

Mindful breathing for cancer pain: efficacy of a single 20-minute session – a randomised controlled study

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ABSTRACT

Objectives Cancer pain is a prevalent and challenging symptom affecting a significant number of patients globally, with inadequate control remaining a substantial challenge despite advancements in pain management. Non-pharmacological interventions, including mindfulness-based approaches, have shown promise in alleviating cancer-related pain. This study aimed to explore the efficacy of a single session of 20-minute mindful breathing in reducing pain among patients with cancer.
Methods A randomised controlled study was conducted at the University of Malaya Medical Centre, Malaysia, involving adult cancer inpatients with a pain score of $\geq 4/10$. Participants were randomly assigned to a 20-minute mindful breathing intervention or a 20-minute supportive listening control group. Outcome measures included pain intensity, pain unpleasantness and Hospital Anxiety and Depression Scale score, assessed before and after the intervention.

Results The 20-minute mindful breathing sessions demonstrated significant efficacy in reducing pain intensity, pain unpleasantness and anxiety compared with the control group.

Conclusion This research broadens the repertoire of cancer pain management by highlighting the rapid and holistic benefits of a single session of 20-minute mindful breathing. The findings suggest the potential integration of brief mindfulness exercises into routine cancer care to enhance pain management and overall well-being.

INTRODUCTION

Cancer pain represents a pervasive and distressing symptom affecting a substantial proportion of patients with cancer worldwide. The prevalence of cancer-related pain varies across malignancies

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Cancer pain is a prevalent and challenging symptom.
- ⇒ Mindfulness-based approaches have shown promise in alleviating cancer pain.

WHAT THIS STUDY ADDS

- ⇒ 20-minute mindful breathing effectively and rapidly reduces pain intensity, pain unpleasantness and anxiety in patients with cancer.
- ⇒ The study bridges the gap in the literature by exploring the impact of a brief mindfulness intervention, offering a less time and logistic-intensive means of managing pain supplementing the existing literature in the field.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Clinical: This brief and accessible intervention offers a complementary approach to traditional pharmacological strategies.
- ⇒ Research: It contributes valuable evidence to the limited research on the efficacy of short-duration mindfulness intervention for patients with cancer.

and stages, with estimates suggesting that approximately 30%–50% of patients with cancer experience moderate to severe pain during their illness.^{1 2} The aetiology of cancer pain arises from a complex interplay of factors, including tumour-related compression, invasion of surrounding tissues, neuropathic mechanisms, and treatment-induced side effects.^{3 4} Despite advancements in pain management, inadequate control of cancer-related pain remains a significant challenge, adversely affecting patients' quality of life.^{5 6}

Cancer pain management remains a dynamic field with evolving strategies



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aimed at optimising analgesia while minimising adverse effects. Opioids, such as morphine, oxycodone and fentanyl, continue to play a central role in the pharmacological management of cancer pain, particularly for moderate to severe pain.^{2 3} However, concerns about opioid-related side effects and the risk of addiction underscore the importance of a balanced approach, incorporating adjuvant analgesics, non-pharmacological interventions and interventional procedures.^{5 6} Adjuvant medications, including anti-convulsants and antidepressants, address neuropathic components of cancer pain, contributing to a more comprehensive multimodal pain relief strategy.² Furthermore, interventional procedures, such as nerve blocks and intrathecal drug delivery, can be valuable in refractory cases.^{3 6}

Non-pharmacological interventions offer patients additional avenues for pain relief. Strategies encompass a spectrum of modalities, including psychosocial interventions such as cognitive behavioural therapy and mindfulness-based programmes, physical therapies such as exercise programmes and physiotherapy, and complementary therapies such as acupuncture and massage.⁷⁻¹¹ These have the potential to mitigate opioid-related side effects and enhance the overall analgesic effect of pharmacotherapy.^{12 13}

Among the non-pharmacological interventions, mindfulness-based interventions have gained recognition as valuable components of cancer pain management. Mindfulness programmes, such as mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT), emphasise present-moment awareness and non-judgmental acceptance, fostering a sense of control and resilience in individuals facing cancer pain.^{14 15} Research indicates that mindfulness interventions can significantly reduce pain intensity and improve overall well-being in patients with cancer.¹⁶ These approaches also contribute to better emotional regulation, decreased anxiety, and enhanced quality of life.¹⁷⁻²⁰

