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Impact of mindfulness-based tri-modal prehabilitation on functional recovery and selected surgical outcomes of patients with colorectal cancer admitted to surgical hospital wards: the first international randomised control trial for mindfulness-based tri-modal prehabilitation

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ABSTRACT

Introduction Colorectal cancer (CRC) is the third most common and second most deadly cancer worldwide, with significant morbidity and mortality risks. Despite advancements in surgical care, postoperative complications and recovery challenges persist. The severity of these issues is linked to preoperative functional capacity and emotional distress. Mindfulness, known for enhancing emotional well-being, is being considered as a promising intervention in cancer care. This study investigates the effectiveness of mindfulness-based tri-modal prehabilitation in improving functional recovery and surgical outcomes for patients with CRC.

Methods and analysis The sample size of this prospective, randomised controlled trial was calculated based on the primary outcome, which is the detection of the clinically significant difference in a 6 min walk test (6MWT). With our population variables, the size of the sample was estimated for an α level of 0·05 (two-sided) and 80% power to detect a clinically meaningful difference between groups at postsurgical follow-up of 32 m, with an estimated variability of 64 m based on previous studies. The final sample size is 72 patients, in both arms. Both groups will receive a 4-week standard tri-modal prehabilitation. The intervention group will receive a mindfulness practice module. Outcomes will be measured at four different time intervals for each patient. Secondary outcome measures cover nutritional status, psychological status and selected biomarker status. Patient recruitment to the study started in April 2022.

Ethics and dissemination This study was approved by the Ethics Review Committee of the Faculty of the Medical Sciences University of Sri Jayewardenepura (Registration No: FMC/ USJP ERC 29/19) and the Ethics Review Committee of Colombo South Teaching Hospital (Reference number 915). The research results will be published in peer-reviewed publications and presented at international conferences.

Trial registration number SLCTR/2020/022.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Considerable effort is being made to avoid observer bias through the separation of roles and blinding of trial staff.
⇒ High statistical power (80%) to detect clinically meaningful differences between groups, which were derived based on previous studies.
⇒ Utilisation of reliable and validated tools for outcome measurement.
⇒ The prehabilitation process conducted at home may lead to potential subjectivity and reporting bias as physical supervision is not possible.
⇒ The study does not account for all variables that could influence surgical outcomes, such as variations in surgical techniques or surgeon expertise.

INTRODUCTION

Colorectal cancer (CRC) is the third most prevalent type of cancer globally, with more than 1.80 million cases and 862 000 deaths yearly.[1] Although surgery is the only curative option, postoperative complications occur in up to 50% of patients. They are associated with

higher morbidity and mortality rates, lower health-related quality of life and increased expenditure on healthcare. The number and severity of complications are closely related to preoperative functional capacity, namely, nutritional status, psychological state and smoking behaviour.[2] The levels of psychophysiological reserve capacity and comorbidities affect tolerance to surgery and recovery.[3] The postoperative period might not be the most effective time to ask surgical patients to create significant changes in their lifestyle due to many factors. After the surgery, they are tired and concerned about the healing process and still as being depressed and anxious as they await additional treatments for their underlying condition. Therefore, interventions during preoperative would be much more promising as they could alleviate some of the emotional distress surrounding the anticipation of surgery and recovery. Moreover, the recent evidence suggests that the potentially modifiable patient factors were prevalent and that the risk of severe postoperative complications increases with the number of risk factors present preoperatively. In this sense, the preoperative period is one of the most beneficial times to improve the physical and mental conditions of the patients.[4]

Prehabilitation is a multimodal approach involving physical exercise and nutritional and psychosocial interventions to enhance functional capacity in anticipation of a forthcoming physiological stressor.[5] The overarching prehabilitation intends to promote preoperative functional reserve, leading to better postoperative functional recovery and a decreased incidence of complications.[6] Recent studies suggest that multimodal prehabilitation consisting of an exercise programme, a nutrition intervention and psychological coping is reliable and supportive care for patients with CRC undergoing surgery.[2 7–13]

The practice of mindfulness is one of the most popular ways to meditate. Mindfulness is defined as paying attention in a particular way, on purpose, in the present moment, and non-judgmentally and is one of the most widely used and effective techniques to evoke a relaxation response.[14] There is evidence that those who practice mindfulness meditation benefit from stress-related symptoms and disorders.[15] Furthermore, it has been demonstrated that mindfulness reduces inflammation and stress hormone levels.[16 17] A 12-week mindfulness-based intervention conducted among patients with cancer was effective in relieving anxiety and depression.[18]

As the current prehabilitation procedure is based on standard physiological, nutritional and psychological interventions, the proposed study is expected to shed some light on the role of mindfulness as a potential clinical application during the prehabilitation process.

