Effects of Mindfulness Meditation on Trait Mindfulness, Perceived Stress, Emotion Regulation, and Quality of Life in Hemodialysis Patients: A Randomized Controlled Trial

Study Protocol

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Introduction

End-stage renal disease (ESRD) has been reported to be a major cause of disability and increased mortality worldwide. In patients with ESRD, hemodialysis is a critically vital therapy that prolongs survival and improves quality of life through the excretion or removal of poisonous metabolic waste from the human body (1). However, compliance with treatment has been found to be poor among ESRD patients (2). Such incompliance can be attributed to the different sources of stress associated with hemodialysis, including hemodialysis complications, time-consuming treatment schedules, restriction of dietary and fluid intake, and prescription of multiple medications (3, 4). These sources of stress, in addition to the signs and symptoms of ESRD, result in diminished health-related quality of life, which is associated with increased risks of morbidity, mortality, and incompliance with hemodialysis therapy (3, 5).

Despite the significant physical, emotional, and social burdens of stress, stress-reduction strategies have been inadequately used in patients undergoing hemodialysis. This may be contributed to the small-scale studies on psychotherapies with variable and holistic outcomes and the limited availability of evidenced-based coping interventions that are significantly supported (6). Mind-body therapies, which comprise a variety of techniques that increase the capacity of the mind to influence the functions of the body using emotional strategies, have gained increasing popularity worldwide in recent years. Evidence shows that mind-body therapies are affordable, easily-practiced, and safe, and that they improve perceived stress, health-related outcomes, and quality of life among various community-dwelling and clinical populations (7, 8). One of the most popular mind-body therapies in the literature is mindfulness meditation, which has been found to be a feasible, beneficial, and well-tolerated therapy in hemodialysis patients (6).

It is theoretically claimed that mindfulness meditation can positively impact perceived stress, known also as stress appraisal, and quality of life through the improvement of trait mindfulness and emotion regulation (9). Hemodialysis is appraised as an uncontrollable, threatening situation, since hemodialysis patients must undergo hemodialysis for their entire lives for survival. Therefore, hemodialysis is not a cure for terminal renal diseases but rather a maintenance therapy (10). It is claimed that repeated mindfulness-based practices cultivate and improve the natural mental capacity of mindfulness, called trait mindfulness (9). Trait mindfulness is described as the mental capacity to pay attention to, be aware of, and accept current experiences in a non-judgmental way (11). This developed mental capacity enables psychological distance through a process of decentered attention, through which one's attention (e.g., thoughts, emotions, and sensations) shifts from the contents of consciousness to the process of consciousness itself. In turn, this can help to stop initial automatic uncontrollable appraisals and broaden attention and awareness to include previously overlooked positive aspects of self, context, or events. Based on this new information, it becomes possible to flexibly select adaptive responses and to reappraise events as beneficial or meaningful (i.e., positive reappraisals). Trait mindfulness also enables individuals to acknowledge and accept their current experiences, even if these experiences are uncomfortable. In addition, trait mindfulness helps individuals to not engage in judgmental or negative thinking or avoidance of these experiences, resulting in less reactivity to stressful situations and increased quality of life (9, 10).

Research supports these theoretical claims, whereby mindfulness meditation has been found to be highly effective for a variety of health outcomes in several psychiatric and medical illnesses (8, 12). For patients undergoing hemodialysis specifically, few studies have demonstrated that mindfulness meditation significantly improves trait

mindfulness (13, 14), stress symptoms (14, 15), emotion regulation (16), and quality of life and general health (15, 17) in Western and Asian countries. However, no study has examined the effectiveness of mindfulness-based interventions among ESRD patients undergoing hemodialysis in the Arab countries such as Kuwait. Therefore, any generalization of these previous study findings to other hemodialysis patients of different cultures such as ESRD patients in Kuwait is limited due to the different belief systems and self-care practices of these cultures. Thus, the current study aimed to examine the effects of a mindfulness-based intervention on trait mindfulness, perceived stress, emotion regulation, and health-related quality of life in ESRD patients undergoing hemodialysis in Kuwait.

Theoretically, investigating the effects of mindfulness meditation on the selected variables may provide insight into the mechanisms through which mindfulness meditation impacts quality of life in hemodialysis patients. The current study findings may enrich the body of knowledge on mindfulness meditation and bridge the gap in the literature regarding the effects of mindfulness meditation on patients receiving hemodialysis. Practically, the findings of the present study may guide decision-makers in adopting mindfulness meditation in Kuwaiti hospitals.

Methods

Design

This study used a repeated-measures, randomized, wait-list, control design and was conducted between January 2021 and May 2021 in the dialysis center at Jahra Hospital, Kuwait. Seventy-four ESRD patients undergoing hemodialysis were recruited using convenience sampling. Jahra Hospital is a governmental hospital with one of the biggest dialysis centers in Kuwait, with a female ward, male ward, and isolation ward. The center holds 70 dialysis machines/beds, with an average number of 30 patients managed per day.

