



'5 Minutes Mindful Breathing' Smartphone Application for Reduction of Perceived Distress: A Pilot Study

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Background: We have found our 5-minute mindful breathing technique to be effective in reducing distress in palliative cancer patients. As palliative cancer patients tend to experience high levels of distress, the integration of this technique into a smartphone-based application could be a viable intervention option for these patients as well as their caregivers.

Objective: We aim to further examine the efficacy of our mindful breathing module on distress reduction within the context of a smartphone-based application for palliative cancer patients and caregivers over a seven day period. We hypothesized that the intervention group (access to mindful breathing module) would have significantly greater distress regulation than the control group (access to soothing music) over seven days of using the smartphone-based application.

Methods: 35 subjects were recruited from the palliative care ward at University Malaya Medical Centre (UMMC) and randomly assigned to either the control (access to soothing music) or intervention (access to mindful breathing module) group respectively. They then used and followed instructions as per the smartphone-based application for seven days.

Results: While both groups reported a reduction in distress in using the application, there was no significant difference in reported distress levels between those who had access to the mindful breathing module and those who had access to only soothing music over the seven days. Our hypothesis was not supported.

Conclusion: Although not significantly greater than the control group, the intervention group reported a reduction in distress using the smartphone application, which suggests that the integration of mindfulness and smartphone applications could potentially play a role in future distress reduction for patients and caregivers in view of its accessibility, ease of administration and anonymity.

Introduction

Cancer is one of the most common chronic diseases globally, with its incidence and mortality rapidly growing. In 2018 alone, there were 18.1 million predicted new cancer cases and 9.6 million cancer-related deaths [1]. Due in part to intense treatments, heavy economic burden as well as comorbidities, chronic diseases including and especially cancer bring with them an additional increased risk of poor mental health [2-3]. The National Comprehensive Cancer Network [4] defines cancer-related distress as a "multifactorial unpleasant emotional experience of a psychological (cognitive, behavioural, emotional), social and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment". Psychological distress is a broad construct, encompassing common emotions such as sadness, vulnerability, and fear as well as more debilitating issues such as clinical depression and intense anxiety. Heightened psychological distress in patients with cancer is often associated with negative outcomes such as



lesser treatment adherence [5], higher mortality risk [6-7], and poorer quality of life for both patients as well as their caregivers [8-9]. Consequently, the NCCN[4] recommends that patients be routinely screened for distress, regarding it as the “6th vital sign” in cancer.

Often defined as the intentional and non-judgmental awareness of the present-moment experience [10], mindfulness may be especially helpful in dealing with uncertainty underlying the distress from cancer diagnoses. The practice of mindfulness leads to distress reduction through several mechanisms: (1) the interruption of automatic negative thoughts through intentional awareness,(2) the reduction of worry and rumination through focusing on the present moment, and (3) the reduction of negative appraisals through non-judgmental awareness [11].

When experiences are not judged as positive or negative, good or bad, one would be able to simply notice and accept the experiences as they are while letting go of the struggle to control that which is uncontrollable (eg. illness progression, death) [12]. Ultimately, the aim of MBT is to teach individuals to deal more effectively with the distress experience as it arises in the present moment, including being non-judgmental towards their awareness of feelings, thoughts, and bodily sensations [13-14].

Mindfulness-based treatments (MBT), offered widely as Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT), have been of particular interest in distress reduction due in part to the growing body of literature amassing support for its efficacy in alleviating symptoms of depression and anxiety in both chronic disease patients [15-16], cancer patients [17-18-19], as well as their caregivers [20]. Despite well-established benefits, getting access and participating conventional MBT can be challenging for patients undergoing treatment as these MBT are typically expensive and time consuming, consisting of 1.5 to 2.5 hours of face-to-face group sessions spanning the course of eight weeks as well as both in- and out-of-session practice. Patients with terminal illness often experience fluctuating states of physical impairment, mental distress and consciousness in addition to suffering from treatment side effects [21]. As such, cancer patients and their caregivers, whose own distress often parallels that of the patient [9], may find attending these sessions extremely difficult [22]. Beyond that, these interventions require experienced therapists to implement them and thus tend to be less accessible as well as more costly. With these in mind, a 5-minute mindful breathing exercise was developed to address these limitations.

