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Complementary Medicine Intervention in Breast Cancer Patients with Pain

A. M. Tacón[1*]

[1]Texas Tech University, Lubbock, TX, USA.

Author's contribution

The sole author designed, analyzed and interpreted and prepared the manuscript.

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ABSTRACT

Aims: The purpose here was to investigate for the first time effects following five-weeks of a complementary medicine intervention or mindfulness-based intervention (MBSR) in cancer patients with chronic pain. Specifically, psychological inflexibility in pain, pain self-efficacy, and expressive suppression were investigated for the first time in breast cancer patients with cancer-related pain.
Study Design: One group pre-post intervention design.
Place and Duration of Study: Lubbock, Tx medical center, spring 2010.
Methodology: Sample: The sample consisted of 46 participants with 36 women in stage II (78%) and 10 (22%) in stage III with a mean age of 55 years. The MBSR intervention was held in a hospital counseling center for 1.5 hours/week for eight-weeks, with preliminary data collected at five weeks (reported here), at the end of the full program three weeks later, and three months post the 8-week program. Preliminary data here were collected on standardized instruments before (pre) and after (post) the five-week point of the eight-week MBSR program to evaluate intervention effects on the following: Psychological inflexibility in pain, pain self-efficacy, emotional regulation of suppressive expression, and pain intensity.
Results: Psychological inflexibility in pain scores prior to the program (M=60.05, SD=14.22) decreased significantly by the end of five-weeks of the program (M=57.68, SD=13.46) (t=3.76, *P* =

**Corresponding author: E-mail: ANNA.TACON@ttu.edu;*

0.01); Pain self-efficacy prior to the program (M=20.61, SD=11.47) increased significantly by the end of the five-week period of the mindfulness intervention (M=22.47, SD=10.63) (t=3.11, *P* < *0.05*); Emotional regulation strategy of suppression before the program (M=22.77, SD=7.75) dropped significantly by the end of the five-week mark (M=19.63, SD=8.43) (t=3.68, *P = 0.01*); lastly, pain intensity prior to the beginning of the intervention (M=33.67, SD=8.48) did not change significantly by the end of the five-week mark (M=32.86, SD=8.20) (*P* > *.05*).

Conclusion: These findings after five weeks of the intervention should be interpreted cautiously, for replication and future research need to be conducted at this time period. The results, however, provide data in the neglected area of cancer patients with cancer related pain and the possibility of effective yet shortened mindfulness interventions.

Keywords: Cancer; breast cancer; cancer-related pain; complementary medicine; mindfulness; MBSR.

1. INTRODUCTION

It is estimated that approximately 60 million people experience chronic pain with estimates of chronic pain prevalence near 20-25 percent, depending on country and region [1]. Population-based research demonstrates greater pain prevalence among women relative to men; epidemiological studies across multiple geographic areas show that women are more sensitive to and experience more intense pain than men [2-3]. Pain is the most persistent and incapacitating symptom experienced by cancer patients [4]. While biological and neuropathic pain etiologies are common in cancer, cognitive and affective aspects can more strongly contribute to pain ratings than sensory aspects [5]. Yet, more research as to emotional and cognitive factors exist in non-malignant pain samples than those with cancer pain. The purpose here is to investigate for the first time the effects of a mindfulness-based complementary medicine intervention after 5-weeks on the cognitive and emotional factors of psychological flexibility in pain, pain self-efficacy, and emotional regulation, as well as pain ratings in breast cancer patients with cancer-related pain.

