Cover Page

Official title:

The Immediate Effect of Mindfulness-Based Supportive Therapy (MBST) vs Supportive Listening on Palliating Suffering in Palliative Care Cancer Patients: A Randomised Controlled Trial

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The Immediate Effect of Mindfulness-Based Supportive Therapy (MBST) vs Supportive Listening on Palliating Suffering in Palliative Care Cancer Patients: A Randomised Controlled Trial

Version Number:

1.1

Version Date:

16 July 2020.

Time Frame:

1 August 2020 to 31 December 2020.

Research Statement and Literature Review:

Suffering is a multidimensional experience of severe distress that occurs when there is a significant threat to the intactness of the whole person. [1] It is a common experience for patients facing cancer and terminal illness. In palliative care, the prevalence of suffering can be as high as 80%. [2] Twenty-eight percent of end-of-life cancer patients reported unbearable suffering. [3] Types of suffering at the end of life include troublesome symptoms, loss of function, and loss of control, burdening of others, unfinished business, social isolation, family dispute and fear of

death. [4, 5] Despite decades of medical and pharmacological advances, suffering remains widespread and unbridled.

To address suffering, the biomedical approach is insufficient. At times, it can even create more suffering. [6] This is evidenced by healthcare-related suffering such as the lack of attention, the lack of listening, the lack of empathy and the lack of compassion. [7] Alongside treating the disease and its distressing symptoms, it is equally important to treat patient as a whole person because suffering is experienced by person, not just the body.

Mindfulness is a moment-to-moment awareness, cultivated by paying attention to the resent moment, non-judgmentally. [8] It allows a person to cultivate non-interference with experiences by allowing inputs to enter awareness in a simple noticing of what is taking place. When a person stops producing more discursive thoughts, the mind that experiences suffering may naturally settle down. Mindfulness-based supportive therapy (MBST) is a novel psychotherapy designed specifically to address psycho-existential suffering in palliative care. [9] It has five components – mindful presence, mindful listening, mindful empathy, mindful compassion and mindfulness of boundaries.

Although mindfulness has been shown to reduce stress and suffering, and MBST may produce positive outcomes in the palliative care setting, currently there is still no study that examines the effect of MBST on suffering patients. [10] In our current study, we aim to examine the effect of MBST on reducing suffering of palliative care cancer patients.

Objective:

The objective of this study is to determine the efficacy of MBST on reducing suffering of palliative care cancer patients.

Methodology:

This study will be conducted in the University Malaya Medical Centre. The study design is a parallel group, single-blinded, randomized controlled trial. The trial will be registered at the Clinical Trials registry and conducted in accordance to the Declaration of Helsinki. The investigators will be recruiting patients by screening patients under the care of the palliative care team at University Malaya Medical Centre. Patients fulfilling the inclusion and exclusion criteria will be approached and included in the study if they give their informed consent to participate.

Inclusion criteria:

- Stage III and IV cancer patients aged 18 years and above
- The overall suffering score of 4/10 and above based on The Suffering Pictogram [11]

Exclusion criteria:

- Patients who are confused based on The Confusion Assessment scoring (CAM)
- Patients who are non-communicative verbally
- Patients with psychiatric illness

Patients who are eligible will be informed about the nature of the study. The study is voluntary and patients can withdraw from the study at any time. Patients who are interested to participate will be randomly allocated to either the intervention group (MBST) or the control group (supportive listening) based on computer generated random numbers. Allocation concealment will be performed using sealed envelopes.

Patients in the intervention group will receive a 30-minute MBST session by a palliative care physician trained in mindfulness practice. The MBST consists of a session that involves interviewing patients with open-ended questions on suffering experiences (Table 1). During the session, the practitioner will practice mindful breathing simultaneously while listening to patients. The practitioner will acknowledge the distress of patients when it is appropriate, but without losing their attention on mindful breathing. The detailed instructions of delivering the MBST are presented in Table 1.

Patients in the control group will receive a 30-minute supportive listening session by a palliative care physician who has no experience in mindfulness practice. The session involves interviewing patients with the same open-ended questions on suffering experiences (Table 1). The practitioner will acknowledge the distress of patients when it is appropriate. The detailed instructions of delivering the supportive listening are presented in Table 1. Outcomes will be measured at baseline and at minute 30.

Primary outcomes (patients): Suffering will be measured using the Suffering Pictogram. [11] It is a brief and validated instrument used to measure the experience of suffering in palliative care. Patients are required to rate their overall suffering at the centre of the pictogram with a numerical scale of 0 to 10 (0 = no suffering, 10 = worst possible suffering). The pictogram

contains eight items rated on a Likert scale – discomfort, worry, fear, anger, sadness, hopelessness, difficulty in acceptance and emptiness. The total suffering score of the eight items ranges from 0 to 32, with higher score reflecting more suffering.

Psychological distress will be examined using the Hospital Anxiety and Depression Scale (HADS). [12] The HADS consists of 14 items rated on a Likert scale yielding a score of total score (0-42), an anxiety score (0-21) and a depression score (0-21), with higher score reflecting higher distress.

Quality of life (QOL) will be assessed by the Functional Assessment of Chronic Illness Therapy (FACIT-Sp). [13] It contains 39 items (range from 0 to 4, with higher scores reflecting higher QOL) forming an overall total score and five subscales scores: physical, social, emotional, functional and spiritual.

Patient's perception of practitioner empathic engagement will be measured with the Jefferson Scale of Patient's Perceptions of Physician Empathy. It is a 5-item instrument (range from 1 to 5, with higher scores reflecting a greater degree of physician's empathy).

Secondary outcomes (practitioners): Secondary outcomes will be measured by the Perceived Stress Scale (PSS) and the Frieburg Mindfulness Inventory (FMI).

Sample size:

Using G*Power 3.1 power calculation software, a sample size of 68 (34 per arm) will provide 80% power to detect an effect size of 0.7. Therefore, assuming if the standard deviation of the sample is 4 units, a sample size of 68 will provide 80% power to detect a reduction in total

suffering scores from an estimated 6/32 to 3/32, with a two-tailed type I error rate of 0.05. Taking into account of possible 20% dropout rate, the final estimated sample size was 80 (40 per arm).

Statistical Analysis:

Statistical analysis will be conducted using SPSS, to determine the clinical and statistical significance of the study results.

References:

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Gantt Chart:

	2020			2021	
Activities	Jul – Aug	Sep - Oct	Nov – Dec	Jan - Feb	Mar - April
Recruiting samples					
Data entry					
Data analysis					
Article writing					
Article correction					
Publication submission					