Thai Buddhism-Based Mindfulness for Pain Management in Thai Outpatients with Cancer: A Pilot Study

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ABSTRACT

Objective: This study aimed to evaluate Thai Buddhism-based Mindfulness (TBBM) feasibility based on recruitment and retention rates and to obtain preliminary data regarding changes (effect sizes) in pain severity and other outcomes when comparing control to intervention participants following TBBM use. Methods: A randomized controlled trial was conducted in the Outpatient Department at Sawanpracharak Hospital, Thailand, from April 2018 to February 2019. Seventeen participants completed the pretest and posttest. Both groups (control group [n = 10] and intervention group [n = 7]) received usual care and watched a 25-min educational video about cancer pain. The intervention group participated in a 3-day mindfulness training program at a Buddhist temple and continued practicing at home for 8 weeks. Data were collected at baseline and at 1 and 2 months postintervention. Results: One-hundred and thirty-five participants met the eligibility criteria; 112 (82%) declined to participate and 6 of 23 (26%) were lost to follow-up/dropped out. Control and intervention participants had an average age of 44 (± 8.77) and 56 years (± 7.41), respectively. When compared to the control group, the TBBM participants reported no statistically significant improvements in pain or other outcomes. While not statistically significant, the effect size indicated that pain did improve in the TBBM group (Cohen’s d = 0.41). Conclusions: Given the suboptimal recruitment and retention rates, modification of the intervention is warranted. Further, our findings suggest that the intervention had a moderate effect on pain. To evaluate efficacy, future adequately powered studies are needed to test a more feasible TBBM intervention. Key words: Cancer, mindfulness, management, pain

Introduction

Globally, cancer is the second leading cause of mortality, accounting for 9.6 million deaths in 2018.[¹] Thailand has the fifth highest death rate from cancer in South-East Asia Region countries at 128 men and 83 women per 100,000.[²] Of Thai patients with cancer, 62% experience pain,[³] a major health problem that can be caused by both cancer (93%) and its treatments (21%).[⁴]

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Cancer pain is a complex, dynamic, subjective experience that is influenced by physiological, sensory, affective, cognitive, and behavioral factors. Although pharmacological/analgesic treatment is effective, adverse side effects such as constipation, nausea, and dizziness are common. Nonpharmacological treatment may be another option for patients. Internationally, mindfulness interventions are commonly used by patients with cancer as an effective nonpharmacological treatment for psychological problems including distress, anxiety, stress, depression, and improvement of quality of life (QoL). However, the effect of mindfulness on pain as the primary outcome has not been sufficiently investigated.

Mindfulness is the process of healing the whole person: physical, psychological, and spiritual. Mindfulness, or “paying attention in [a] particular way: To the purpose, in the present moment, non-judgmentally” (p. 4), has three components – intention, attention, and attitude – all of which occur simultaneously from moment to moment as a process. Thai Buddhism-based Mindfulness (TBBM), developed by the Thai monk Luangpor Teean Jittasubho, is the process of cultivating self-awareness by attending to the present act of moving the hand while having continuous awareness and an open mind to perceiving pain, thoughts, and emotions called dynamic meditation. Practitioners – those who engage in TBBM – do not self-judge but simply become aware of how their thoughts, feelings, and behaviors influence their pain experience. Through this practice, individuals transform their thoughts and behaviors into pain-modifying strategies. Since the TBBM intervention is grounded in the Buddhist tradition, it may be well accepted by Thai people living with cancer. TBBM intervention is applicable for patients with cancer who are receiving chemotherapy, radiation therapy, and palliative care because it is a simple and natural way of self-awareness practicing. This study aimed to evaluate TBBM feasibility based on recruitment and retention rates and to obtain preliminary data regarding changes (effect sizes) in pain severity, pain interference, and other outcomes (i.e., anxiety and depression, locus of control, mindfulness, and QoL) when comparing control to intervention participants following TBBM use.

Methods

Design

This two-arm randomized controlled pilot trial [Figure 1] was conducted in the Outpatient Department of Sawanpracharak Hospital, Thailand, from April 2018 to February 2019. Study procedures were approved by the Sawanpracharak Institutional Review Board (Approval No. 12/2561). The ClinicalTrials.gov identifier for this trial is NCT03351010.