1.1 Psychological Flexibility

An important cognitive factor in the treatment literature of chronic, persistent *nonmalignant* pain, is psychological flexibility (PF), here coined as cognitive freedom from psychological rigidity and avoidant strategies in response to unpleasant internal experience. Psychological flexibility is the ability to act effectively in accordance with a valued life in the presence of unpleasant thoughts, emotions or bodily symptoms, and is the overarching treatment process in Acceptance and Commitment Therapy (ACT) [6-8]. Psychological flexibility can be conceptualized as a process of being in the present moment (mindfulness) *without* avoidance and judgment, behaving in adaptable ways, and adjusting behaviors in order to achieve valued ends or goals [6,9]. The maintenance of distress is viewed as related to fused cognitions; thoughts and previous experience become paired until merely the thought evokes the same emotional reaction as the actual experience [10]. Thus, adaptive living in the presence of unpleasant experience is usurped with increased suffering---not because of external events---but by the internal processing strategies of those events. No study to date has investigated the effects of a mindfulness intervention on PF in women with breast cancer.

1.2 Pain Self-efficacy

Bandura defined self-efficacy as “people's judgments of their capabilities to organize and execute courses of action required to attain designated types of performances” [11,391]. According to Bandura’s social cognitive theory, self-efficacy is conceptualized as a reflection of a “resilient self-belief system” in the face of obstacles, that is, the confidence to persistently and successfully perform or engage in specific activities or tasks [12]. Here, pain is the obstacle focused on in women with cancer in order to increase such a “resilient self-belief” resource to cope effectively with malignant pain. Studies show that general self-efficacy enhances cancer adjustment by patients’ engaging in behaviors due to the confidence of being able to effectively manage their symptoms [13-14]. Pain self-efficacy refers to the belief and confidence one has to live a meaningful life and trust one’s expectation of being able to successfully manage and deal with pain [15]. The recognition of pain self-efficacy as an important factor in chronic

pain experience has increased over the past two decades, likely due to increasing awareness of biopsychosocial interactions; for example, that beliefs or judgments individuals hold as to their ability to affect personal health may impact prognosis [15-16]. In terms of cancer, Porter and colleagues view pain self-efficacy as critical to a cancer patient's ability to manage the physical and psychological challenges unique to this disease [17]. Yet, no study has investigated mindfulness effects on pain self-efficacy in women with cancer; secondly, no known MBSR study specifically has used Nicholas' established pain self-efficacy measure [15].

1.3 Emotion Regulation

The avoidance of internal experience can affect emotion regulation [18], and the avoidance of valued activities are considered to be related to verbal processes, which can affect behavior [6, 8]. Also, the avoidance of internal experience when emotionally aroused can manifest as expressive suppression or as inhibiting emotionally expressive behavior [18]. Historically, a plethora of studies demonstrate emotional suppression tendencies in those with breast cancer as well as a diversity of instruments with which to measure this characteristic [19]. Maladaptive emotional suppression strategies in women with breast cancer is associated with more emotional distress, depression and anxiety symptoms, poorer physical health and quality of life [20-22]. Schlatter and Cameron recommended interventions aimed at reducing emotional suppression to help breast cancer patients cope with side effects of chemotherapy [23]. Additionally, mindfulness is viewed as an effective strategy for emotion regulation [24-25]. While interest in mindful emotion regulation exists [e.g.,26] no study has examined the effects of a mindfulness intervention on this important factor using Gross' well-known measure of the Emotion Regulation Questionnaire (ERQ) in women with breast cancer and pain [27].

1.4 Mindfulness Meditation

According to Kabat-Zinn and the basis for the Mindfulness-Based Stress Reduction (MBSR) program, mindfulness is the disciplined practice of ''paying attention in a particular way, on purpose, in the present moment, and non-judgmentally'' [28;4]. Mindfulness encourages a "beginner's mind" of each moment with detached, non-judging awareness --- being an authentic witness to one's thoughts, feelings, perceptions, sensations---as well as providing a means of self-monitoring and self-regulating one's arousal [28]. MBSR studies document beneficial findings for cancer populations. For example, the MBSR has been shown to significantly reduce stress levels and state anxiety, cancer distress and fatigue, pain anxiety and pain catastrophizing, pain intensity, as well as improve cancer coping, and health locus of control in cancer populations [29-32].

