STUDY PROTOCOL

Study Protocol: A Cluster Randomized Controlled Trial of Mindfulness Intervention to Reduce Low Back Pain, Psychological Symptoms and Enhance Work Productivity Among Academics in Malaysian Tertiary Education

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ABSTRACT

Introduction: Despite the acknowledged impact of psychological factors on musculoskeletal pain (MSP), there remains limited evidence supporting the efficacy of mindfulness interventions in addressing this specific issue. Both mental health issues and MSP are prevalent among academics, yet there is a scarce study on the application of mindfulness interventions to these specific concerns. Therefore, we aimed to provide a study protocol that will focus on assessing the impact of mindfulness interventions on alleviating low back pain (LBP) and psychological symptoms and improving work productivity among academics. **Methods:** A single-blind, parallel cluster randomized controlled trial will be conducted on 86 academics in the Northern Region of Peninsular Malaysia. At baseline, all participants must undergo the screening criteria for inclusion which are academics with a cut-off score of ≥16 for anxiety and a cut-off score of ≥11 for depression symptoms, and pain intensity of LBP should be at least ≥35mm. Participants will be randomized at cluster level to receive either mindfulness intervention or control group. The intervention will be given over 5 weeks, with each session lasting 60 minutes/week. Outcome measures such as LBP, depression and anxiety symptoms, and work productivity will be measured at baseline and after 5-weeks. **Discussion:** This trial marks the inaugural investigation into the effect of mindfulness intervention on LBP symptoms, symptoms of depression and anxiety, and work productivity among academics in Malaysian tertiary education. Our findings will significantly contribute to the successful implementation of mindfulness practices in the working setting. **Trial Registration:** NCT06214884
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INTRODUCTION

Mindfulness defined as the awareness that arises by intentionally paying attention to the present moment without judgment (1). The concept of mindfulness intervention was originally introduced by Jon Kabat-Zinn, a post-doctoral medical student at the University of Massachusetts Medical School. He is a dedicated practitioner of mindfulness, firmly convinced that this approach holds the potential to enhance individual psychological well-being. While mindfulness is deeply rooted in Buddhist tradition, it is essential to recognize that contemplative practices are promoted by various religious beliefs. For instance, in Islam, there exists a form of mindfulness contemplative practice known as 'muraqaba.' Contemplative practices encompass a wide array of techniques and activities aimed at fostering focused attention, mindfulness, and profound reflection. These practices are commonly associated with diverse spiritual and philosophical traditions but can also be approached from a secular perspective. Previous studies have established a strong connection between long-term engagement in contemplative practices and enhanced

well-being (2, 3).

Mindfulness intervention has demonstrated its efficacy across various facets of mental health. According to previous meta-analyses, mindfulness-based therapy stands out as a promising approach for addressing anxiety and mood disorders within clinical populations. This conclusion is drawn from an extensive meta-analysis encompassing 39 studies involving a total of 1,140 participants who received mindfulness-based therapy for a spectrum of conditions, including cancer, generalized anxiety disorder, depression, and other psychiatric or medical ailments (4). The findings indicate that mindfulness-based therapy yielded moderate effectiveness in ameliorating anxiety (Hedges' g = 0.63) and mood symptoms (Hedges' g = 0.59) from the outset of treatment to its conclusion in the overall study sample. Meanwhile, in the context of patients dealing with anxiety and mood disorders, the intervention exhibited notably robust effect sizes (Hedges' g) of 0.97 for anxiety improvement and 0.95 for mood symptom enhancement. Notably, these effect sizes remained consistent regardless of the publication year or the number of treatment sessions, and their benefits endured throughout follow-up periods (4).

A search through the PubMed database found that research focusing on mindfulness interventions in the workplace garnered attention in 2012 and the trend has been on the rise through 2022. In addition to assessing the effectiveness of mindfulness intervention on the mental health aspects among employees, several other studies investigate its efficacy in reducing the self-reporting of musculoskeletal disorders (5, 6). Musculoskeletal disorders are commonly reported issues among workers, and these disorders are often characterized as recurring (7). There is evidence suggesting that individuals with chronic musculoskeletal disorders can lead to a decline in workplace productivity.