Theoretical framework

The Theory of Unpleasant Symptoms was used to guide this research. This theory is scientifically relevant because it outlines the interactions among the physiological (age, gender, cancer type, and stage characteristics), psychological (anxiety and depression), and situational factors (trauma exposure) that influence pain outcomes. Higher pain severity is associated with decreased daily function or more pain interference. Higher pain severity is also associated with maladaptive thinking (cognition) or an external locus of control whereby an individual believes that they have no control over their pain. Conversely, psychological conditions influence pain severity. Given the potential mediating effects of psychological, cognitive, and situational variables/influencing factors, and the potential effect of mindfulness mediation to ameliorate these influencing factors, we quantified anxiety, depression, locus of control, and trauma exposure in our target population of Thai patients with cancer-related pain.

Participants

Participants were recruited from the Outpatient Department, Sawanpracharak Hospital, a regional hospital and cancer center under the Ministry of Public Health, Nakhonsawan province, Thailand. Inclusion criteria were as follows: (1) outpatient diagnosed with cancer of any type or stage, (2) 18 years of age or older, (3) worst pain score >4 in the past 7 days, (4) able to read and write the Thai language, (5) Karnofsky Performance Status >70%, and (6) willing to travel to the Buddhist temple. The exclusion criteria were as follows: diagnosis of any psychiatric illness that would prevent the patient from giving informed consent or from participating fully in the study and comorbidities (e.g., arthritis, bone metastasis, deformity, and certain neurologic conditions) that would impair performance of the hand and arm movements of the intervention.

Randomization

Consented participants were randomly assigned to either the intervention or control group using a 1:1 allocation schema and a table of computer-generated sequential random numbers. After patients completed the baseline assessments, the principal investigator (PI; S. Ngamkham) opened the sealed envelope to reveal the group allocation.

Recruitment and assessments

At the Outpatient Department of Sawanpracharak Hospital, nurses recruited patients with cancer who met...
the criteria and referred them to the PI, who determined eligibility and explained the study, including its objectives and procedures, to eligible patients. Those who decided to participate in the project provided signed informed consent, after which they were randomly assigned. After baseline assessments were completed, the PI opened the sealed envelope to reveal the group allocation.

**Thai Buddhism-based Mindfulness intervention**

Both the control and intervention groups received usual care and watched a 25-min cancer pain education video, which was developed by the PI. The video contains information about the definition and causes of cancer pain, pain mechanisms, and pain assessment. After watching the video, all participants were given the opportunity to ask questions of the PI. For example, some participants asked about the pain-relieving effects of herbs. In addition, the intervention group participated in the 8-week self-awareness mindfulness training program created by the Buddhist monk Luangpor Teean Jittasubho. During a 3-day, 2-night stay at Phromburi Temple in Sing Buri province, an expert monk individually trained each participant to perform the 15-position hand movement series [Figure 2], which was then practiced at home for the rest of the 8-week intervention. While practicing the mindfulness hand movements, participants could stand, lie down, or sit in any position on a chair or on the floor. Regardless of position, they were instructed to be aware of every moment. In order to encourage adherence to the TBbM intervention and to provide attention control, the PI made follow-up phone calls to the participants in both the groups every 2 weeks.

**Assessment time points and measures**

Participants in both the groups were to complete all questionnaires at baseline (Time 0) and at 8-week follow-up (Time 4) and report only their worst pain at 4 weeks (Time 2) [Table 1].