Despite the growing body of research supporting the efficacy of mindfulness-based interventions in managing cancer pain, the evidence on the impact of a single session of a brief guided mindfulness exercise remains limited. The majority of studies investigating the effectiveness of mindfulness exercises in the context of cancer pain focused on structured programmes spanning several weeks, typically 8 weeks, such as MBSR or MBCT.^{14 15} While these programmes demonstrate positive outcomes, acknowledging the time and commitment constraints faced by many patients with cancer is crucial.

Previous research indicates variability in the effectiveness of different durations of mindful practice, highlighting the ‘dosage’ effects of mindfulness. Specifically, shorter sessions, such as a single 5-minute mindful breathing exercise, have been found ineffective in alleviating pain in palliative care settings.²¹ In

contrast, studies have demonstrated that single sessions ranging from 10 to 20 min of mindful meditation can provide immediate analgesic effects for those with acute or chronic pain without cancers.²²⁻²⁴ Furthermore, Palmer *et al*'s finding indicates while both 10 and 20-minute sessions are comparable in enhancing mindfulness states, longer duration, such as 20 min, may predict a greater reduction in anxiety among individuals with higher trait mindfulness levels.²⁴ Therefore, we conducted this study to examine the efficacy of a single session of 20-minute mindful breathing in reducing pain among patients with cancer.

METHODOLOGY

A parallel-group, non-blinded, randomised controlled study was conducted at the University of Malaya Medical Centre (UMMC), Malaysia, between 1 September 2021 and 3 December 2022.

Inclusion criteria encompassed adult patients aged 18 years and above, diagnosed with any type of cancer, hospitalised for cancer-related reasons and presenting with a pain score of $\geq 4/10$ on the numerical rating scale (NRS). This cut-off was selected to indicate pain of moderate to severe intensity.^{25 26} Exclusion criteria were the presence of confusion based on the Confusion Assessment Method, non-communicative status or an inability to maintain concentration for at least 20 min, as determined subjectively by the researchers during the interview and study explanation process.²⁷

Patients with cancer admitted as inpatients to UMMC were screened for eligibility, and those meeting the criteria were enrolled in the study after obtaining written consent. Participants were randomly assigned to either the intervention or control group in a 1:1 allocation ratio. Randomisation was achieved using a computer-generated random number list, with allocations concealed in sealed envelopes opened only on patient recruitment.

The intervention group received a 20-minute mindful breathing session guided by one of four research assistants, all of whom were medical doctors and had undergone training by the primary investigator—an experienced palliative care physician skilled in mindfulness techniques. Training involved a concise explanation of mindfulness concepts and practices, followed by a 20-minute mindful breathing session guided by the trainer. Emphasis was placed on para-language (rate, rhythm, intonation, pause, etc) and body language (eye contact, facial expression, posture and body movement) during intervention delivery, with each research assistant being supervised in the actual delivery of the 20-minute session subsequently. The mindful breathing session was conducted in the participants' preferred language (English, Malay or Mandarin) and consisted of four steps, each lasting 5 min: identifying the in-breath and out-breath, following the entire length of the breath, bringing the mind back to the body and relaxing the body.²⁸

Conversely, participants in the control group underwent a 20-minute supportive listening session led by one of the same four research assistants. During this session, patients were interviewed about their illness experiences using semi-structured questions. Research assistants were trained to listen without interruption and acknowledge participants' distress appropriately. **Box 1** outlines the instructions for conducting the 20-minute mindful breathing and the semi-structured questions for the 20-minute supportive listening.