In a previous study, an adapted mindfulness program was conducted over eight weeks among nursing technicians who were experiencing chronic musculoskeletal pain at a university hospital in Brazil. The results revealed that the mindfulness intervention led to a significant reduction in pain scores, as well as improvements in psychological well-being (reducing depression and anxiety) and a decrease in pain catastrophizing. As a result, there was a notable enhancement in their overall scores related to health-related quality of life (5). In another study, a different intervention was employed, combining mindfulness with physical elements (resistance training specific to affected areas and motor training) and cognitive aspects (health education). This combined intervention was tested among laboratory technicians in Denmark. The results demonstrated a positive significant treatment by time interaction in reducing their pain intensity, compared to a control group. When additional exploratory analyses were carried out independently for each body region, a significant reduction in pain was observed for the neck, shoulders, upper back, lower back, and pain connected to the hands (6).

Despite the well-established clinical evidence and the expanding research focus on mindfulness in workplace contexts, the exploration of mindfulness within the teaching population remains relatively novel. Teaching in a university is a noble profession because the teaching itself contributes greatly to society. However, with great impact comes great responsibility. The great responsibility has caused academics to face mental and emotional strain which eventually affects academics' health. Numerous factors have caused academics to be more likely to report health problems (8). Rising demands for scientific output, the ongoing need to stay informed by participating in congresses and panels, lengthy workweeks that frequently include weekends and holidays, an absence of adequate facilities and working conditions, and technology stress (the body's response to the unavoidable need to adapt to significant technological advancements), to name a few, are some of the factors that contribute to such illness.

In a recent scoping review conducted by Agyapong, Brett-MacLean, Burback, Agyapong, and Wei (2023), various approaches to psychological interventions aimed at reducing stress and burnout among teachers were explored (9). The most frequently studied interventions included Mindfulness-Based Interventions, either alone or in combination with yoga or Cognitive Behavioral Therapy (CBT), followed by Rational Emotive Behavioral Therapy (REBT). It is worth noting that the participants in these studies encompassed primary, secondary, and special education teachers. While the effectiveness of mindfulness-based interventions, CBT, and yoga, whether administered individually or in combination, exhibited promising results, caution should be exercised when generalizing these findings to academics due to the heterogeneity of their work nature.

Based on the fact mentioned above, it is imperative to initiate mindfulness interventions among academics targeting to reduce low back pain, and psychological symptoms and enhance work productivity. As of our latest information, there are no existing programs accessible for this specific implementation in Malaysia. The specific objectives for this trial were as follows

1) To identify the efficacy of the mindfulness intervention in reducing the pain intensity of LBP among academics.
2) To identify the efficacy of the mindfulness intervention in reducing depression and anxiety symptoms among academics.
3) To identify the efficacy of the mindfulness intervention

in improving work productivity among academics..

METHODS

Study design
This is a single-blind, randomized control, parallel trial in which the participants will be randomized into a 1:1 ratio.

Setting
This study will be conducted at the public universities in the Northern region area on the West Coast of Peninsular Malaysia which covers Pulau Pinang, Kedah, and Perlis.

Participants
The study population will be among academics of UiTM campuses located in the Northern region. The participants will be invited to participate in the study voluntarily and need to undergo the screening process for their eligibility.

Inclusion/exclusion criteria
All academics aged 28-50 years old and able to understand the Malay language will be invited to participate in this study. A screening process will be conducted before the participants are invited to this study. The purpose of screening is to obtain the participants who fulfilled the inclusion criteria. Participants will be invited to this study if they report moderate to severe symptoms of anxiety with a cut-off score of ≥16 using Beck Anxiety Inventory (BAI), mild to severe symptoms of depression with a cut-off score of ≥11using Beck Depression Inventory (BDI), and the presence of LBP during the past month with pain intensity should be at least >35mm using Visual analogue scale (VAS).

However, participants who disclosed pregnancy or had the intention to conceive in the near future, had a history of accidents affecting the spinal region, were diagnosed with congenital anomaly of the spine, rheumatoid arthritis, infections of the spine or discs, ankylosing spondylitis, spondylolisthesis, spondylosis, spinal tumor, systemic lupus erythymatosus, or osteoporosis or had either spinal, intra-abdominal or femoral surgery in the previous 12 months will be excluded.