Despite accumulating mindfulness studies in cancer population, a paucity exists as to the knowledge of MBSR's effects in those with cancer-related pain, and no known research has investigated MBSR effects on psychological inflexibility, pain self-efficacy or emotion regulation. Therefore, the aim of the present study was to address this literature gap by investigating the effects of a mindfulness intervention on these specified factors in women with breast cancer and cancer-related pain. Here, preliminary data will be reported after five-weeks of the intervention as part of the traditional eight-week program. Data on the pain intensity ratings also were collected for comprehensiveness of the pain experience. Since investigating mindfulness effects on pain specific psychological flexibility-inflexibility, pain self-efficacy, and emotion regulation were exploratory in women with breast cancer, no hypotheses were made. Based on previous findings [32], it was hypothesized that pain ratings would improve at the end of the five-week mark.

2. MATERIALS AND METHODS

2.1 Design

A one group pre-test/post-test design was used to investigate changes in the primary intervention factors of interest to this study. Specifically, preliminary pre-post measures were assessed before and at the end of the five-week mark of the eight-week MBSR intervention on the factors of focus in the current study: psychological inflexibility, pain self-efficacy, and emotional suppressive regulation in women with breast cancer suffering from persistent pain. Data were collected following the full eight-week program as well as three months post the eight-week mark, which will be presented at another time. Pain intensity ratings were assessed as a standard measure to reflect a biopsychosocial approach.

2.2 Recruitment

Following Human Subjects Ethical Approval by the institutional review for research, participants were recruited through medical facilities by fliers, media advertisements, and referrals from physicians and the American Cancer Society in a southwestern community of approximately 200,000 residents. Informed consent forms were signed prior to the beginning of the intervention.

2.3 Intervention

The MBSR program was held in a hospital counseling center for 1.5 hours/week for eight-weeks, with preliminary data collected at five weeks, at the end of the full program three weeks later, and three months post the 8-week program. Several mindfulness interventions with cancer patients modified the program length to six weeks [33] and excluded the traditional, full 1 day, 8-hour silent retreat, which was done here out of consideration for the participants' health. Thus, it was decided to collect preliminary data at the five-week point to determine if significant changes could be detected. Participants were trained in the mindfulness practices of: body scan, sitting meditation, hatha yoga and mindful walking as condition permitted. For the latter two more physical strategies, other mindfulness strategies were substituted as needed. As described elsewhere [29-32,34] the body scan is a journey through the geography of the physical body. It involves a gradual, thorough sweeping of attention through the entire body, focusing non-critically on sensations or feelings in body regions with suggestions of breath awareness, acceptance, and relaxation. Hatha yoga involves simple stretches and postures (asanas) designed to strengthen the body and increase flexibility via relaxation of the musculoskeletal system and the development of mindful movement. Yoga is considered to be "meditation in motion," wherein focused body awareness of each movement is gently coordinated with breathing. Sitting meditation involves attention to the breath and other psychophysical perceptions, with an observational yet non-judging awareness of cognitions and distractions that constantly flow through the mind. Walking meditation is the practice of paying attention to sensations during this mundane activity of physical movement. The women received formal guidance and direction of mindfulness practices; compact discs were provided for daily homework of techniques learned in the weekly sessions.

2.4 Outcome Measures

Data were collected on standardized instruments before (pre) and after (post) the five-week point of the eight-week MBSR program to evaluate intervention effects on the following outcome variables.