The study assessed outcomes at two time points, specifically at minute 0 (T0) and minute 20 (T20), for both the intervention and control groups, conducted by the same investigator. Primary outcomes included pain intensity and pain unpleasantness in general, both quantified using an NRS ranging from 0 to 10. This scale is a widely accepted and validated method for clinically measuring pain.^{29 30} Additionally, secondary outcomes were evaluated using the Hospital Anxiety and Depression Scale (HADS), a self-report instrument consisting of 14 items rated on a 4-point Likert scale (range 0–3). HADS is recognised for its reliability, validity and ease of use and is designed to assess the severity of anxiety (HADS-A) and depressive symptoms (HADS-D) in general hospital patients.³¹ While HADS has been widely used to measure the symptoms of anxiety and depression over the past week, for the purpose of this study, we used it to measure the current state of mood. Furthermore, demographic information and pertinent clinical data, such as cancer types and stages, Eastern Cooperative Oncology Group (ECOG) status, analgesic usage and oral Morphine Equivalent Daily Doses (MEDD), were retrieved from the hospital's Electronic Medical Records system.

Data analyses were conducted using SPSS software (version 26.0). Categorical variables were presented as percentages, while continuous variables were expressed as means with corresponding SD. Between-group comparisons for demographic data employed the χ^2 test for categorical variables and the independent samples t-test for continuous variables. Significance testing for between-group comparisons of outcome changes was performed using independent samples t-tests. All statistical tests were two-tailed, and a significance level of 0.05 was applied.

A calculated sample size of 32 patients, distributed evenly with 16 individuals in each experimental arm, was determined based on statistical power considerations. The study aimed to detect a permissible difference of 2 units in pain intensity, assuming an anticipated SD of 1.³² The statistical analysis was designed as a two-tailed test with a type I error rate set at 0.05 and a desired power level of 80%. To account for potential participant attrition, a dropout rate of 20% was factored into the sample size calculation.

Box 1 Instructions for 20-minute mindful breathing

Step 1 (5 min): identifying the in-breath and the out-breath

Make yourself comfortable. Relax your body. Close your eyes gently. Take two deep breaths slowly. Then, breathe naturally. Notice the flow of air through your nose. Rest your attention gently on the breath. Breathing in, you know you are breathing in. Breathing out, you know you are breathing out. In, out, in, out, in, out. If you are distracted by any sounds, body sensations, thoughts or feelings, gently come back to your breath. Be aware of your in-breath and out-breath for the next few minutes.

Step 2 (5 min): following the entire length of the breath

Continue to relax your body with your eyes closed. Continue to pay attention to your breath. Follow the entire length of your breath. Follow the beginning, middle and end of your in-breath, and the beginning, middle and end of your out-breath. If you are breathing in a long breath, you know you are breathing in a long breath. If you are breathing in a short breath, you know you are breathing in a short breath. If you are breathing out a long breath, you know you are breathing out a long breath. If you are breathing out a short breath, you know you are breathing out a short breath. Do not force yourself to take a long or short breath. Just breathe naturally. Be aware of the entire length of the breath. In, in, in, out, out, out. In, in, in, out, out, out. If you are distracted by any sounds, body sensations, thoughts or feelings, gently come back to your breath. Follow the entire length of your breath for the next few minutes.

Step 3 (5 min): bringing the mind back to the body

As you follow the entire length of your breath, bring your mind back to your body. Instead of thinking about the past or future, bring your mind back to now. Bring your mind and body together as one. As you breathe in, feel your whole body moving with your breathing in. As you breathe out, feel your whole body moving with your breathing out. Breathing in, you are aware of your whole body as you are breathing in. Breathing out, you are aware of your whole body as you are breathing out. Feel the different parts of your body as you breathe in and out. Then, feel the body as a whole, fully united with your mind. Feel the wholeness of yourself with each breath for the next few minutes.

Step 4 (5 min): relaxing the body

Once your breathing is harmonious, your body will relax naturally. Feel whether there is any tension in your body. Breathe and relax the tension one by one, from the top to the bottom. Relax your head, face, neck, arms, forearms, hands, chest, abdomen, legs and feet. Then relax your whole body all at once. Breathing in, you calm your body when you are breathing in. Breathing out, you smile. Again, breathing in, you calm your body when you are breathing in. Breathing out, you smile. In, out, calm, smile. In, out, calm, smile. In, out, calm, smile. Feel your breath flowing through your body and calming your body. Feel your breath leaving your body and smile. Continue to relax your whole body for the next few minutes.