Sample size estimation
G*Power 3.1. is used to compute the sample size estimation based on the specific objectives of interventional studies. The input parameters are pre-set with an alpha of 0.05, two-tailed, and study power of 0.95. We employ for t-tests to examine the difference in means between two independent groups, utilizing the t-test family for hypothesis testing and statistical analysis. For two group trials, we set the allocation ratio is 1:1. Meanwhile, the study effect size (d=0.8) is determined based on the findings of a previous study conducted by (10). In order to prevent the possibility of drop-out and to attain sufficient power, additional 10% has been added. In the end, the target sample size is 86 with 43 participants per group.

Conduct of the study

Screening process
Academic members will be invited to take part in this study through an advertisement sent via staff email. To enroll, participants are required to read the information form thoroughly and provide informed consent if they understand and agree to take part. The study aims to collect data on socio-demographic factors, psychological symptoms, musculoskeletal symptoms, and work productivity.

Upon completion of data collection, all information gathered will be analyzed. Participants who reported moderate to severe anxiety symptoms (with a cut-off score of ≥16), mild to severe depression symptoms (with a cut-off score of ≥11), and LBP intensity of at least >35mm on the Visual Analogue Scale (VAS) were eligible to be invited for an interventional study.

Randomization
Four public universities located on the West Coast of Peninsular Malaysia's Northern region will be selected for this study, forming four clusters based on their geographical location. Clusters A and B will be allocated to the interventional group, while clusters C and D will be allocated to the control group. Eligible participants within each cluster will be invited to participate voluntarily. To prevent bias, participants will not be informed of their cluster's assignment to the treatment or control group. Allocation will follow a 1:1 ratio. Participants will be organized into clusters based on their workplace to minimize intervention contamination and promote better adherence (11).

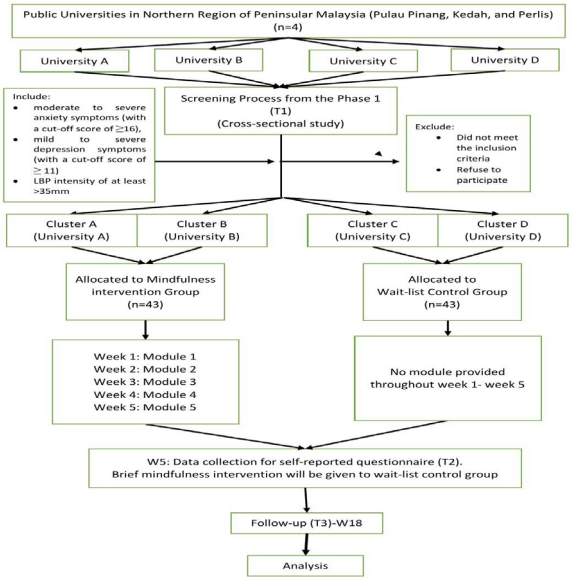

Figure 1: Study Flow chart based on Consolidated Standards of Reporting Trials (CONSORT)

Mindfulness intervention

This intervention program named "MINDFULNESS FOR ALL (MFA)" will be developed on the conceptual basis of traditional mindfulness programs. It includes teachings on the philosophical underpinnings of mindfulness and offered psycho-education on the psychological and neuropsychological mechanisms of action (12). The formal structure closely resembles that of traditional mindfulness programs but has been adapted to cater to the unique needs and demands of employees.

The MFA will take place in a group setting with 20-25 participants per cluster. Due to participants' convenience, the delivery mode of each intervention session would be conducted online. At the end of the session, they will be provided the task and supplementary materials (e-book, short audio, and video) to be applied after the session.

The modules will be delivered by two trainees. Both trainees have received certificates from the mindfulness-based strategic awareness training course. Participants in the intervention group will be joining the modules for five sessions weekly for 60 minutes/session. Details on the modules can be referred in Table I.