After modification and translation into Thai,[32] the Brief Pain Inventory-Short Form (BPI-SF) was used to measure worst pain (primary outcome variable) and pain interference (secondary outcome variable). The 9-item questionnaire quantifies pain location and intensity (worst, least, average, and current), and items are scored using a numerical rating scale of 0 (no pain) to 10 (pain as bad as one can imagine). The ninth question quantifies how much pain interferes with general activity, mood, walking ability, normal work, relations with others, sleep, and enjoyment of life, using a numerical rating scale of 0 (no interference) to 10 (completely interferes). The total pain interference subscale score is the sum of all interference item scores. Empirical evidence supports satisfactory validity and internal consistency reliability based on high Cronbach’s alpha coefficients for pain severity (0.89) items and the pain interference subscale (0.88).[32]

Anxiety and depression, known mediating variables that influence pain severity, were quantified using a Thai-language version of the 14-item Hospital Anxiety and Depression Scale (HADS).[33] HADS contains seven items in each of two subscales that measure anxiety and depression. Items are scored 0–3; subscale scores are computed by summing the scores of the seven individual items. The total score range of each subscale is 0–21, with higher scores indicating more severe symptoms. Internal consistency reliability is adequate, based on subscale Cronbach’s alpha coefficients: anxiety (0.85) and depression (0.82).[33] Three HADS cut-point scores reflect levels of symptom severity: nonanxious and nondepressed (0–7 scores), doubtful (8–10 scores), and anxious and depressed (>10).[33]

The 6-item Childhood Traumatic Events Scale (CTES)[34] was used to measure childhood traumatic events (before age 17) as a mediator of worst pain. It has four domains: (1) death of a close family member or friend, (2) parental separation, (3) serious illness, and (4) physical abuse, including sexual assault. Item responses range from 1 (not at
The psychometric properties of the CTES have not been published, but we have significant experience using this instrument and believe that it has acceptable face validity.\[34,35\] This tool was translated into Thai by the PI and was validated by 5 pain experts who speak both Thai and English (content validity index \([CVI]\) = 0.76). Internal consistency reliability was tested in 42 patients with cancer; the alpha coefficient \((\alpha = 0.51)\) was lower than acceptable established cutoffs.

The Mindfulness Assessment Scale (MAS)\[36\] was used to investigate self-awareness mindfulness as a secondary outcome; 15 items represent 3 domains (i.e., knowing, intention, and automatic responses). The MAS items quantify mindfulness based on a 1–6 rating scale; higher scores reflect a higher level of mindfulness. Cronbach’s alpha coefficients for knowing (0.82), intention (0.67), and automatic response (0.70) suggest moderate internal consistency reliability.\[36\]

The Beliefs about Pain Control Questionnaire\[37,38\] contains 13 Likert-scale items within three factors that measure the individual’s locus of control: personal (internal factor; 5 items), powerful others (doctor intervention; 4 items), and chance (4 items). Item responses range from 1 (strongly disagree) to 6 (strongly agree). A higher score indicates stronger endorsement of the item. Evidence supports moderate internal consistency reliability based on Cronbach’s alpha coefficients (0.68).\[38\] The PI translated this tool into Thai; 5 pain experts who speak both Thai and English assessed its content validity \((CVI = 0.83)\). Internal consistency reliability of the translated measure was adequate when tested in 42 patients with cancer \((\alpha = 0.72)\).

Table 1: Data collection timeline

| Data Collection                  | Time 0 | Time 1 2 weeks | Time 2 4 weeks | Time 3 6 weeks | Time 4 8 weeks |
|---------------------------------|--------|----------------|----------------|----------------|----------------|
| Measures                        |        |                |                |                |                |
| Demographic questionnaire       | X      |                |                |                |                |
| Cancer data form                | X      |                |                |                |                |
| Concomitant analgesics form     | X      |                |                |                |                |
| NRS for worst pain              | X      |                |                |                |                |
| BPI                             | X      |                |                |                |                |
| HADS                            | X      |                |                |                |                |
| CTES                            | X      |                |                |                |                |
| MAS                             | X      |                |                |                |                |
| BPCQ                            | X      |                |                |                |                |
| FACT-G                          | X      |                |                |                |                |
| Phone follow-up                 | X      | X              |                |                |                |
| NRS: Numerical Rating Scale; BPI: Brief Pain Inventory; HADS: Hospital Anxiety and Depression Scale; CTES: Childhood Traumatic Events Scale; MAS: Mindfulness Assessment Scale; BPCQ: Beliefs about Pain Control Questionnaire; FACT-G: Functional Assessment of Cancer Therapy-General
The 27-item Functional Assessment of Cancer Therapy-General (FACT-G) Version 4-T\(^{(39)}\) was used to measure the secondary outcome of QoL in 4 domains of well-being: physical (7 items), social/family (7 items), emotional (6 items), and functional (7 items). Items are scored using a five-point Likert scale of 0 (not at all), 1 (a little bit), 2 (somewhat), 3 (quite a bit), and 4 (very much). The total FACT-G score is obtained by summing the subscale scores; a higher total score indicates better QoL. The Thai language FACT-G has demonstrated good content validity and reliability (α = 0.86) when used with Thai cancer patients.\(^{(39)}\)