In the similar studies related to the prehabilitation of patients with CRC, the 6MWT was widely used as a practical and reliable tool for assessing functional capacity and endurance in patients, making it an appropriate measure for primary outcomes.[19–23] Therefore, we used 6MWT as a primary outcome measure tool for this study. Moreover, past research suggests a strong correlation between psychological well-being and physical recovery, highlighting the interconnectedness of these domains. According to studies, prehabilitation considerably increases 6 min walk test (6MWT) performance, with one study indicating an increase of 78.9 m in the prehabilitation group compared with a reduction in the control group.[22] In addition, the 6MWT has been established as a low-cost, reliable measure of postoperative recovery that correlates well with other physical function evaluations.[24] Additionally, prehabilitation programmes have consistently resulted in significant increases in 6MWT results, suggesting improved functional ability before surgery.[10 25]

This study aims to assess the impact of mindfulness-based tri-modal prehabilitation on functional recovery and selected surgical outcomes of patients with CRC. The 6MWT is considered the primary outcome measurement. The secondary outcome measures are indicators of nutritional status, psychological status and selected biomarkers.

METHODS

Study design

This is a randomised controlled trial with two arms. Written informed consent (see online supplemental appendix 1) will be obtained from all patients. The trial will be conducted according to the rules of the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura as well as the Ethics Review Committee of Colombo South Teaching Hospital in Sri Lanka. Moreover, a safety monitoring panel will be established with relevant experts to monitor the safety of patients.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting or dissemination plans of our research.

Study population and sample size calculation

Adult patients over 18 years of age undergoing elective colorectal resection for cancer who are fit enough to perform planned physical exercises are eligible for inclusion.

The sample size was estimated with the following assumptions.

1. A difference of 32 m walk in the 6MWT, which is the primary outcome of this study, produces a meaningful impact on the lives of the subjects based on previous similar studies (δ).[5]
2. The estimated variability is 64 m based on previous studies (σ).[5]
3. The power of the study is 80%.
4. α level is 0.05% (two-sided).

$$n = \left(Z_{\alpha/2} + Z_{\beta}\right)^2 \times \sigma_d^2/\delta^2$$

The sample size required in each of the two (02) groups is 31. To allow for 15% attrition, 72 patients, 36 in each

arm, will be recruited in total. These factors together with stratified randomisation will give more than 80% power to detect the expected minimum clinically important difference between the two groups. We expect a dropout rate of 10% based on previous pilot studies. Therefore, the sample size is defined to allow for 15% attrition.

Exclusion criteria are patients who are awaiting palliative colorectal surgery, patients undergoing emergency colorectal surgery, patients who are not fit enough to perform a 6MWT and patients unable to perform the planned physical exercise (eg, Amputees, Cormorbities which prevent planned exercise protocol) and patients already participating in mindfulness, yoga, exercises or any other contemplative practices more than 30 min per day.

Randomisation

Patients will be randomised 1:1 using a random number table to the intervention group or control group with stratification by gender and age group. Patients will be allocated either to the intervention group, which will receive 4 weeks of mindfulness-based tri-modal prehabilitation, or to the control group, which will receive 4 weeks of standard tri-modal prehabilitation.

In the participating centre, both the investigator and the surgeon responsible will verify the eligibility. If the indication for surgery is established, patients will be screened by the medical research team for health conditions that prohibit participation in the programme. They will then be called by the research investigator, and an appointment will be made to provide written and oral information about the trial during a scheduled outpatient appointment. Patients will be given enough time to enquire about the details of the trial and to decide whether or not they wish to participate. Patients will be required to sign the informed consent form in the presence of the surgeon or investigator.

Considerable efforts will be made to avoid observer bias through the separation of roles and blinding of trial staff. A research assistant, independent of patient recruitment and data collection, will be responsible for the coordination of patient appointments. The intervention will be delivered by trained personnel who will remain blinded to outcome data throughout the study. On completion of the study, a biostatistician blinded to group allocation will analyse outcome data.