Based on a series of mini-mindful practices developed specifically for terminally ill patients, the 5-minute mindful breathing exercise focuses on mindful breathing as it is one of the central practices in mindfulness from which other practices are anchored [23]. Mindful breathing requires the individual to direct their attention to the present moment, particularly to the sensation of breathing, while non-judgmentally taking note of when their mind wanders away. In our previous studies, participants were assigned to the treatment “5-minute mindful breathing” arm or to the control “listening” arm, where they would simply be listened to [11-14]. In both the pilot study [11] and randomized controlled trial [14], we demonstrated the efficacy of this 5-minute mindful breathing in rapidly reducing distress to a greater extent among palliative cancer patients as well as their caregivers compared to the “listening” control arms. In our randomized controlled trial conducted on palliative cancer patients (n=60), this subjective finding was further supported by significant physiological changes associated with distress reduction such as decreased breathing rate, blood pressure, pulse rate, galvanic skin response, and an increased skin surface temperature [14]. Instructions for the practice were designed to be clear and simple [11]. Any healthcare professional would be able to follow the instructions and administer it without needing specific training.

Rationale of the Study

Worldwide, the number of smartphone users today surpasses three billion and this figure is

forecasted to increase by several hundred million in the next few years [24]. Given the high user prevalence and rapid rate at which technology evolves, internet or smartphone-based interventions could play a vital role in addressing the barriers that prevent distressed cancer patients and their overburdened caregivers from receiving the help they need. Smartphone-based mental health interventions and research into them alike have rapidly increased in recent years, with many studies demonstrating their potential as effective screening tools for depression in varying sample populations [25-26-27], in depressive symptom management [28] and in stress and anxiety management [29-30-31]. Several studies have even found smartphone based interventions to have comparable efficacy to face-to-face interventions [30-32]. Nonetheless, this area of study is still relatively new and there exists a lack in both evidence-based mindfulness smartphone-based apps in the market as well as the literature examining those currently available [33-34-35]. Chandrashekar [33] stressed the above but continued to emphasise the potential of smartphone-based apps in delivering high efficacy mental health interventions with lowered costs and increased accessibility.

With the above in mind, the 5-minute mindful breathing app was conceptualised based on the aforementioned prior research (pilot study [11], randomized controlled trial [14]) which found strong evidence for the efficacy of the 5-minute mindful breathing technique on distress reduction. To our knowledge, the present study represents the first randomized controlled pilot study investigating the efficacy of a smartphone-based 5-minute mindful breathing module in reducing psychological distress for palliative cancer patients in a Malaysian setting. While this is in no way suggesting that this application substitute conventional therapy, it could provide some aid in distress reduction for those with limited accessibility to effective psychotherapy or psychological intervention as well as act as a supplement for those who currently receive such treatment. The present study aimed to examine the effectiveness of a newly developed smartphone-based 5-minute mindful breathing module for distress reduction in palliative cancer patients.

Objectives

To determine the efficacy of smartphone-based APP of 5-minute mindful breathing for the reduction of distress or suffering in palliative cancer patients.

Materials and Methods

Study Design and Subjects

This study was a randomized controlled trial lasting seven days. Subjects were recruited from the palliative care ward at University Malaya Medical Centre (UMMC).

Sample Size

Based on the previous study, the estimated number of subjects for this pilot study was 20 per arm. A total of 35 subjects were recruited and randomly assigned to the control (19 subjects) and intervention (16 subjects) groups respectively. However as the trial progressed, more subjects started to drop out, resulting in no participants in the control group by the 6th day and only three participants in the intervention group at the end of the study.