Semi-structured questions for 20-minute supportive listening

Continued

Box 1 Continued

Could you tell me about your illness? Could you tell me a little about yourself? How about your life? What about your family and friends? Could you share with me things that are important to you in your life?

RESULTS

Out of a total of 259 individuals who were approached and screened for potential participation in the study, 37 opted not to participate, with 29 due to fatigue and the remaining eight citing language barriers. Furthermore, 182 patients were excluded from the study as their reported pain intensity fell below the predefined threshold of 4. The remaining cohort, comprising 40 patients, underwent randomisation to either the 20-minute mindful breathing intervention group (n=21) or the 20-minute supportive listening control group

(n=19). The study achieved a 100% response rate, with all 40 enrolled patients successfully completing the study and subsequently being included in the analyses. [Figure 1](#) provides a comprehensive overview of the flow process from recruitment to analyses.

[Table 1](#) presents demographic information and treatment characteristics for both the intervention and control groups. The mean age of participants across both groups was 63.3 years. Most participants were married (82.6%), and various cancer types were represented, with colorectal cancer being the most prevalent (32.5%). Approximately two-thirds of the patients were using opioids (64.9%), with an average oral MEDD of 23.1 mg. No significant differences were observed between the intervention and control groups concerning demographic variables and baseline characteristics such as pain intensity, pain unpleasantness, total HADS score, HADS-A and HADS-D.