The experimental design and study flow diagram are shown in figure 1. After the study has been explained and consent is obtained, there will be a multidisciplinary assessment. Based on the intake by the physical trainer, the nutritionist and the mindfulness trainer, an individual tri-modal prehabilitation programme will be started for 4 weeks in both groups.

Study outline

As per the current procedure at the unit, there is a 4-week preoperative period, which will be used to deliver the prehabilitation care (intervention or control) for those who will be recruited to the study.

During this period, the intervention group will receive mindfulness-based tri-modal prehabilitation, while the control group will receive tri-modal prehabilitation with no component of mindfulness protocol. Preoperative 4 weeks of abstinence from smoking and alcohol are strongly recommended before surgery. Standard enhanced recovery after surgery protocol that is practised in the hospital will be applied to all patients during the perioperative period (both cases and control groups). After the surgery, both groups will receive rehabilitation as per the standard protocol.

The standard rehabilitation processes will continue throughout the 8-week postoperative period for both groups. As patients will find it difficult to commence exercises immediately after surgery, they will follow routine postoperative care for 2 weeks. Then, light exercises will be introduced with a gradual increase in intensity over time. By 4 weeks postoperatively, they will follow the full exercise regime.

The standard multidisciplinary tri-modal prehabilitation programme comprises three elements: exercise programme, nutritional intervention and psychological coping and a brief description of each component is given below.

Exercise programme

Patients will be asked to perform unsupervised exercises daily for 30 min per session. A standard excise regime will be developed by a clinical expert comprising 5 min of warm-up exercises, 20 min of aerobic exercises and 5 min of cool-down exercises. The module will be video recorded using a trained person performing exercises, and a Digital Video Disc (DVD) will be given to patients with the necessary instructions.

Daily compliance will be recorded by contacting patients.

Nutrition intervention

The nutritional status of patients enrolled in the prehabilitation programme will be evaluated by a qualified nutritionist at the recruitment using a subjective global assessment. A 24-hour dietary recall survey will be conducted. Modifiable dietary behaviours such as excess alcohol, cigarette consumption or fat intake will be identified, and the patient will be counselled accordingly. Each patient will be prescribed an appropriate diet.

The 24-hour dietary recall survey will be run at each visit to check compliance.

Psychological coping

A clinical expert will develop a standard module of relaxation and breathing techniques. The module comprises unsupervised 10 times deep slow breathing exercises for relaxation. The module will be video recorded, and a DVD will be given with the necessary instructions. For