Subject Selection

Inclusion criteria: (1) Aged 18 years and above, (2) Palliative care patient or caregiver of palliative patient, (3) Diagnosed with cancer of any type, (4) Owns a smartphone device with network connection and sufficient knowledge to use it, and (5) Experienced moderate to severe distress (Scores 4 or above on the Distress Thermometer).

Exclusion criteria: (1) Experiences delirium or confusion, (2) Experiences breathing difficulties/respiratory distress, and (3) Unable to maintain concentration for at least 20 minutes.

Procedure

Participants first answered the Distress Thermometer, where they rated their distress on a scale of 1-10. They were then screened based on the aforementioned inclusion and exclusion criteria. Upon acceptance and consent into the study, all participants were instructed to download the smartphone-based app from their respective app store (either Apple or Android). They were then given a unique username and password in order to gain access to their respective version of the app (either the control or treatment version). Google analytics was integrated into the smartphone app in order to track the duration of usage as well as the individual functionalities within the app used by each user including how many times an individual clip was listened to. The login information as well as the analytics obtained from the participants was stored in a HIPAA-compliant cloud-based web server located in Singapore (Amazon S3 Cloud Services). No personal patient-related identifiers was stored in the cloud-based server.

All participants were given access to an FAQs about the app's functionalities and were instructed to rate their suffering on a 10-point scale (higher rating indicates higher distress) across a period of seven days. An analytic tool was accessible for all participants to view a trend of their ratings across time.

Those in the control group only received access to soothing music. Participants in the intervention group on the other hand were given access to a special module titled "5 minutes mindful breathing," which consists of a compilation of audio tracks of the mindful breathing exercise previously examined in our prior studies [11-14]. All participants were briefed about the study and were requested to use the app daily during the study period. They were expected to allocate time and find a suitable place everyday for seven days to follow the instructions as per the app. Participants received no compensation for their participation.

Statistical Analysis

Distress was measured using the Distress Thermometer, where scores ranged from 0 to 10 with a higher number indicating higher distress. This measurement was taken once before the intervention (pre) and again after the intervention (post) for both groups. The same procedure was then repeated daily for a total of seven days.

An align ranked transformation method in ARTool was used to transform the non-normal data [7]. The data was then analysed using mixed ANOVA with groups (control versus intervention) as a between-subjects factor and time (pre and post) as a within-subject factor. The interaction between groups and time were also analysed. The scores for each day were also averaged up from seven days of data collection before being analysed using the same mixed ANOVA. All statistical analyses were carried out with SPSS 23.

The analyses were done for the within-group change in distress score from pre- to post treatment for each group and also to compare the between-group (control versus intervention) change in distress scores. The objective was to see which group had significant and hence more effective

distress reduction.

Results

The average age of study participants was about 47 years old. A majority of the participants were married Chinese females and most had a secondary school educational level or higher. Participants were mostly undergoing chemotherapy for different kinds of cancer and reported an average distress score of 5 (Table 1).

Socio-demographic	Control (n=19)	Intervention (n=16)*
Age, mean (SD)	47.95 (14.362)	47.31 (11.563)
Gender, n (%)		
Male	7 (36.8)	9 (56.3)
Female	12 (63.2)	7 (43.7)
Race, n (%)		
Malay	4 (21.1)	6 (37.4)
Indian	2 (10.5)	3 (18.8)
Chinese	13 (68.4)	7 (43.8)
Marital status, n (%)		
Single	4 (21.1)	2 (12.5)
Married	15 (78.9)	14 (87.5)
Employment status, n (%)		
Yes	4 (21.1)	10 (62.5)
No	15 (78.9)	6 (37.5)
Educational level, n (%)		
Primary	2 (10.5)	0
Secondary	9 (47.4)	5 (31.2)
Tertiary	8 (42.1)	11 (68.8)
Clinical	Control (n=19)	Intervention (n=16)*
Type of cancer, n (%)		
AML		1 (6.3)
Breast cancer	5 (26.1)	
Burkitt lymphoma	1 (5.3)	
Cervical intramedullary tumour		1 (6.3)
Cervical cancer	1 (5.3)	
CNS Lymphoma		1 (6.3)
Colorectal cancer		1 (6.3)
Endometrial Adenocarcinoma	1 (5.3)	
GB tumour		1 (6.3)
GCT with testicular cancer		1 (6.3)
Haemangiopericytoma	1 (5.3)	
HCC		1 (6.3)
Hogkin lymphoma		1 (6.3)
Leukemia	1 (5.3)	
Lymphoma	2 (10.3)	1 (6.3)
Malignant peripheral nerve sheath tumor	1 (5.3)	
Metastatic follicular thyroid cancer and recurrence granulosa cell tumour of R ovary	1 (5.3)	
Metastatic prostate cancer	1 (5.3)	
NPC	1 (5.3)	1 (6.3)