Table I: Overview of 'Mindfulness for All' modules for academics

Module	Program Outlines	Hours	Methods
W1- Deepening Day	1. Ice-breaking session 2. Introduction to mindfulness: Enhancing on health and well-being 3. Mindfulness practice and its application	1	1. Two-way interaction between trainer and participants 2. Slides presentation 3. Slides presentation/ Guided mindfulness practice
W2- Practicing self-care with Mindfulness	1. Welcome & recap previous session 2. Topic Introduction a. Understanding self-care and mindfulness 3. Self-care strategies and Mindfulness Practice (Targeted for physical and mental health)	1	1. Two-way interaction between trainer and participants 2. Slides presentation and discussion session 3. Discussion on various self-care strategies and practices that can be applied into daily activities/ Guided self-care visualization exercise.
W3 – Practicing daily life activities with Mindfulness	1. Welcome & recap previous session 2. Topic introduction a. Understanding daily life activities and mindfulness 3. Mindfulness in Everyday activities: When and How?	1	1. Two-way interaction between trainer and participants 2. Slides presentation 3. Slides presentation/Guided practice session
W4 – Integrating mindfulness into your workplace	1. Welcome & recap previous session 2. Topic Introduction a. Understanding mindfulness in the workplace 3. Mindfulness into work tasks 4. Mindful communication and team interaction	1	1. Two-way interaction between trainer and participants 2. Slides presentation 3. Slides presentation/Guided practice session 4. Slides presentation/Guided practice session
W5 - Reflection and commitment for future mindfulness practice	1. Welcome 2. Reflecting on mindfulness journey 3. Goal setting and commitment 4. Resources and Next steps	1	1. Two-way interaction between trainer and participants 2. Appreciative reflection 3. Slides presentation/guided practice session 4. Slides presentation/guided practice session

Wait-list control group

The wait-list control group will receive their training two weeks after the interventional group completes their training. There will be a 90-minute online training session aimed at introducing participants to mindfulness in general and encouraging them to practice mindfulness by teaching several techniques. There will be no potential harm occurring among the subjects in the wait-list control group.

Outcome measurement

A self-administered questionnaire will be used to collect the information. Information that will be collected in this baseline study includes socio-demographic factors such as age, gender, and ethnicity. Besides socio-demographic factors, information on low back pain, psychological symptoms (depression and anxiety), and work productivity will be collected at baseline and after five weeks.

Presence of Musculoskeletal pain

The questions about musculoskeletal pain focused on seven anatomical sites will be adapted based on the Nordic Musculoskeletal Questionnaire. The seven anatomical sites include low back, neck, right or/and left shoulder, right or/and left elbow, right or/and left wrist/hand and right or left knee, and right or left ankle with the binary response (yes/no). The instrument has an acceptable psychometric property and is widely applied in the Malaysian working population (13). During the screening process, participants will be asked whether they had experienced pain for each anatomical site, during the past months that had lasted for longer than a day which were illustrated diagrammatically.

CONTINUE

After the intervention, the occurrence of musculoskeletal pain will be re-assessed by asking whether they had experienced pain for each anatomical site, during the past months that had lasted for longer than a day which were illustrated diagrammatically.

Pain intensity
Visual Analogue Scale (VAS) will be used to measure the participants' pain intensity during the pre and post-test. A VAS is commonly presented with a unidimensional line, usually 100 mm long, starting from 0 'no pain' to 100 'severe intolerable pain'. Participants who reported pain at each anatomical site will be further asked to indicate which point along the line best represents their pain intensity (14).

Absenteeism and Presenteeism
This study will adapt an instrument known as the Work Productivity and Activity Impairment General Health (WPAI-GH) Questionnaire (15). The WPAI-GH aimed to measure work productivity namely absenteeism and presenteeism. This tool has found extensive application in study populations, encompassing both clinical and non-clinical settings (16, 17). In this study, there are five items with a recall period of the preceding month, encompassing the following items including currently employed (Q1), hours missed due to LBP (Q2), hours missed for other reasons (Q3), hours actually worked (Q4), degree of LBP affected productivity while working (Q5).

Absenteeism is defined as the percentage of time missed from work because of LBP and is calculated by the formula Q2/(Q2 + Q4) Ч 100%. Presenteeism is measured by the degree of LBP which affects productivity while working during the past month on a rating scale ranging from 0 " LBP did not affect my working" to 10 "LBP completely prevented me from working". Presenteeism is calculated by the formula (Q5/10) Ч 100% (18). Outcomes absenteeism and presenteeism are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity. Several local studies have adopted the WPAI Questionnaire among various working populations.