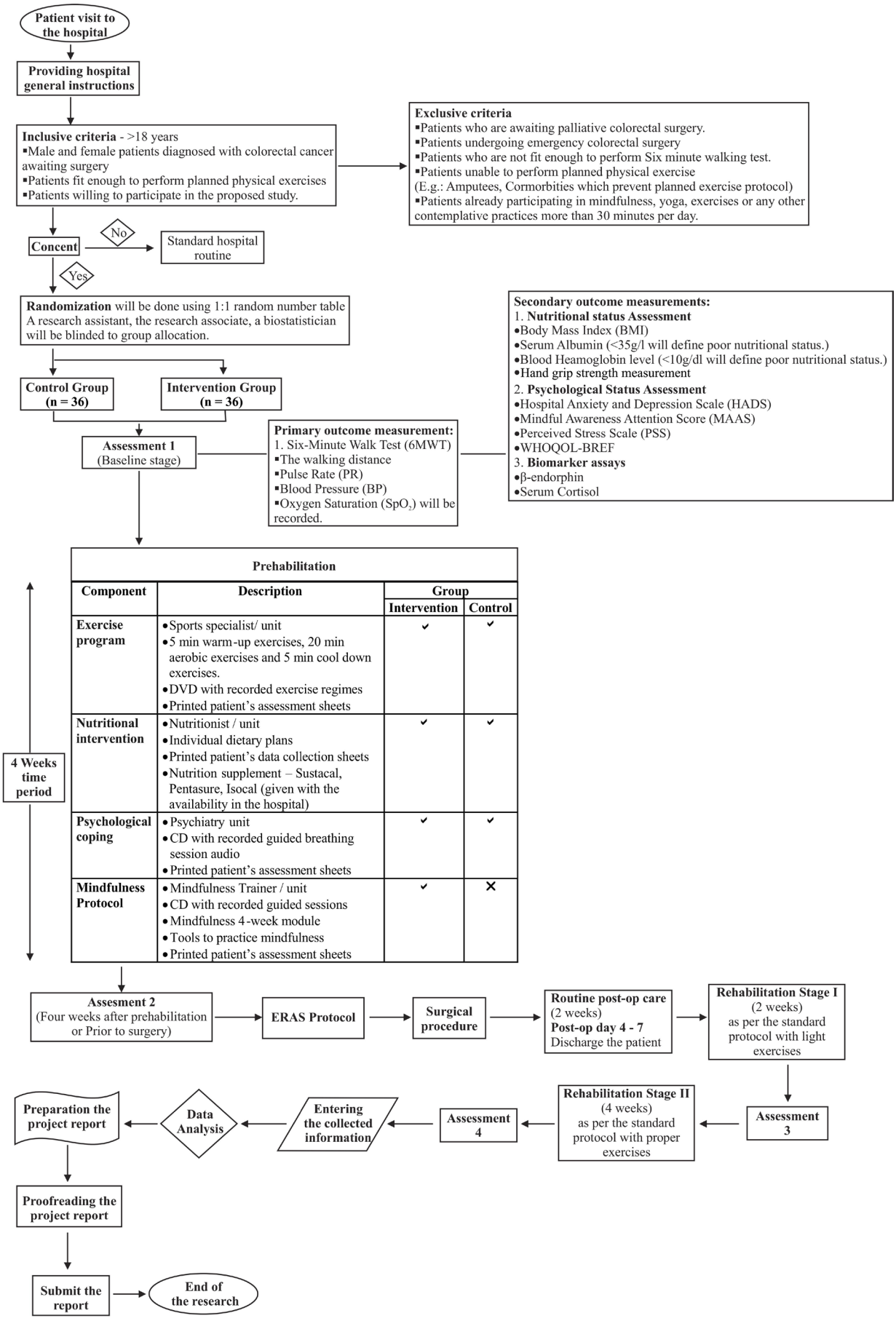

Figure 1 Experimental design and study flow diagram.

psychological support, the patients will be contacted by the investigator by phone.

Mindfulness protocol

The mindfulness-based 4-week programme will be delivered by a trained mindfulness practitioner during the prehabilitation process for the intervention group. The mindfulness trainer will explain the basic concepts of mindfulness and the significance of mindfulness practice for the patient's well-being. Thereafter, the trainer will guide the patients on how to practice mindful walking, mindful sitting and mindfulness while attending to day-to-day work. Audio and video materials will be provided for the patients. The module will be developed under the guidance of the director Centre for Mindfulness-Based Practices and Research. For necessary support, the intervention group will be contacted by the investigator over the telephone.

Study outcomes

Outcomes will be measured at four different time intervals for each patient; at the start of the trial, 4 weeks after prehabilitation or before the surgery, 4 weeks postoperatively, and 8 weeks post-operatively.

The primary outcome will be measured using the 6MWT. The 6MWT is a submaximal exercise test that entails measurements of distance walked over 6 min. It provides information regarding functional capacity and response to therapy. The walking distance is 30 m in length, with every 3 m marked. Turnaround points should be marked with a cone. Then, record the walking distance. Moreover, pulse rate, blood pressure and oxygen saturation will be measured.[26]

The secondary outcome measures will be nutritional status, psychological status and selected biomarkers.

Nutritional assessment will be done using the Malnutrition Universal Screening Tool, body mass index, serum albumin, blood haemoglobin level and hand grip strength measurement.

Psychological assessment to assess depression and anxiety will be done using the Hospital Anxiety and Depression Scale (HADS), Mindful Awareness Attention Score (MAAS), Perceived Stress Scale (PSS) and the World Health Organisation Quality of Life-BREF (WHOQOL-BREF) questionnaire. All the psychological markers will be validated before using it.

Biomarker assays will be done to analyse serum β-endorphin and serum cortisol. Five (05) mL blood samples will be collected at each data collection time interval to assess biomarkers.

Serum cortisol levels will be determined at random due to variations in hospital clinic schedules, which might create variability. External stresses or changes in daily routines may impact cortisol levels and result in data variability. Individual variations in cortisol secretion patterns might also affect comparability among participants.