Primary lung cancer with distant mets	1 (5.3)	
Relapse pleomorphic sarcoma	1 (5.3)	
Recurrence distal femur osteosarcoma		1 (6.3)
Schwannoma		1 (6.3)
Synovial sarcoma	1 (5.3)	
Duration of cancer (months), median (IQR)	12.0 (14.0)	5.5 (1.8)
Current treatment, n (%)		
Chemotherapy	8 (42.1)	4 (25.0)
Chemotherapy, radiotherapy	1 (5.3)	1 (6.2)
Chemotherapy, hormonal therapy, past surgery	2 (10.5)	
Chemotherapy, hormonal therapy, radiotherapy, past surgery	2 (10.5)	
Chemotherapy, past surgery	3 (15.7)	4 (25.0)
Hormonal therapy, radiotherapy	1 (5.3)	
Nil	1 (5.3)	4 (25.0)
Past surgery	1 (5.3)	3 (18.8)
Distress score, median (IQR)	5.0 (1.5)#	5.0 (2.8)

Table 1: Socio-demographic and Clinical Characteristics of the Study Subjects.

*n, Frequency; SD, Standard deviation; IQR, Inter quartile range; * 13 out of 16 patients in the intervention group agreed to participate in the trial; # the median score was calculated based on 17 participants from the control group.

For most days, subjects reported significant reduction of distress after having the intervention, regardless of it being the special module of “5 minutes mindful breathing” (intervention) or soothing music (control). However, between group comparison suggested that there was no significant difference in distress reduction between these two groups (Table 2).

Day	Time Groups (n)	Mean (SD)	ART Mean (SD) [1]		ART Mean (SD) [2]		ART Mean (SD) [3]	p value [3] (groups X time)
1	Pre-Intervention (n=13)	5.46 (1.506)	73.46 (40.093)	0.479	90.15 (37.092)	≤ 0.001	75.77 (39.970)	0.440
	Control (n=19)	5.84 (1.803)	83.89 (40.561)		87.37 (40.035)		77.95 (43.059)	
	Post-Intervention (n=13)	4.62 (1.850)	72.54 (45.415)	65.00 (45.588)	82.62 (42.867)			
	Control (n=19)	4.42 (2.116)	83.00 (49.240)	68.42 (50.632)	75.05 (49.376)			
2	Pre-Intervention (n=9)	5.67 (2.062)	69.67 (52.102)	0.701	84.44 (50.544)	< 0.01	70.89 (51.519)	0.150
	Control (n=11)	6.18 (1.722)	80.95 (43.244)		85.91 (42.153)		77.86 (42.479)	
	Post-Intervention (n=9)	5.78 (1.787)	74.28 (42.054)	67.39 (41.095)	82.28 (42.645)			
	Control (n=11)	5.09 (2.256)	79.14 (47.070)	64.14 (52.559)	71.73 (53.994)			
3	Pre-Intervention	6.00 (2.000)	78.29 (51.813)	0.623	95.29 (47.123)	0.302	80.29 (53.391)	0.801

