

A randomised controlled trial of the effects of mindfulness practice on medical student stress levels

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OBJECTIVE This study aimed to determine whether the practice of mindfulness reduces the level of stress experienced by senior medical students.

METHODS We carried out a multicentre, single-blinded, randomised controlled trial with intention-to-treat analysis in three clinical schools attached to the University of Tasmania, Hobart, Tasmania. Participants included 66 medical students in their final 2 years of study in 2009. Participants were block-randomised to either an intervention or a usual care control group. The intervention used an audio CD of guided mindfulness practice designed and produced for this trial. Participants were advised to use the intervention daily over the 8 weeks of the trial. All participants completed two self-report questionnaires, at baseline and at 8 weeks, respectively. The intervention group also completed a questionnaire at 16 weeks to provide follow-up data. The primary outcome measure was the difference over time in scores on the Perceived Stress Scale (PSS). The secondary outcome measure referred to differences over time in scores on the subscales of the Depression, Anxiety and Stress Scale (DASS).

RESULTS Mean baseline scores on the PSS and the stress component of the DASS were 15.7 (maximal score of 40) and 13.2 (maximal score of 42), respectively, both of which exceed scores in age-matched normative control data. Using multivariable analysis, participants in the intervention group demonstrated significant reductions in scores on the PSS (-3.44 , 95% confidence interval [CI] -6.20 to -0.68 ; $p < 0.05$) and the anxiety component of the DASS (-2.82 , 95% CI -4.99 to -0.64 ; $p < 0.05$). A borderline significant effect was demonstrated on the stress component of the DASS (-3.69 , 95% CI -7.38 to 0.01 ; $p = 0.05$). Follow-up at 8 weeks post-trial revealed that the effect was maintained.

CONCLUSIONS Mindfulness practice reduced stress and anxiety in senior medical students. Stress is prevalent in medical students and can have adverse effects on both student health and patients. A simple, self-administered, evidence-based intervention now exists to manage stress in this at-risk population and should be widely utilised.

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INTRODUCTION

The World Health Organization¹ defines health not just as the absence of disease, but as 'a state of complete physical, mental and social well-being'. In a university medical degree course in which students are taught about managing the health of others, there is an imperative to provide them with effective, evidence-based ways to manage their own stress.² Stress and psychological distress in doctors and medical students are common and are well recognised as important health issues.^{3,4} However, further research is required to identify effective interventions for managing this stress.⁵

Mindfulness-based stress reduction (MBSR) has been shown to be an effective evidence-based intervention to reduce stress in a variety of clinical and non-clinical populations, but it has not yet been subjected to rigorous analysis as a stand-alone intervention in doctors and medical students.^{6–8} Mindfulness is defined as 'the awareness that emerges through paying attention on purpose, in the present moment, and non-judgementally to the unfolding experience moment by moment'.⁹

Medical student well-being has implications for patient care and safety. The incidence of burnout, linked with psychological distress, rises steadily across the final years of undergraduate medical training and continues into internship.¹⁰ There is also a relationship between doctor distress or depression and medical error.^{11,12} To help ensure patient and doctor safety, we need to focus on developing effective, evidence-based interventions to address stress in medical students as an early intervention strategy.

Our trial sought to take an evidence-based therapy and apply it to a sample of medical students representing a population shown to be in need of an effective stress management intervention.¹³ This study adds to the existing literature by utilising a single-blinded, randomised control design to study the benefits of one specific self-directed mindfulness intervention for stress management in medical students.

METHODS

Study design

We conducted a multicentre, single-blinded, randomised controlled trial (RCT) with intention-to-treat analysis.

Participants

Eligible participants were medical students in their final 2 years of their degree course, distributed across three clinical schools attached to the University of Tasmania, Hobart, Tasmania, in 2009. Participants were recruited via a face-to-face information session and an e-mail inviting participation in the trial. Participants provided written consent. They were screened to exclude individuals with potentially significant psychological distress in need of immediate assessment and management, using the K10 questionnaire.¹⁴ The K10 is a questionnaire developed to screen for psychological distress. A person with a K10 score of ≥ 30 has 10 times the population risk of meeting the criteria for an anxiety or depressive disorder.¹⁵ Exclusion criteria were participation in the pilot trial or a K10 score of ≥ 30 .

This trial received ethics approval from the University of Tasmania Human Research Ethics Committee. It ran from June 2009 to October 2009.