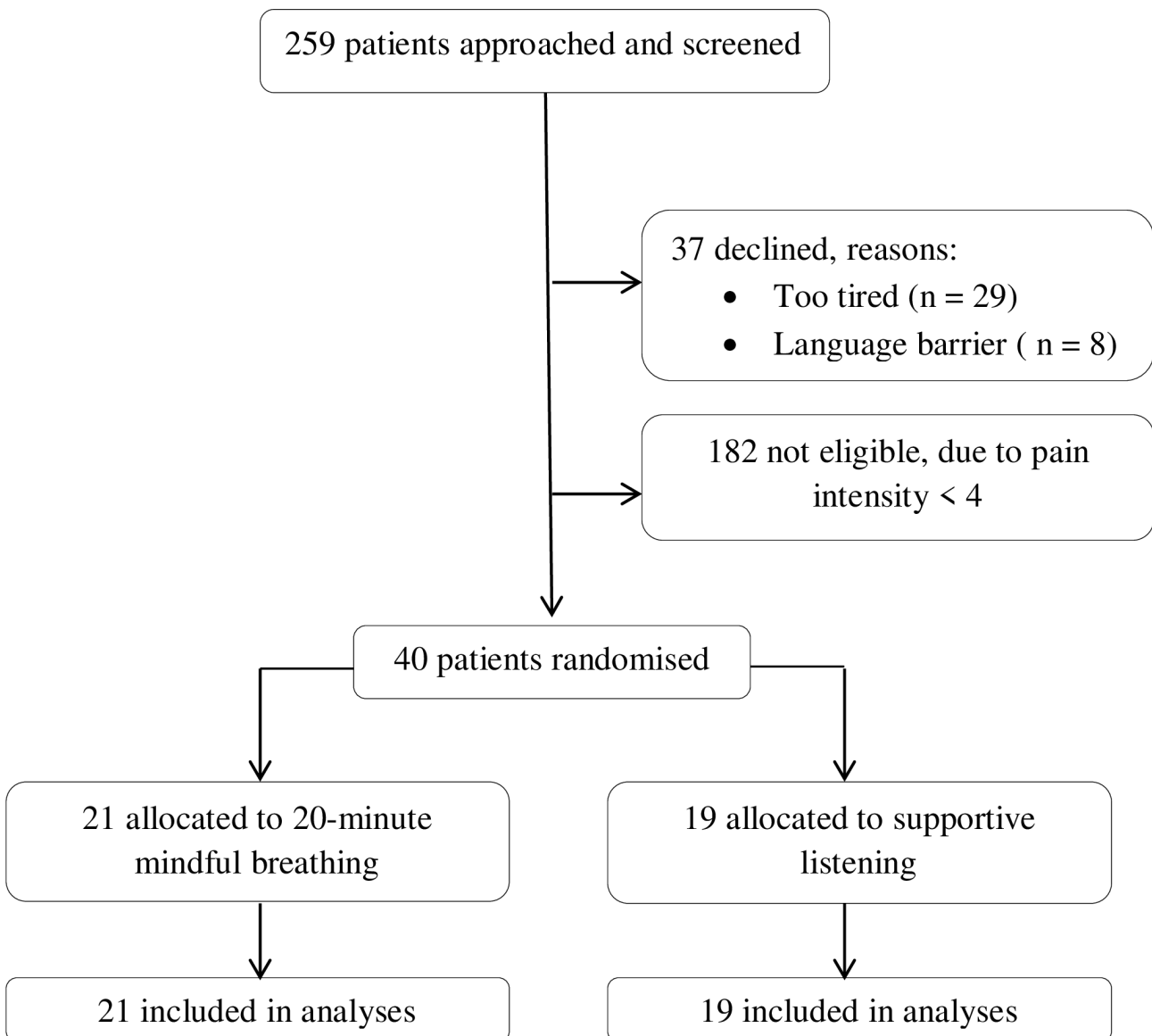


Figure 1 Consolidated Standards of Reporting Trials flow diagram.

Table 1 Demographic and baseline characteristics

Characteristics	Group		P value
	20-minute mindful breathing (n=21)	20-minute supportive listening (n=19)	
Age in years, mean (SD)	63.1 (12.0)	63.5 (10.8)	0.916
Gender, n (%)			0.215
Male	7 (33.3)	11 (57.9)	
Female	14 (66.7)	8 (42.1)	
Ethnicity, n (%)			0.469
Malay	10 (47.6)	10 (52.6)	
Chinese	9 (42.9)	6 (31.6)	
Indian	1 (4.8)	3 (15.8)	
Others	1 (4.8)	0 (0)	
Religion, n (%)			0.739
Islam	10 (47.6)	10 (52.6)	
Buddhism	8 (38.1)	5 (26.3)	
Hinduism	1 (4.8)	2 (10.5)	
Christian	2 (9.5)	2 (10.5)	
Others	0 (0)	0 (0)	
Marital status, n (%)			0.401
Married	17 (81.0)	16 (84.2)	
Single	2 (9.5)	2 (10.5)	
Divorced	0 (0)	1 (5.3)	
Others	2 (9.5)	0 (0)	
Education level, n (%)			0.154
Primary	7 (33.3)	6 (31.6)	
Secondary	5 (23.8)	10 (52.6)	
Tertiary	7 (33.3)	3 (15.8)	
None	2 (9.5)	0 (0)	
Diagnosis, n (%)			0.461
Colorectal cancer	5 (23.8)	8 (42.1)	
Breast cancer	4 (19.0)	2 (10.5)	
Gynaecological malignancies	4 (19.0)	1 (5.3)	
Lung cancer	1 (4.8)	3 (15.8)	
Haematological malignancies	1 (4.8)	2 (10.5)	
Urogenital malignancies	2 (9.5)	0 (0)	
Sarcoma	1 (4.8)	1 (5.3)	
Thyroid cancer	1 (4.8)	0 (0)	
Skin cancer	0 (0)	1 (5.3)	
Stage of cancer, n (%)			0.399
Remission	1 (4.8)	0 (0)	
Stage 1	2 (9.5)	2 (10.5)	
Stage 2	5 (23.8)	1 (5.3)	
Stage 3	5 (23.8)	5 (26.3)	
Stage 4	8 (38.1)	11 (57.9)	
Duration of sickness in months, mean (SD)	21.7 (33.3)	16.7 (22.0)	0.588
ECOG status, n (%)			0.743
ECOG 0	4 (19.0)	2 (10.5)	
ECOG 1	10 (47.6)	11 (57.9)	
ECOG 2	4 (19.0)	3 (15.8)	
ECOG 3	3 (14.3)	2 (10.5)	
ECOG 4	0 (0)	1 (5.3)	
On opioids, n (%)	14 (66.7)	12 (63.2)	1.000
Oral MEDD, mean (SD)	23.3 (23.9)	22.9 (30.5)	0.965