	(n=7)							
	Control (n=3)	5.67 (2.082)	64.17 (62.929)		65.67 (59.763)		60.67 (62.391)	
	Post-Intervention (n=7)	4.29 (1.254)	78.57 (35.879)		74.29 (35.994)		85.14 (36.288)	
	Control (n=3)	5.33 (2.517)	62.33 (71.822)		49.00 (67.816)		55.33 (47.981)	
4	Pre-Intervention (n=5)	5.20 (1.483)	76.50 (40.274)	0.282	92.80 (37.598)	< 0.05	77.40 (39.448)	< 0.05
	Control (n=1)	8.00 (-)	126.00		128.50		123.00	
5				0.516		< 0.05		0.597
	Post-Intervention (n=3)	5.00 (3.000)	74.33 (71.755)		67.67 (66.124)		79.67 (71.429)	
	Control (n=1)	9.00 (-)	136.50		119.50		126.50	
6*	Pre-Intervention (n=3)	4.67 (2.517)	75.83 (63.985)	na	90.33 (63.375)	0.297	78.00 (65.200)	na
	Control (n=0)	-			-		-	
	Post-Intervention (n=3)	4.00 (1.732)	75.83 (50.518)		73.67 (49.941)		84.50 (49.363)	
	Control (n=0)	-			-		-	
7*	Pre-Intervention (n=3)	4.33 (2.082)	75.50 (56.606)	na	89.33 (54.572)	0.516	78.83 (55.844)	na
	Control (n=0)	-			-			
	Post-Intervention (n=3)	2.67 (2.082)	71.50 (54.911)		63.33 (54.629)		79.00 (55.018)	
	Control (n=0)	-			-		-	

Table 2: Mixed ANOVA Analysis Involving Groups (control versus intervention), Time (pre and post) and Groups by time Interaction.

* ART, Align ranked transformation; X, Interaction between factors; *, p values of [1] and [3] cannot be calculated due to the absence of control group; na, not available.

The results were the same when the scores were averaged up from seven days and analysed. There was reduction in distress scores from pre to post treatment in both groups but no significant difference in the reduction between the two groups (Table 3).

Time	Groups (n)	Mean (SD)	p value (groups)	p value (Time)	p value (groups X Time)
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Pre (average)	Control (n=19)	5.90 (1.500)	0.797	< 0.001	0.265
	Intervention (n=13)	5.48 (1.523)			
Post (average)	Control (n=19)	4.51 (2.077)			
	Intervention (n=13)	4.65 (1.396)			

Table 3: Analyses of the within-group (pre- to post treatment) and between-group (control versus intervention) Change in Distress Score.

*n, number of participants; SD, standard deviation.

Discussion

The results showed no significant difference in distress reduction between those in the intervention group (access to mindful breathing module) and those in the control group (access to soothing music) from day one to day seven during the study period. Palliative cancer patients in the intervention group did not have significantly greater distress reduction than those in the control group over the seven days of using the smartphone-based application, thus our hypothesis was not supported. There could be a few factors that explain these results. One of the notable limitations of the present study is the high maturation or dropout rate. By the seventh day, the numbers of participants dropped from 19 to 0 and 13 to 3 in both the control and intervention groups respectively. As mentioned earlier, cancer patients tend to have fluctuating attention, motivation and energy level and hence their consistency in using the application daily may pose a challenge especially if they were to view it as a formal task. Second, though the effect size of the present study was based on results from the previous randomized controlled trial which found a positive efficacy of 5-minute mindful breathing, the derived effect size may be over optimistic. While the study was conducted to look into feasibility, adverse events and effect size before the development of a full-scale study, the small sample size posed to be a significant limitation, further exacerbated by the high dropout rate. Taking our previous study results into consideration, a much larger sample size is needed as the efficacy of the intervention may have been restricted by the replacement of human contact with smartphone device. Given the nature of the research, this much larger sample is also necessary in order to have an acceptable dropout rate that will not present a serious potential bias and skew the findings.