2.4.1 Psychological inflexibility in pain

Psychological flexibility/inflexibility was assessed by the 12-item Psychological Inflexibility in Pain Scale (PIPS) [8,10]. This measure specifically focuses on PF as it pertains to pain experiences. The PIPS measures the tendency to engage in behavior that serves to avoid pain and distress and assesses the frequency of pain-related thoughts likely to lead to avoidance behavior The PIPS contains two subscales of avoidance and cognitive fusion as rated on a 7-point Likert scale (1 = *never true*, 7 = *always true*), with higher scores indicative of greater psychological inflexibility (range 12–84). Sample avoidance items include the following: "I avoid planning activities because of my pain", and "I don't do things that are important to me to avoid pain." The cognitive fusion subscale is intended to measure the enmeshment of pain-related thoughts and actual events, that is, the ability to separate or defuse oneself from his/her thoughts about the pain and possible causes. Sample items include: "It is important to understand what causes my pain," and "It is important that I learn to control my pain." The PIPS has satisfactory properties, that is, good factor structure and internal consistency, reliability as well as convergent validity, and has been translated for use in other countries [8,10,35]. The total score was used.

2.4.2 Pain self-efficacy

Self-efficacy pertaining to ongoing pain was assessed by Nicholas' 10-item Pain Self-Efficacy Questionnaire [15], which is based on Bandura's theory and the concept of self-efficacy. The PSEQ is widely used in clinical and research settings and studies support the psychometric properties of the PSEQ [15]. The PSEQ assesses the confidence that people with persistent pain have in successfully being able to perform activities. A sample item is, "I can cope with my pain in most situations." Items are presented on a 7-point Likert scale (0 = not at all confident to 6 = completely confident), and summed for a total score with a possible range from 0 to 60; higher scores indicate greater pain

self-efficacy. The PSEQ has been translated into multiple languages [e.g.,36-37].

2.4.3 Emotion regulation

The Emotion Regulation Questionnaire (ERQ) was used to measure suppressive tendencies [27]. The ERQ has been used in over 200 publications and has been translated into 21 different languages with good psychometric properties [e.g.,38-39]. The ERQ consists of 10 items with two subscales. The Expressive Suppression subscale of four items (range 4 – 28) was used, and contains items such as... "I keep my emotions to myself." Participants rate the items on a 7-point Likert scale (1 = strongly disagree, 7 = strongly agree), with higher scores indicating greater use of the emotion regulation strategy.

2.4.4 Pain intensity

The pain rating index (PRI) of the McGill Pain Questionnaire, short form (MPQ-SF), was used in this study to measure pain intensity [40]. This well-known measure has been used with cancer populations and contains two dimensions: the sensory dimension consisting of 11 items; and, the affective dimension consisting of 4 items. The pain level is determined by the sum of scores for the 15 items (range 0 to 45), with higher scores indicating greater pain. The MPQ-SF has demonstrated construct validity as well as internal reliability and test-retest reliability [40].

3. RESULTS

Statistical analyses of the data consisted of paired t-test analyses that were conducted using an SPSS software program to assess *pre*-and-*post* changes for each outcome variable at the end of the five weeks.

3.1 Participants

The sample consisted of 46 participants with 36 women in stage II (78%) and 10 (22%) in stage III with a mean age of 55 years (see Table 1). The majority were Caucasian (93%), Protestant (90%), married (86%), with a modal family income between $ 22,500 and $ 69,110 (85%). Most were educated beyond high school (77%), 8 women were working part-time (17%), and 20 women (43%) indicated a family history of cancer. Cancer pain was confirmed by the attending oncologist in order to participate. Time from diagnosis and treatment ranged from 16-months to 3.5 years at the time of the intervention. Exclusion criteria included: no cancer associated pain or chronic pain status, current primary sites other than breast, less than 18 years of age, and psychopathology according to physician diagnoses. Also, none of the women expressed practice of mindfulness strategies. Participants kept their standard medical care during the program, since complementary therapies are not intended to replace primary care.

3.2 Pre-post Results

The factor of psychological flexibility/inflexibility as it pertains to pain showed significant changes from the pre-to-post five-week period. Scores prior to the program (M=60.05, SD=14.22) decreased significantly by the end of five-weeks of the program (M=57.68, SD=13.46) (t=3.76, P = 0.01). This indicates a reduced tendency to engage in avoidance and cognitive fusion. Refer to Table 2 for results.