Continued

Table 1 Continued

Characteristics	Group		P value
	20-minute mindful breathing (n=21)	20-minute supportive listening (n=19)	
On benzodiazepines, n (%)	1 (4.8)	0 (0)	1.000
On neuropathic adjuvants, n (%)	2 (9.5)	3 (15.8)	0.905
Types of pain, n (%)			0.831
Somatic	13 (61.9)	10 (52.6)	
Visceral	6 (28.6)	7 (36.8)	
Neuropathic	2 (9.5)	2 (10.5)	
Mixed	0 (0)	0 (0)	
Baseline			
Pain intensity, mean (SD)	5.4 (1.7)	5.6 (1.5)	0.699
Pain unpleasantness, mean (SD)	6.1 (1.7)	5.8 (2.3)	0.580
Total HADS, mean (SD)	18.2 (8.3)	17.4 (8.1)	0.740
HADS-A, mean (SD)	9.1 (5.0)	7.7 (3.3)	0.297
HADS-D, mean (SD)	9.1 (4.4)	9.7 (5.5)	0.730

ECOG, Eastern Cooperative Oncology Group; HADS, Hospital Anxiety and Depression Scale; MEDD, Morphine Equivalent Daily Dose.

Table 2 presents the between-group comparisons of outcome changes. Independent samples t-tests were employed to examine the differences in primary and secondary outcomes between the intervention and control groups. The intervention group ($M=-1.38$, $SD=1.32$) exhibited a significantly greater reduction in pain intensity in comparison to the control group ($M=-0.47$, $SD=0.91$), $t=2.553$, $p=0.015$. The effect size, quantified by Cohen's d, denoted a large effect ($d=0.80$), signifying a robust impact of the intervention on pain intensity reduction. Similarly, a more pronounced reduction in pain unpleasantness was observed in the intervention group ($M=-2.05$, $SD=1.50$) than in the control group ($M=-0.63$, $SD=0.90$), $t=3.578$, $p=0.001$, with an even larger effect size ($d=1.15$).

Concerning secondary outcomes, a greater reduction in the total HADS score was noted in the intervention group ($M=-3.24$, $SD=3.15$) compared with the control group ($M=-0.79$, $SD=1.72$), $t=3.009$, $p=0.005$, with a Cohen's d of 0.97. Subsequent analyses revealed a significant reduction in the HADS-A scale within the intervention group ($M=-2.62$, $SD=2.11$) compared with the control group ($M=-0.37$, $SD=1.26$), $t=4.045$, $p=0.000$, Cohen's $d=1.29$.

However, the reduction in the HADS-D scale in the intervention group ($M=-0.62$, $SD=1.56$) compared with the control group ($M=-0.42$, $SD=1.77$) did not reach statistical significance, $t=0.375$, $p=0.710$. Outcome changes are depicted through Waterfall charts in [figure 2](#). No adverse events were reported in either group during or as a consequence of the study.

DISCUSSION

The results of our study indicated that a 20-minute mindful breathing session demonstrates efficacy in the rapid relief of pain intensity, pain unpleasantness and anxiety among individuals diagnosed with cancer. This observation underscores the potential of brief mindfulness interventions to rapidly impact the cancer pain experience. Although research has demonstrated the efficacy of brief mindfulness exercises, such as 5-minute, 20-minute and 30-minute mindful breathing sessions, in alleviating suffering, breathlessness, fatigue and other symptoms among patients with cancer, the efficacy of such exercises in reducing pain remained unproven.³³⁻³⁷ A previous randomised controlled study on the impact of 5-minute mindful breathing on pain reduction did not attain statistical significance.²¹

Table 2 Between-group comparisons of outcome changes

Parameters, mean (SD)	Group		Mean differences	95% CI		df	t	P value
	Intervention	Control		LL	UL			
Pain intensity	-1.38 (1.32)	-0.47 (0.91)	0.91	0.19	1.62	35	2.553	0.015
Pain unpleasantness	-2.05 (1.50)	-0.63 (0.90)	1.42	0.62	2.22	38	3.578	0.001
Total HADS	-3.24 (3.15)	-0.79 (1.72)	2.45	0.80	4.10	38	3.009	0.005
HADS-A	-2.62 (2.11)	-0.37 (1.26)	2.25	1.12	3.38	38	4.045	0.000
HADS-D	-0.62 (1.56)	-0.42 (1.77)	0.20	-0.87	1.27	38	0.375	0.710

HADS, Hospital Anxiety and Depression Scale.