Psychological symptoms (Anxiety and Depression)
A Malay-translated version of the Beck Anxiety Inventory (BAI) consisting of 21 items will be utilized in this study to assess the anxiety symptoms. The participants need to respond to each item on a four-point Likert scale, ranging from 0 "not at all" to 3 "severely". The range of total scores is from 0 to 63, with higher numbers suggesting greater degrees of anxiety. The recommended clinical classification of scoring results is as follows: 0–7 suggests minimal anxiety, 8–15 suggests mild anxiety, 16–25 suggests moderate anxiety, and 26–63 suggests severe anxiety. According to the manual, the suggested cut-off for clinically significant anxiety on the BAI is 16 (19). Previous local study has shown that the BAI-Malay version has excellent internal consistency (α=.92) and high test-retest reliability (r=.75) (20).

Meanwhile, a Malay-translated version of the Beck Depression Inventory (BDI) will be used to assess the depression symptoms. It consists of 21 items and each item needs to be answered on a four-point Likert scale, ranging from 0 to 3. Each item was asked about the unique symptoms of depression which are more reflective of the diagnostic criteria that are described by the American Psychiatric Association (APA) (21). The possible range of total score is between 0 – 63. Then, the total score can be categorized into three groups which reflect the severity levels: 0–10 points for "not depressed", 11–17 points for "mild to moderately depressed", and 18–63 points for "clinically relevant depression". Previous study indicated that the current Malay version of the BDI-II is psychometrically strong and appropriate for use in assessing depressive symptomatology among Malaysians (22).

Ethical Clearance
This study was approved by Research Ethics Committee, Universiti Sains Malaysia, USM/JEPeM/21120770.

Data handling and statistical analysis
All the participants' information will be entered into the statistical software using SPSS version 26.0. The data will be cleaned and checked for coding errors. Different enumerators will do the double-entered to check for duplication and outliers before the implementation of statistical analysis.

This study will perform an Independent T-test for continuous data and $\chi 2$ test for nominal and ordinal data to compare the baseline characteristics of participants between the interventional group and wait-list control group. A normality test will be conducted to check the normal distribution for each numerical variable. Appropriate statistical test Mann-Whitney test will be used if the data is found not normally distributed. A linear mixed model (LMM) will be used to analyze the study objectives. The reason for utilizing LMM in our analysis is because of its flexibility to include both random and fixed effects, its ability to include categorical independent variables, and handling the data missingness (23). All analyses will be based on an intention-to-treat approach.

DISCUSSION

Low back pain is a prevalent musculoskeletal health condition reported among the working population, including academics. The relationship between pain and psychological conditions is intricate and multifaceted; nevertheless, their association with the working population has been substantiated elsewhere (24, 25). Psychological symptoms play a significant influence on mental health, a condition that has garnered global

attention. If both health issues (psychological and LBP) are recurrent among academics, the repercussions may extend beyond individual lives, negatively impacting institutions (by exacerbating presenteeism) and the country (leading to increased expenditure to cover treatment costs as secondary prevention).

There is no doubt that mindfulness offers considerable benefits to the individual, enhancing various aspects of their well-being and overall quality of life. Implementing the mindfulness in the workplace wellness program in the various institutions have flourishing positive outcomes towards their employee especially in the Western countries (26). To our knowledge, the incorporation of mindfulness practices into workplace wellness programs within our local institutions is currently limited and not mandatory.

To foster a nurturing work environment that aligns with sustainable development objectives, integrating mindfulness practices into standard workplace wellness programs with flexible work hours to promote engagement, or incorporating mindfulness intervention activities into daily work routines, is essential. Techniques such as mindful stretching, posture awareness, and body scan meditation help alleviate physical discomfort, while mindful breathing, walking, and eating reduce stress and promote mental well-being (27).

Our initial findings reveal that LBP and anxiety symptoms have significantly contributed to a decrease in presenteeism. This decrease in presenteeism was notably larger than the decrease in absenteeism, causing concern regarding the impact on the institution. Presenteeism is characterized by the phenomenon where individuals continue to attend their jobs despite experiencing complaints and ill health that should ideally necessitate rest and taking time off work (28). Past cross-sectional study conducted by (29) suggested that the improvement of work productivity is not only preventing LBP but also psychological distress. Based on the aforementioned considerations, our interventional study may yield promising results, and providing effective solution for academics to manage LBP, psychological distress and improve work productivity.

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