Exploratory results for pain self-efficacy revealed significant changes from the pre-to-post five-week post period. Specifically, pain self-efficacy prior to the program (M=20.61, SD=11.47) increased significantly by the end of the five-week period of the mindfulness intervention (M=22.47, SD=10.63) (t=3.11, $P < 0.05$).

Another exploratory analysis of this study was that of expressive suppression. Results showed that this emotional regulation strategy before the program (M=22.77, SD=7.75) dropped significantly by the end of the five-week mark (M=19.63, SD=8.43) (t=3.68, P = 0.01).

It was predicted that pain intensity would significantly improve as indicated by a reduction in pre-to-five-week post scores for pain ratings as measured by the MPQ-SF. While results showed decreasing pain intensity from the beginning of the intervention (M=33.67, SD=8.48), findings did not reach significance by the end of the five-week mark (M=32.86, SD=8.20) (P >.05) Thus, the single hypothesis of this preliminary report based on previous research was not supported.

4. DISCUSSION AND CONCLUSION

The purpose here was to investigate for the first time the effects of a mindfulness-based intervention after 5 weeks on psychological flexibility/inflexibility pertaining to pain, pain self-efficacy, and emotional regulation in women with

breast cancer and cancer-related pain. Pain intensity ratings also were assessed. Preliminary data were collected at the end of the 5-week mark [during the eight-week program] due to consideration for the patients' condition; also, data were collected early to see if changes occurred during this shortened period of intervention time.

Table 1. Demographic characteristics

Characteristic	n	%
Patients (N = 46)		
Age $\bar{X}$ = 55	-	-
Ethnicity		
Caucasian	43	93
Hispanic	3	7
Education		
High School	11	24
Some college	6	13
Undergraduate	23	50
Masters degree	4	9
Doctoral or advanced degree	2	4
Employment		
Part-time	8	18
Unemployed	36	78
Retired	2	4
Religion		
Protestant	41	90
Catholic	5	10
Married		
Yes	40	86
No	1	2
Divorced	5	12
Income		
Less than $22,500	0	0
$22,500 - $69,110	39	85
$69,111 - $99,999	5	10
> $100,000	2	5
Family history cancer		
Yes	20	43
No	26	57
Stage (at diagnosis)		
II	36	78
III	10	22
I & IV	0	0
Treatment history		
Chemotherapy	31	67
Chemo & Radiation	15	33
Medical treatment		
Non-opioids	11	24
Opioids (low level)	10	22
Opioids (strong level)	12	26
Combination	13	28

Psychological flexibility is an important cognitive factor in the treatment literature of chronic nonmalignant pain, however, no known MBSR study has investigated it in women with breast cancer until now. Psychological inflexibility is associated with psychological rigidity and avoidant strategies in response to unpleasant events, here, the unpleasant experience of pain. Exploratory investigation at the end of five-weeks revealed improvement in scores. Specifically, scores for psychological inflexibility regarding pain decreased significantly, suggesting that mindfulness-based techniques may counter internal rigidity processing patterns by reducing the use of avoidant and cognitive fusion strategies. Simply put, mindfulness is the opposite of avoidance. This is consistent with psychological flexibility conceptualized as being mindfully in the moment without avoidance and judgment, behaving in adaptable ways, and adjusting behaviors in order to achieve valued ends or goals [6,9]. It is encouraging that significant changes were revealed at the five-week intervention point in this initial study, which, of course, needs further investigation and replication. Yet, a program shorter than the standard eight-weeks for those with cancer pain may serve their needs and health status more compassionately.