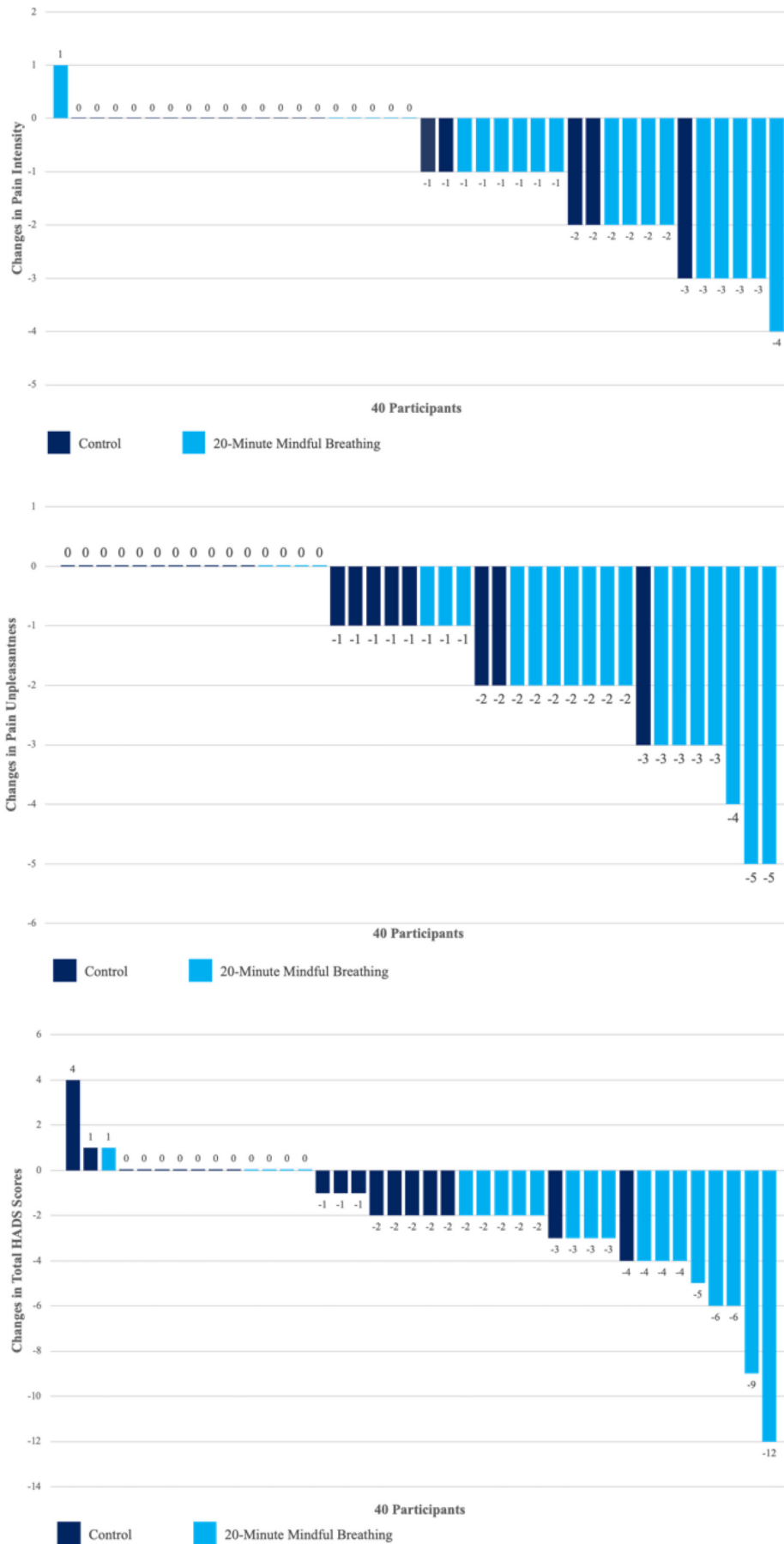


Figure 2 Waterfall charts for outcome changes.