**Miscellaneous measures**

The demographic questionnaire collected information about participants’ age, gender, religion, education, income, and employment status. The cancer data form was used to collect cancer data (type, stage, and treatment). In addition, qualitative data were collected to evaluate the 25-min video educational program using only an open-ended question. Participants were asked, “What did you think about the educational program?”

**Statistical analysis**

Data were analyzed using the International Business Machines, Statistical Package for Social Sciences for Windows, Version 25.0 software (IBM Corp., Armonk, NY, USA).\(^{(40)}\) The percentage of participants who dropped out was used to evaluate recruitment and retention rates (i.e., feasibility). Descriptive statistics (number, percent, mean, range, and standard deviation [SD]) were used to describe sample characteristics and all outcome variables. Differences in sample characteristics between the groups were tested by Chi-square. Wilcoxon signed-rank tests were used to evaluate the efficacy of the TBbM intervention and ANOVA for analysis of pain change over time. All statistical tests were performed at a two-tail 5% level of significance. Cohen’s d was calculated to determine effect sizes. For evaluating the video educational program, the qualitative data were analyzed and categorized into participants’ understanding and application to their life.

**Results**

Twenty-three patients were consented, registered, and randomized to either control (n = 11) or intervention group (n = 12). In total, 17 completed the posttest: 10 from the control and 7 from the intervention groups.

**Characteristics of participants**

Tables 2a and b describe the baseline demographic characteristics. No significant differences were found between the intervention and control groups. The mean age was 44 years (± 8.77) in the control and 56 years (± 7.41) in the intervention groups. Most of the participants were Buddhist and female, with low education and income. They were diagnosed with cancer of various types and stages (I–IV); all were receiving chemotherapy. Patients were using a variety of pain medications such as warm balm cream, acetaminophen, celecoxib, gabapentin, and intravenous morphine.

**Feasibility**

Figure 3 shows the overall flow of participants through the study. Of 135 eligible patients, 112 (82.9%) declined to participate. Reasons for declining included lack of time and/or interest, health problems (e.g., severe pain, drowsiness, and nausea vomiting), family problems, time conflicts due to pending chemotherapy or radiation treatments, and the cost of traveling to the temple.

Of the 23 enrolled participants, 17 (73.9%) completed the postintervention test. All enrolled participants viewed the 25-min cancer pain education video. All participants
described the video as helpful and easy to understand and stated that their new knowledge would help them to better manage their pain. Seven participants (58%) reported that the TBbM intervention helped them feel peaceful, but traveling to the temple was inconvenient.

**Efficacy**

The TBbM participants reported that there was no statistically significant improvement in pain [Table 3] when compared to the control group. While not statistically significant, the effect was moderate (Cohen's d = 0.41). Regarding change over time [Table 4], there were statistically significant within-group differences in worst pain when comparing baseline to Time 2 and Time 4 scores in both the control ($\chi^2 = 11.002, P = 0.004$) and intervention groups ($\chi^2 = 12.333, P = 0.002$).

The descriptive results for the secondary outcomes and mediating variables are shown in Tables 5 and 6. When compared to the control group, the TBbM participants showed no statistically significant improvements in any variables, and effect sizes were small (Cohen's d < 0.30). CTES scores revealed no evidence of early childhood trauma for anyone.

For the qualitative results, 23 enrolled participants watched the cancer pain education program for 25-min long. All participants reflected that the educational program was particularly useful and easy to understand, thus feeling that they knew how to manage any pain they had.