The inclusion criteria for participation in this study were being a patient with ESRD undergoing hemodialysis three times a week, being aged 18 years old or over, and being able to read and write in Arabic. The exclusion criteria included being a patient with cognitive dysfunction or mental retardation, taking psychopharmacological drugs, or undergoing psychotherapy. A research assistant, who was not involved in the recruitment or patient assessment processes, randomly assigned the participants to the intervention group (n=37) or the control group (n=37) using a simple 1:1 computer-generated sequence. The trial is reported in accordance with the CONSORT guideline.

Determination of the Sample Size

The required sample size was calculated using G-power version (3.1). Given a mixed-design (within groups and between groups) repeated measures ANOVA, power of 0.95, moderate effect size of 0.25, and α of .0125, the required sample size was 56 subjects. A P-value of 0.0125 was set as the significance level for the main analysis tests. The p-value was adjusted due to multiple testing by dividing the p-value of .05 by 4 (number of dependent variables). In a similar study, an attrition rate of 30% and a non-attendance rate of 30% (excluding dropouts) were estimated (18). Thus, taking into consideration of 60% attrition and nonattendance rates, the final total sample size was 89 patients.

Data Collection Instruments

The study data were collected using an Arabic self-report questionnaire with five parts:

Demographic characteristics. This section included a question for each following variable: Age, gender, employment status, nationality, family status, and educational levels.

Trait mindfulness. Mindfulness is defined as open or receptive awareness of and attention to what is taking place in the present (19). An Arabic version of the Mindful Attention Awareness Scale (MAAS) was used to measure trait mindfulness (20). The MAAS is one-dimensional and comprises 15 items measured on a six-point Likert-type scale ranging from 1 (almost always) to 6 (almost never). The score range is between 15 and 90, with higher scores indicating higher levels of trait mindfulness. The original scale has shown strong psychometric properties when validated among college students. The scale showed single-factor construct and a Chronbach's alpha of 0.82 among a sample of university students (19). Correlational, quasi-experimental, and laboratory studies have shown that the MAAS taps a unique quality of consciousness that is related to, and predictive of, a variety of self-regulation and well-being constructs (19). The Arabic MAAS has been shown to have excellent internal consistency and convergent validity among an Arab population (20). In our study, the Chronbach's alpha values for the MAAS was 0.93.

Perceived stress. The Arabic version of the Perceived Stress Scale (PSS) was used to measure the degree to which situations in one's life are appraised as stressful (unpredictable, uncontrollable, or overloaded) (21). The scale comprises 10 items which are measured on a 5-point Likert scale (0=never, 4= very often) and which are relatively free of content specific to any subpopulation group. The total possible score ranges from 0 to 40, with higher scores indicating higher levels of perceived stress (stress appraisal) (22]. The PSS has been validated for use among college students. The internal consistency coefficient for the PSS is .84 and the scale's test-retest reliability is .85 (22]. The Arabic PSS has been shown to have adequate reliability and validity and is considered a suitable instrument for assessing perceived stress in Arab people (21]. the Chronbach's alpha values for the PSS was 0.82.

Emotion regulation. Emotion regulation is defined as the processes by which individuals influence which emotions they have and how they experience and express these emotions (24). The Arabic version of the Emotion Regulation Questionnaire (ERQ) was used to assess emotion regulation among the study sample (23). The questionnaire items are scored on a 7-point Likert-type scale ranging from 1 (strongly disagree) to 7 (strongly agree) and are divided into two subscales, namely cognitive reappraisal and expressive suppression. Higher scores indicate greater emotion regulation abilities (24). The Arabic version of the ERQ has shown valid and reliable results among the Arab population (23). In our study, the Chronbach's alpha values for the ERQ was 0.81.

kidney disease-quality of life. The Arabic version of the kidney disease-Quality of Life questionnaire (KDQOL-36) is used to assess kidney disease-related quality of life and consists of four subscales: Generic Core (Physical Component Summary (PCS, 12 items) and Mental Component Summary (MCS, 12 items)); Symptoms/Problems (12 items); Burden of Kidney Disease (4 items), and Effects of Kidney Disease (8 items) (25). The scores of the different subscales are calculated according to the KDQOL-36 scoring system. Raw, pre-coded numeric values for each item are transformed linearly to a range of 0 to 100, with higher scores reflecting better kidney disease-quality of life (26). The Arabic version used in this study showed good psychometric qualities among Arab patients with chronic renal failure (25). In our study, the Chronbach's alpha values for KDQOL-36 was 0.93.

