distress. Dashed lines are fixed parameters whereas solid lines are estimated in the model. See Byrne 2010 or Mirman 2014 (references in the main text) for further detail on such models. Abbreviations: BAS=baseline (prior) meditation experience, COH=cohort; GEN=gender; I=intercept; S=slope; Q=curve; BD=baseline distress (CORE-OM); T1M=meditation measured at post-intervention; T2M=meditation measured during exam term; T3M=meditation measured at one-year follow-up; PD=post-intervention distress (CORE-OM); ED=exam-term distress (CORE-OM); FD=follow-up distress (CORE-OM).

Galante et al. – Supplementary Materials

Supplemental Figure 4. Growth mixture model conceptual path diagram testing the influence of informal mindfulness practice (time-varying co-variates) on psychological distress. See Byrne 2010 or Mirman 2014 (references in the main text) for further detail on such models. Abbreviations: BAS=baseline (prior) meditation experience, COH=cohort; GEN=gender; I=intercept; S=slope; Q=curve; BD=baseline distress (CORE-OM); T1I=informal mindfulness measured at post-intervention; T2M=informal mindfulness measured during exam term; T3M=informal mindfulness measured at one-year follow-up; PD=post-intervention distress (CORE-OM); ED=exam-term distress (CORE-OM); FD=follow-up distress (CORE-OM).