Intervention

The intervention comprised an audio compact disc (CD) of guided mindfulness practice designed and produced for this trial. The CD contained 30 minutes of spoken guided mindfulness practice which participants were asked to follow independently every day over a period of 8 weeks. Adherence to the intervention was ascertained by a diary recording whether or not the intervention was used on each day of the 8-week trial period. All participants across all locations commenced the intervention or control period and completed the questionnaires within the same week. The mindfulness intervention CD was given to the control group at the end of the 8-week trial period as an incentive to remain in the trial.

Objectives

This trial aimed to determine whether mindfulness practice reduces the stress of senior medical students.

Outcomes

Outcome tools used were the Perceived Stress Scale (PSS) and the Depression, Anxiety and Stress Scale (DASS). These are validated, self-reported, publicly available and widely used psychological instruments for measuring stress.^{16,17} The PSS is a psychological instrument used for measuring the perception of stress.¹⁸ It was chosen for this trial because

perception plays an important role in stress. Psychological stress has been defined as occurring when an individual perceives that environmental demands tax or exceed his or her adaptive capacity.¹⁹ The 10-item version of the scale was chosen for this trial. Each item asks the participant to appraise his or her feelings and thoughts using a 5-point Likert scale (0 = never, 4 = very often). A maximal score of 40 indicates high perceived stress. The DASS is a set of three self-report scales designed to assess the severity of the core symptoms of depression, anxiety and stress, respectively.¹⁶ Each DASS scale contains 14 items, each of which is scored on a 4-point severity or frequency scale (0 = did not apply to me at all, 3 = applied to me very much or most of the time). The maximal score on each scale is 42 and indicates severe depression, anxiety or stress, respectively. The 42 items are listed in random order in the questionnaire. The stress scale detects levels of non-specific arousal. It assesses: difficulty in relaxing; nervous arousal and being easily upset or agitated; irritability or overreaction, and impatience. The anxiety scale assesses: autonomic arousal; skeletal muscle effects; situational anxiety, and subjective experiences of anxious effect. The depression scale assesses: dysphoria; hopelessness; devaluation of life; self-depreciation; lack of interest; anhedonia, and inertia. The DASS was chosen for its capacity to discriminate between these three states and to indicate severity. The DASS scale manual defines stress as 'a persistent state of over-arousal which reflects continuing difficulty in meeting taxing life demands'.¹⁶ Data from these two questionnaires were collected at baseline (T1) and at the end of the 8-week trial period (T2) from all participants. The primary outcome was the difference over time in PSS scores. The DASS scores were analysed as secondary outcomes. Follow-up data were collected at 8 weeks after the end of the intervention (16 weeks from commencement of the trial; T3) in the intervention group to investigate the ongoing effect of the intervention.

Sample size calculation

The target sample size for the trial was 42 students per group (control and intervention). This number is based on data from a previous study of university students, which found a mean pre-test PSS score of 18.11 (standard deviation [SD] 6.19).²⁰ These data are consistent with findings from the small unpublished pilot trial undertaken in our cohort last year. The trial was powered to detect a 4-point difference (SD 0.6) in PSS score, using a two-tailed test, $\alpha = 0.05$ and power = 0.80, and allowing for a 10% dropout

rate. The cohort from which we recruited our participants numbered 194 students.

Randomisation and blinding

Eligible participants were randomised centrally, using block randomisation with block sizes of two, to the intervention arm or the usual care control arm. Randomisation was not blinded to the individual participant because of the nature of the intervention. Participant packs were prepared centrally. All packs contained a CD cover so that trial packs in the two arms of the study looked identical. The purpose of this was to conceal allocation. Both the research assistant who scored and entered data and the statistician who analysed the results were blinded to group allocation. Participants were specifically advised not to inform others about which group they were in and not to discuss the intervention. Participants were also advised not to give the intervention to anyone else.

Statistical analysis

Results were analysed on an intention-to-treat basis. We compared psychological outcomes across the two arms at baseline and again after the 8-week intervention period. We used *t*-tests and chi-squared tests to compare differences in means and proportions as appropriate. Random-effects mixed-model analysis was used to account for correlated readings within each individual over time and examine the associations between each outcome and study arm (intervention versus control). A significant interaction effect of outcome by arm was interpreted as a significant effect of the intervention. Because of the relatively small numbers in each group, each analysis was also adjusted for age and gender. Standard diagnostic checks of model adequacy and unusual observations were performed. A *p*-value of < 0.05 (two-tailed) was considered statistically significant. All statistical analyses were performed using Intercooled Stata Version 10.0 for Windows (StataCorp LP, College Station, TX, USA).