The phenomenon wherein 20-minute mindful breathing exhibited a more pronounced effect on reducing pain unpleasantness compared with pain intensity has been observed in several studies. For instance, in a study by Garland, mindfulness was found to significantly attenuate the unpleasantness associated with pain, with a modest impact on pain intensity.³⁸ This discrepancy could be attributed to the nature of mindfulness practices, which emphasise non-judgmental acceptance and altered perception of pain rather than merely diminishing its sensory intensity.

This study contributes to the literature by investigating the efficacy of a single session of 20-minute mindful breathing in reducing pain among patients with cancer. While structured mindfulness programmes have shown positive outcomes, the practical constraints faced by patients with cancer, such as time and commitment, necessitate exploring more feasible interventions. This study's novel approach provides valuable insights into the potential benefits of a brief mindfulness exercise, addressing a current gap in the literature.

The strengths of this study lie in its randomised controlled design, rigorous methodology and comprehensive examination of both primary and secondary outcomes. The study's successful randomisation, evidenced by the absence of significant baseline differences, enhances internal validity. The inclusion of diverse cancer types and the use of standardised measures contribute to the generalisability of the findings. Additionally, the 100% response rate and the absence of adverse events underscore the feasibility and safety of the 20-minute mindful breathing intervention. The intervention can be quickly learnt and applied with beneficial effects.

The results suggest that a single session of 20-minute mindful breathing holds promise in reducing pain intensity and unpleasantness among patients with cancer, similar to findings by Day *et al.*²² This has important implications for clinical practice, offering a brief and accessible intervention that complements traditional pharmacological approaches. The observed reductions in anxiety and the total HADS score further highlight the potential holistic benefits of this intervention. Additionally, another study found that a single 45-minute session significantly improved anxiety but not depression, underscoring the importance of considering session duration in effective mindfulness practices.³⁹ The findings encourage the integration of brief mindfulness exercises into routine cancer care to enhance pain management and overall well-being.

Despite its strengths, the study has several limitations. The sample size, although determined based on power considerations, is relatively small and the study was conducted at a single medical centre. Although the statistical effect size was substantial, it is noteworthy that the minimum clinically important difference, particularly with regard to pain intensity, was

not attained, despite being achieved for pain unpleasantness.⁴⁰ Another limitation is the use of the HADS, which is validated for assessing symptoms of anxiety and depression over the past week but not for moment-by-moment changes. Therefore, using the HADS to capture state-based mood changes could pose a limitation. However, it is worth noting that other studies have employed the HADS in a momentary assessment context to evaluate mood states.^{41 42} The lack of long-term follow-up also restricts our understanding of the intervention's sustained effects. Additionally, the self-report nature of pain intensity and psychological outcomes introduces the potential for subjective bias. The pain score assessed using the NRS was for pain in general. It was not specific to cancer pain but rather encompassed all types of pain experienced by the participants.

Future research should involve larger, multicentre studies with longer follow-up periods to validate the sustained impact of brief mindfulness interventions. Exploring the differential effects of mindful breathing across various cancer types and stages could provide valuable insights. Comparative effectiveness research, examining the integration of brief mindfulness exercises with other pain management strategies, is warranted. Additionally, investigating the optimal frequency and duration of such interventions would guide their practical implementation. In light of pain being inherently subjective, there is a prospective avenue for investigating patient-specific attributes that may serve as predictors of efficacy in mindfulness-based interventions. Such an inquiry holds promise for fostering a more personalised paradigm in the realm of pain management.

In conclusion, this study advances our understanding of cancer pain management by demonstrating the efficacy of a single session of 20-minute mindful breathing. The findings suggest that this brief intervention holds promise in reducing pain intensity and unpleasantness, as well as alleviating anxiety among patients with cancer. While further research is needed to consolidate these findings, the study contributes valuable insights into a feasible and accessible non-pharmacological approach to enhance pain management in cancer care.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Medical Ethics Committee of University of Malaya (MREC no: 20191028-7948), and the research adhered to the principles outlined in the Declaration of Helsinki. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

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