Statistical analysis

Data (coded on study code) will be entered in the SPSS (V.23.0, IBM, SPSS, Chicago, Illinois). Categorical variables will be analysed using χ^2 tests (or Fisher's exact test for small samples), while continuous variables will be employed (parametric) t-tests and (non-parametric) Mann-Whitney tests for symmetrically and asymmetrically distributed data, respectively. The significance of differences in dichotomous data will be tested using generalised estimating equations or linear mixed models. If there are chance of imbalances in baseline patient characteristics hypothesised to influence the main outcomes, then statistical techniques that allow adjustment for confounding variables will be used as secondary analyses. A paired analysis between the groups, matched for age and gender, will be conducted. If there is more than 5% missing data, sensitivity analyses allowing for different assumptions, such as the best or worst possible scenario, will also be reported for the main outcomes of the study.

Compliance with the intervention will be observed and recorded throughout the study. The compliance will be considered as a variable, and a necessary statistical procedure will be employed to mitigate the possible confounding effect. A similar procedure will be employed in case of any deviation.

Data sharing plan

We will retain the data acquired from this study for up to 5 years until the clinical trial ends. All data will be securely maintained and managed in compliance with institutional and ethical requirements to protect confidentiality and privacy. Access to the data will be limited to research team members who are actively participating in the study. We have no intention of sharing the information with any third party. Any data provided for verification or further study will be anonymised to protect participants' identities.

ETHICS AND DISSEMINATION

Ethical approval for this study was granted by the Ethics Review Committee of the Faculty of the Medical Sciences University of Sri Jayewardenepura (Registration No: FMC/USJP ERC 29/19) as well as the Ethics Review Committee of Colombo South Teaching Hospital under reference number 915. The registration number of the Sri Lanka Clinical Trials Registry is SLCTR/2020/022. Important protocol modifications will be addressed to relevant parties. Patient recruitment to the study started on 20 April 2022 and will conclude in December 2025. The research results will be published in peer-reviewed publications and reported at international conferences.

Trial status

The trial is presently in progress with ongoing recruitment.

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Contributors All authors contributed to the design of this protocol. BG, STCM and NMP initiated the project. The protocol was drafted by NMP and was refined by BG, MNG, CSK, JUMW, SMDPSA, TK, JMCJ and STCM. Statistical advice was provided by STCM. BG, MNG, NMP, SMDPSA, JMCJ and STCM were responsible for drafting the manuscript. STCM is responsible for the overall content as guarantor. All authors contributed to the manuscript and read and approved the final manuscript. The research group consists of all local investigators who are responsible for translation, ethical board approval and participant recruitment. They have all read, refined and approved the final manuscript.

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Competing interests BG is an Honorary Consultant Surgeon at the Surgical Professorial Unit, Colombo South Teaching Hospital, Sri Lanka and a Professor in Surgery at the Department of Surgery, Faculty of Medical Sciences, University of Sri Jayewardenepura, Sri Lanka. MNG is a Professor in Pediatrics at the Department of Pediatrics, Faculty of Medical Sciences, University of Sri Jayewardenepura, Sri Lanka. NMP is an MPhil candidate in the Department of Biochemistry, Faculty of Medical Sciences, University of Sri Jayewardenepura, Sri Lanka and a Research Assistant at the Centre for Mindfulness-Based Research and Practices, University of Sri Jayewardenepura, Sri Lanka. CSK is a Medical Officer at Apeksha Cancer Hospital, Maharagama, Sri Lanka. JUMW is an MSc Candidate in Psychology (Conversion) at the University of Dundee, Nethergate, Dundee, Scotland, United Kingdom and a Research Assistant, at Sati Pasala Foundation, Sri Lanka. SMDPSA is a Senior Lecturer at the Department of Psychiatry, Faculty of Medical Sciences, University of Sri Jayewardenepura, Sri Lanka. TK is a Medical Officer (Microbiology) at District General Hospital, Vavuniya, Sri Lanka. JMCJ is a Professor in Immunology, Allergy, and Molecular Medicine; Head of the Department of Immunology and Molecular Medicine, Faculty of Medical Sciences, University of Sri Jayewardenepura, Sri Lanka; Director of the National Centre for Primary Care and Allergy Research, University of Sri Jayewardenepura, Sri Lanka; and Director of Operations and Clinical Services at the Allergy, Immunology and Cell Biology Unit, University of Sri Jayewardenepura, Sri Lanka. STCM is a Senior Lecturer at the Department of Biochemistry, Faculty of Medical Sciences, University of Sri Jayewardenepura, Sri Lanka and Director of the Centre for Mindfulness-Based Research and Practices, University of Sri Jayewardenepura, Sri Lanka.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication A written informed consent form for participation and publication will be available for every study participant.

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