RESULTS

Participants

Of the 66 participants recruited, 32 were randomised to the treatment arm and 34 to the control arm (Fig. 1). All participants met the eligibility criteria for the trial and were recruited in the 4-week period prior to the trial commencing. One participant

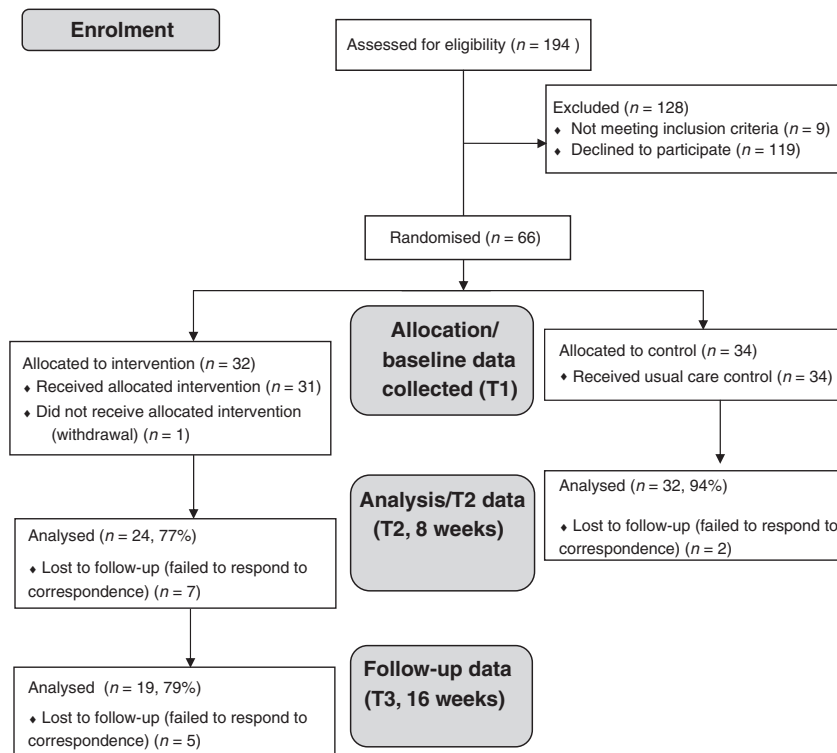


Figure 1 Progress of participants through the trial

withdrew from the trial after it began. This participant had been allocated to the intervention arm, but withdrew before any data had been collected. Baseline data (T1) were collected for all 65 remaining participants.

Baseline characteristics

Table 1 presents the demographics and outcome scores of participants at baseline. There were no statistically significant differences between the two

*Table 1 Characteristics of participants by study arm at baseline**

	Total (n = 65)	Control group (n = 34)	Intervention group (n = 31)	p-value* (control versus intervention)
Mean age (SD), years	23.92 (3.2)	24.4 (4.0)	23.4 (2.1)	0.18
Female sex, n (%)	42 (64.6)	19 (55.9)	23 (74.2)	0.12
Mean PSS score (SD) [†]	15.7 (5.7)	15.0 (4.8)	16.5 (6.5)	0.29
Mean DASS depression subscale score (SD) [‡]	6.2 (6.3)	5.5 (5.6)	6.9 (7.0)	0.39
Mean DASS anxiety subscale score (SD) [‡]	7.1 (6.7)	6.3 (6.9)	8.1 (6.5)	0.27
Mean DASS stress subscale score (SD) [‡]	13.2 (7.7)	12.3 (6.6)	14.3 (8.7)	0.31

* p-values were determined by t-test or chi-squared test as appropriate

[†] The maximal score on the Perceived Stress Scale is 40

[‡] Maximal scores on the depression, anxiety and stress subscales of the DASS are each 42

SD = standard deviation; PSS = Perceived Stress Scale; DASS = Depression, Anxiety and Stress Scale

arms at baseline in either demographics or baseline outcome scores. Compared with age-matched normative controls, the participants in this trial had higher baseline scores for stress and anxiety.¹⁶ Despite this, mean depression, anxiety and stress scores were still within the normal range of severity ratings, although at the upper end of this range.¹⁶ Normative sample means on the DASS subscales for the 20–29-year-old age group are: 6.35 (SD 6.85, range: 0–9) for depression; 4.77 (SD 4.79, range: 0–7) for anxiety, and 11.19 (SD 8.25, range: 0–14) for stress. The mean (SD) score on the PSS across all participants was 15.7 (5.7) out of a possible maximal score of 40. The age-matched normative mean (SD) score on the PSS is 14.2 (6.2). The PSS is a numerical scale and is analysed on degree of change over time.