**Discussion**

This small pilot study aimed to evaluate TBbM feasibility based on recruitment and retention rates and to obtain preliminary data regarding changes (effect sizes) in pain severity, pain interference, and other variables (anxiety and depression, locus of control, mindfulness, and QoL) when comparing control to TBbM-treated patients. In alignment with the Theory of Unpleasant Symptoms,[29,41] the TBbM intervention was hypothesized to address psychological and cognitive factors that could mediate changes in worst pain intensity. Because this randomized control trial was not adequately powered to detect mediation effects, an adequately powered study is needed to test the efficacy of the TBbM intervention and identify mediators of pain improvement.

Recruitment feasibility was poor: the intervention itself was not feasible for patients who were sick, undergoing cancer treatment, caring for families, and under financial constraints. Further, those who underwent chemotherapy at the time of recruitment also found it difficult to participate in the study because of time conflicts.
In terms of retention, the study attrition rate was 26%, suggesting that the current TBbM intervention is not feasible. High illness severity was the main factor influencing participant attrition. Published empirical evidence suggests that a mobile phone mindfulness-based stress reduction intervention for breast cancer survivors was feasible and acceptable. An app/online-based mindfulness intervention has also been well accepted by patients with cancer. Therefore, modification of the intervention to incorporate this technology may address barriers to retention.

We explored efficacy by comparing baseline to postintervention change in pain outcomes between the control and intervention groups. Our findings suggest that pain severity decreased in both the groups over time. However, since no statistically significant differences were found between the intervention and control groups, we cannot conclude that the TBbM intervention was better than education alone to improve pain outcomes. Since worst pain decreased significantly for both the groups when comparing baseline, Time 2, and Time 4, the cancer pain educational program may have been a factor. Evidence indicates that education can be effective in reducing pain severity; hence, study participants’ pain may have improved in both the groups after the pain education program due to subsequent shifts to an internal locus of control – beliefs that one can control their own pain – and knowledge of specific strategies for doing so.

Our findings contradict the results reported by Johannsen et al. and Johns et al. suggesting that mindfulness interventions do improve pain intensity. One possible explanation for this discrepancy is that these prior studies were adequately powered to detect an effect. In addition, our findings suggest that the TBbM intervention had a moderate effect on pain but a small effect on anxiety and depression, mindfulness, locus of control, and QoL variables. Another possible explanation is that practicing the TBbM intervention at the temple for 3 days and two nights may increase patients’ anxiety, particularly in women, due to perceptions within Thai culture. Thai women cannot touch and send something directly to monks. Thus, female patients believed that staying at temple was exceedingly difficult to eat, take a bath, sleep, and live. These results, obtained from our small pilot study, provide preliminary evidence supporting the need for an adequately powered study to test the effectiveness of a modified TBbM intervention that can be easily administered to sick patients.

Limitations

The study sample was small, homogeneous, and not representative of the general Thai population. The low recruitment rate (17% of eligible patients) suggests that selection bias likely compromised the study’s internal validity. Although all monks in the temple are experts in self-awareness mindfulness, participants were trained by different monks, which may have compromised intervention fidelity. Furthermore, the study was underpowered to detect statistically significant changes in the outcome variables, and data regarding analgesic use and dosage – an important, potentially confounding variable – were not collected. Finally, study participants and the PI were not blinded to the intervention assignment, and significant bias could have occurred given that the PI was also the interventionist.

Clinical implementation

Our results suggest that TBbM as currently designed is not a feasible intervention for Thai patients with cancer and should be modified and retested. However, given that participants found the cancer pain educational video and face-to-face discussions with the PI very useful and informative, health-care professionals can encourage self-management behaviors by providing pain-specific educational to patients/families.
Conclusions

Given the suboptimal recruitment and retention rates, the intervention should be modified. Our findings suggest that the intervention had a moderate effect on pain. However, to test the efficacy of a more feasible TBbM intervention, future adequately powered studies that also control for mediating factors and analgesic use are needed.

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Conflicts of interest

There are no conflicts of interest.

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