Pain self-efficacy refers to the belief and confidence one has in self to live a meaningful life and trust one's expectation of being able to successfully manage and deal with pain [15]. Studies have shown that higher self-efficacy in cancer patients is related to better psychological adjustment and decreased symptoms of depression, better well-being and quality of life [41-43]. This was the first study to investigate mindfulness intervention effects as measured by the pain self-efficacy questionnaire in women with cancer [15]. The present data revealed a significant trend of increasing pain self-efficacy scores after five-weeks of the intervention. Since this is the first MBSR study of this kind in a sample of women with cancer, there are no data for comparison. It must be kept in mind that these findings are initial and preliminary, and thus, should be viewed with caution until further studies are conducted.

The emotion regulation strategy of expressive suppression was another novel factor of interest in this MBSR study. Emotional suppression has been studied and documented for decades as: a risk factor for malignant disease; a common emotional pattern among individuals with cancer; and, as being associated with disease progression [44-47]. More specifically, emotion

Table 2. Means and standard deviations dependent variables pre- and- post

Variable	Mean-pre	SD-pre	Mean-post	SD-post	*T (P)*
Psych. Inflexibility	60.05	14.22	57. 68	13.46	3.76** (P =.01)
Pain Self-Efficacy	20.61	11.47	22.47	10.63	3.11* (*P* =.041)
Expressive Suppression	22.77	7.75	19.63	8.43	3.68** (P =.01)
Pain Intensity	33.67	8.48	32.86	8.20	*P* >.05

**P < 0.05; **P = 0.01*

regulation is recognized for its role in disease adaptation in those with breast cancer. The way women regulate/express their emotions affects their psychological well-being as well as endocrine and immune function, which all play a role in prognosis [46,48-49]. In the current study, scores on expressive suppression dropped significantly after five-weeks of the mindfulness program. This is in line with mindfulness as a state of non-judgmental awareness, of simply witnessing one's thoughts, feelings, and experiences with detachment; also, mindfulness is viewed as a strategy for enhancing healthy emotion regulation [28,50-51]. Indeed, mindfulness is considered antithetical to expressive suppression since an individual learns "to accept, rather than reflexively act on thoughts and emotions" [52;566]. Likewise, mindfulness is associated with greater emotion differentiation and less emotional problems [53]. This finding, thus, is consistent with the basic premise of mindfulness.

Finally, the single hypothesis of the study was that pain ratings would decrease significantly at the end of five-weeks of the mindfulness intervention. This hypothesis was based on previous findings [32]. While a trend of decreasing scores for pain intensity ratings was found, it did not reach significance. A possible explanation is that the previous finding was based on data collected at the end of a traditional eight-week MBSR program. Perhaps more intervention time is needed for significant change in pain intensity to be acknowledged cognitively.

Limitations must be acknowledged. First, stage II and III patients participated in this study, hence the biggest limitation is that patients with stage IV disease---those who suffer the most from pain---are not studied here. Next, the data were collected from a sample of women with breast cancer, thus, findings cannot be generalized to other populations or malignant disease groups. Third, the program includes mindful practices (*e.g.*, body scan, mindful walking, etc.) in addition to the traditional [sitting] meditation training. Therefore, it cannot be ascertained whether intervention effects were due to one practice or to a combination thereof. Next, this study was based on a pre-post design lasting for eight weeks, with preliminary data collected and reported here at the end of five weeks. The data were collected early because of a patient-centered compassionate perspective; namely, when working with cancer patients suffering from cancer-related pain with the added toll and exhaustion that pain produces, their condition may prohibit them from participating in an intervention that lasts the full two-months or longer. Lastly, it is recommended that future studies include a comparison group to assess between group differences.

In conclusion, this was the first MBSR-breast cancer exploration in women to investigate the factors of psychological inflexibility regarding pain, pain self-efficacy, and expressive suppression. These preliminary findings after five weeks of the intervention need to be interpreted cautiously, for replication and future research needs to be conducted. Follow-up data at the end of the traditional eight-week program as well as three months post-intervention will be collected and reported at a later time. The results of this study, however, provide data in the neglected area regarding cancer patients with cancer related pain and question the possibility of effective yet shortened mindfulness interventions.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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