Outcome

Table 2 presents the longitudinal change in outcome over time between study arms and shows a statistically significant decrease in scores on the PSS and the anxiety scale of the DASS in participants who received the intervention. It also shows a borderline significant decrease in scores on the stress component of the DASS. Results were analysed on an intention-to-treat basis. Missing data were treated as absent and were not assigned a score. No participants were excluded from the analysis. Given the difference in dropout rates between the intervention and control arms, data were analysed to look for any statistical difference in those who did not complete T2 data. We found no statistically significant difference in age, sex or baseline scores for perceived stress, depression, anxiety or stress in participants who dropped out of the trial, suggesting that they left at random. There were no reported adverse effects of the intervention. Data on adherence to the intervention protocol were

sought; however, only 64% (20/31) of participants completed this record of practice over the 8 weeks of the intervention. Participants were instructed to undertake the intervention daily, for 30 minutes, over the 56 days of the trial period. The mean number of days the mindfulness intervention was undertaken by participants who completed the adherence to intervention record was 26.7 (range: 0–52 days).

Post-trial follow-up

Table 3 presents the follow-up (T3) data in the intervention group. The effect was maintained at follow-up in that the mean level of each outcome at week 16 did not significantly differ from the mean level of outcome at week 8. In fact, there was a small decrease in the mean level of all measures, as shown in Table 3. The T3 data were collected within weeks of the end-of-year assessments, which is probably a stressful period. There was no trial requirement for participants to continue the intervention in the 8-week post-trial follow-up period. However, we did seek data to analyse how many participants chose to continue with the mindfulness intervention. All participants who completed T3 data completed the record of ongoing practice; 68% (13/19) of participants reported no ongoing sessions. The six participants who continued to use mindfulness sessions reported using the intervention on a mean of 12.2 days out of a possible 56 days (range: 3–29 days).

DISCUSSION

The trial findings show that practice of mindfulness can significantly lower stress and anxiety in senior medical students. In multivariable analysis, participants in the intervention group demonstrated

Table 2 Longitudinal change in outcomes over time between the control and intervention arms

Outcome measure	Univariable (95% CI)	Multivariable (95% CI)*
Perceived Stress Scale score	– 3.41 (– 6.18 to – 0.65)	– 3.44 (– 6.20 to – 0.68)
DASS depression subscale score	– 2.02 (– 4.58 to 0.54)	– 2.03 (– 4.58 to 0.53)
DASS anxiety subscale score	– 2.83 (– 5.01 to – 0.65)	– 2.82 (– 4.99 to – 0.64)
DASS stress subscale score	– 3.67 (– 7.38 to 0.04)	– 3.69 (– 7.38 to 0.00) [†]

Values given in bold denote statistically significant results ($p < 0.05$)

* Adjusted for age, sex

[†] $p = 0.050$

95% CI = 95% confidence interval; DASS = Depression, Anxiety and Stress Scale

Table 3 Follow-up effect of the intervention. Longitudinal change in outcomes over time from post-intervention (T2) to post-trial follow-up, at 8 weeks after the end of the intervention (16 weeks from baseline, T3)

Outcome measure	Univariable (95% CI)	Multivariable (95% CI)*
Perceived Stress Scale score	- 0.63 (- 2.87 to 1.62)	- 0.65 (- 2.89 to 1.59)
DASS depression subscale score	- 0.79 (- 3.13 to 1.55)	- 0.88 (- 3.25 to 1.48)
DASS anxiety subscale score	- 0.38 (- 2.48 to 1.72)	- 0.43 (- 2.53 to 1.68)
DASS stress subscale score	0.27 (- 2.71 to 3.25)	0.25 (- 2.73 to 3.23)

Values given in bold denote statistically significant results ($p < 0.05$)

* Adjusted for age, sex

95% CI = 95% confidence interval; DASS = Depression, Anxiety and Stress Scale

significant reductions in scores on the PSS (- 3.44, 95% confidence interval [CI] - 6.20 to - 0.68); $p < 0.05$) and the anxiety component of the DASS (- 2.82, 95% CI - 4.99 to - 0.64; $p < 0.05$). A borderline significant effect was demonstrated for scores on the DASS stress scale (- 3.69, 95% CI - 7.38 to 0.01; $p = 0.050$). No effect was found on the DASS depression scale. Follow-up at 8 weeks post-trial revealed the effect was maintained. Although the study population was not clinically unwell, they demonstrated higher levels of stress than those in age-matched normal subjects. Therefore, the intervention effect demonstrated represents a clinically worthwhile reduction in this population.