Intervention

The experimental group received the Smith's version of mindfulness meditation (27), which is a standardized theory-based intervention found to be effective in improving stress and its related health problems. The Smith's version of mindfulness meditation (27) comprises the following components:

1. Being mindful of breathing, which includes easily taking in a full, deep breath, filling the lungs, simply exhaling, and then breathing naturally. It also includes noticing and simply attending to the air as it flows in and out of the nose and moves deeper into the throat and lungs (5 minutes).
2. Being mindful of the body, which includes attending to how the body feels from head to toes and noticing any sensations that come and go. Upon noticing a sensation, the individual must gently note it, let it go, and continue attending to how the body feels (5 minutes).
3. Being mindful of thought, which includes attending to the mind as thoughts come and go. Whenever a thought or feeling comes to mind, the individual should just notice it, let it go, and continue attending to the mind repeatedly (5 minutes).
4. Being mindful of sounds, which includes attending to the sounds one hears, without thinking about them. The individual must gently notice the sound, let it go, and continuing waiting (5 minutes).
5. Being mindful of taste, which includes imagining a wonderful bowl of pieces of one's favorite fruit and simply attending to a taste sensation, without thought, analysis, or effort (5 minutes)
6. Full meditation, which includes gently opening one's eyes and being mindful of the world of the moment, quietly attending, and waiting. When noticing something, be it a sight, sound, thought, or sensation, the individual must let it go and then resume attending, doing nothing else, and waiting for what comes next (5 minutes).

The experimental group received 30-minute individually administered, guided, chairside interventions during their hemodialysis sessions. This protocol has been found to

be feasible and effective for patients undergoing hemodialysis (6). Smith (2005) explained in his ABC relaxation theory that at least two and preferably five weekly 30-minute sessions of actual training of mind-body therapies should be provided to evoke relaxation, relieve stress, and improve health in general populations. However, for hemodialysis patients, it has been suggested that brief program formatting with at least 400 total minutes may lead to greater health benefits (18). Accordingly, the experimental group received 30-minute mindfulness meditation sessions 3 times a week for 5 weeks (450 minutes)

The participants also received a 2-hour foundation course which was introduced and supervised by one of the study researchers prior to the actual training sessions and which taught the participants the intervention basics, benefits, protocol, and method of access. To ensure the consistent delivery of the intervention, the researcher recorded the intervention instructions in Arabic based on the Smith (2005) protocol and sent the audio-recorded instructions to the participants via WhatsApp or email. The audio-recorded intervention contents were validated by 2 psychologists and experts in meditation. The recorded intervention instructions were accessed by the participants during the sessions using their cell phones and headsets, as recommended (18). This method allowed for up to 3-5 participants to listen to the instructions and perform the intervention simultaneously.

The researcher who was responsible for developing the study intervention and supervising the intervention delivery was an experienced mind-body practitioner who had received a 4-day training course on mindfulness meditation. The researcher attended the sessions to manage any potential interruptions and evaluate the intervention delivery. The participants' privacy was maintained using curtains surrounding each participant during the intervention. The participants were asked not to share any information related to the intervention with the participants in the control group.

The participants in the control group were instructed to sit with their eyes closed and relaxed for 30 minutes 3 times a week for 5 weeks during hemodialysis sessions to control for the nonspecific effects of social interaction and environment (35). The timings of the control group sessions were similar to those of the experimental group, whereby if a given experimental group intervention lasted for 30 minutes, the control group participants would be asked to sit with their eyes closed and relax for 30 minutes also.

Procedure

First, the permission from the instruments used in the study was obtained. Recruitment of participants was conducted by one of the study researchers after obtaining approval to conduct the study from the hospital administrators. The study purposes and protocol were explained to the patients in detail. Patients who agreed to participate in the study and met the eligibility criteria were asked to sign a consent form, and the participating patients were then randomly assigned to the two study groups. The baseline measurements of the study variables were taken using the self-report questionnaires, which were administered by a research assistant who was not involved in any other parts of the study. The study variables were also measured two weeks post the start of the intervention and at the end of the final session for both groups under the same conditions. All measurements were privately taken at the dialysis center.

Data Analysis

SPSS version 25 (SPSS Inc., Chicago, Illinois, USA) was used to analyze the collected data. Prior to the main analysis, outliers and missing data were examined and managed as appropriate. Then, the assumptions of the statistical tests used, normality using histogram graph, homogeneity of variance, and sphericity were checked and managed as appropriate. Mauchly's test of sphericity is used to assess whether the sphericity assumption has been violated. When Mauchly's test of sphericity was significant ($p < .05$),

the degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity. The comparability of the two groups was evaluated in terms of demographic characteristics and the baseline measurements of the dependent variables using t-test and Chi square, based on the measurements of the dependent variables. The main analysis was conducted with repeated-measures ANOVA (mixed design: within and between groups). A P-value of 0.0125 was set as the significance level for the main analysis tests. The p-value was adjusted due to multiple testing by dividing the p-value of .05 by 4 (number of dependent variables).

Ethical Considerations

The study proposal was approved by the Institutional Review Board at Jordan University of Science and Technology and the Kuwaiti Ministry of Health (Number of approval: 78/136/2020). The study was conducted in accordance with the Declaration of Helsinki. The participants were asked to sign informed consent forms which included an explanation of the study purpose and protocol, in addition to a statement indicating that the participants had the right to refuse to participate or withdraw from the study at any time without consequences. The participants were assured that their information would not be made available to others without their consent. The study data were stored in a locked locker after all names were replaced by numbers.

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