To encourage adherence, future research may introduce minimal human intervention by contacting participants on a daily basis. The smartphone app may also feature a daily reminder function for participants to carry out the assigned treatment protocol. Some studies have shown that such human contact and reminder approaches have yielded much better retention and respond rates [27-33-35]. A written manual or optional short information pages within the app can also be provided to the subjects so that they can familiarize themselves with the “standard operating procedure” of the assigned treatment and carrying it out accurately with minimal variation in the administration process. Additionally, gamification strategies such as adding achievement banners or notifications upon completion of a session, in order to increase engagement and in turn adherence. Evidence from literature suggests that adding a mechanism tracking the apps usage or some form of monitoring could be beneficial in increasing patient engagement and thus potentially reduce drop out [33].

Another limitation of the current study is the lack of monitoring over subjects’ behaviours in carrying out the two treatments, raising questions about their adherence and hence the validity of the treatments studied. It was difficult to know for sure if participants in each treatment group adhered to the guidelines of their assigned interventions. Lacking in a standardized protocol, the process and setting of treatment administration were subject to misinterpretation by the participants. In other words, this limitation leaves too much room for nuisance or confounding variables. This was further exacerbated by our limited measurements. In the interest of reducing

possible fatigue effects in an already fatigued population, the assessment periods were kept as short as possible, and thus we did not include a measure for mindfulness. This added to the above as well as made it difficult to conclude if the reduction of distress in either groups were due to mindfulness engagement or other treatment related factors such as relaxation. A study comparing the efficacy of mindfulness meditation (MM) and somatic relaxation (SR) found that both MM and SR were similarly effective in reducing distress among a student sample [36]. These findings as well as the shift in delivery method from face-to-face practitioner to smartphone application may necessitate the need for at least a brief measure of mindfulness within the app.

Furthermore, to minimize bias, the concept of mindfulness was not explained to the subjects who signed up for the trial. The subjects were simply asked to follow the instruction and description in the app. This blinding may have acted as a double-edged sword, contributing to the limitations in this study. While cancer patients already tend to have inconsistent motivation, the lack of understanding of the concept and mechanism of mindfulness may have further decreased their motivation to carry out the technique willingly, making it seem even more like a formal task. As such, fatigue effect will be high as they may not have been motivated to practice the exercise consistently for seven days. For future clinical research, we recommend the coupling of an introduction session of mindfulness concept with the smartphone app in order to increase patient acceptance of the app, moderate patient expectations, and reduce patient anxiety [37]. The content and design of the app may also need further modification to improve the clarity of the mindfulness concept, perhaps with the addition of short optional pages of information regarding the practice.

Though not statistically significant, subjects exposed to the 5-minute mindful breathing exercise did report a reduction in distress right after using the app, consistent with our previous studies [11-14]. Mindful breathing has been shown to reduce distress by intentionally attending to and disrupting negative automatic thoughts [38]. The associated worries and rumination about an unpleasant experience are then reduced by focusing on the present moment (sensation of breathing) non-judgmentally [38]. This will reduce the negative appraisal of the situation and promote better emotional regulation [39-40], resulting in lower distress. In all our studies however, the effect of the 5-minute mindful breathing exercises on distress reduction were relatively short-term. While the exercise did effectively reduce distress during and immediately after, these effects were not long-term [11-14]. This could point to a need to extend the length of study period, and perhaps include a different measure of time such as total app-usage across time, rather than over daily measurements. Finally, it is important to study the reasons behind subject withdrawal of participation as this will help sustain the longevity of the future research by appealing to patients' interest to use the app. As such, future iterations should include a debriefing with the subjects to identify these factors.

In conclusion, brief interventions are increasingly recognised and needed for the management of psychological distress in cancer patients. With the findings from our pilot study and randomized controlled trial that point to the positive efficacy of 5-minute breathing exercise on distress reduction among cancer patients, we attempted to replicate the results through the use of smartphone-based app. Although we failed to demonstrate the significant result in the current study, we believe that smartphone apps still play an important role in conveying the newly established 5-minute mindful breathing exercise in view of its accessibility, ease of administration, and anonymity. Future research should focus on improving the limitations discussed and devising a research design that may better capture the usefulness of smartphone-based app to reduce distress among cancer patients.

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