The results of this trial are consistent with the findings of other studies, but the trial benefits from the superior study design of a single-blinded RCT. Firstly, it confirms the already well-studied hypothesis that medical students experience higher levels of stress than their age-matched peers. Mean baseline scores on the PSS and the stress scale of the DASS were 15.7 (maximal score of 40) and 13.2 (maximal score of 42), respectively. These scores exceed those of age-matched normal controls and are consistent with findings in a systematic review carried out in 2006 which indicated that medical students experience significant psychological distress.³ This trial adds further evidence for the use of mindfulness as an effective stress management tool. A meta-analysis has looked at the ability of MBSR to reduce stress levels in individuals and results suggest that it may help a broad range of people to cope with problems.⁶ A literature review looking specifically at the impact of mindfulness on stress found MBSR to be a safe and effective approach for dealing with stress.⁷

There is an established need to develop stress management resources for medical students. Dunn

*et al.*⁴ conducted a literature review of medical student stress from which they concluded a need to provide resources and opportunities for medical students to become more aware of their own health and well-being and to develop coping strategies. A large survey exploring the views of medical students on the teaching of well-being and support services for managing stress identified 'self-help techniques for coping with stress and distress' as among their top three learning priorities.² There are also wider potential benefits. If medical students learn a stress reduction approach, such as mindfulness, as part of their medical education, they may incorporate this in approaches to treatment of future patients.

The effects of mindfulness in medical students have been investigated previously, although there are limitations within the current literature. Most studies have investigated multifaceted interventions or have not used rigorous methodology. Two earlier RCTs conducted in American medical students involved multiple interventions, including mindfulness.^{20,21} The study by Oman *et al.*²⁰ also utilised the PSS as the outcome measure for studying the effects of an MBSR intervention. These authors found an effect size of - 2.78 ($p = 0.04$).²⁰ However, their intervention was multifaceted, and included group meetings, mindfulness practice and discussion; thus, it is not possible to say which component was useful or whether all are required simultaneously. The RCT carried out by Jain *et al.*²¹ looked at mindfulness training versus relaxation training and found that both groups experienced significant decreases in stress compared with the control group. One possible bias in this study²¹ refers to the self-selection of student participants according to their current experiences of a significant amount of stress. Rosenzweig *et al.*²² found evidence that an MBSR programme lowered psychological distress in medical

students. The results were positive and suggested a use for mindfulness as an effective stress management tool in medical students; however, this was a non-randomised, cohort-controlled study.²² A systematic review by McCray *et al.*⁵ examined 129 articles, but only nine of the studies reported satisfied the authors' inclusion criteria. They noted that two of the studies that showed positive effects used meditation-type interventions, but they advised cautious interpretation in the face of less rigorous methods. Two of these studies were randomised and both used multifaceted interventions.^{23,24} Recently published data confirm the benefits of a mindfulness and self-care programme in the Australian medical student context, but the study from which they are sourced was limited by the lack of a control group and the multifaceted nature of the intervention precludes further interpretation as to which specific components confer benefit.⁸

To our knowledge, the present report describes the first RCT to examine a stand-alone, self-directed mindfulness intervention for stress management in medical students. No group work was undertaken. It also accepted participants with a wide range of baseline stress scores. Although the mean stress score at baseline was above that for age-matched normative control material, our sample included participants with low baseline levels of stress and anxiety.

The ongoing post-trial follow-up data also provide interesting information. No statistically significant decrease is apparent, but it is clear that the effect of the intervention was maintained. This suggestion of a trend towards a small ongoing effect becomes more significant when we acknowledge that the data were collected within a few weeks of the participants' end-of-year assessments.

Limitations

The small sample size, modest adherence and short period of follow-up applied in this study may limit conclusions on the utility of the intervention. However, evidence of a sustained effect was apparent despite these limitations. We did not include a physiological measure of stress. The nature of the intervention made it impossible to blind participants.

CONCLUSIONS

Mindfulness practice reduced stress and anxiety in senior medical students. Stress is prevalent in medical students and can have adverse health effects on both

students and their patients, both now and in the future. A simple, self-administered, evidence-based intervention now exists to manage stress in this at-risk population and should be widely utilised. It can be further researched in other at-risk populations, including doctors and other health professionals, stress in whom may have substantial impact on the effectiveness of clinical practice.

Contributors: EW served as primary researcher and contributed to the conception and design of the study, the acquisition, analysis and interpretation of data, and the drafting of the article. SQ is a biostatistician and contributed to the conception and design of the study and interpretation of data. KO contributed to the conception and design of the study, and to the acquisition and interpretation of data. NT contributed to the acquisition of data. MRN served as a supervising professorial fellow and contributed to the conception and design of the study. All authors contributed to the critical revision of the article and approved the final manuscript for publication.

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