The Efficacy of 20-Minute Mindful Breathing on the Dialysis Recovery Time (DRT) of Haemodialysis Patients: A Randomized Controlled Trial

Introduction

Haemodialysis (HD) is a type of renal replacement therapy that is currently being used to treat over 2 million people worldwide, this number only accounts for a small portion of people who need treatment.¹ Among the 3 types of renal replacement therapy including haemodialysis, peritoneal dialysis and renal transplant, haemodialysis is the most commonly used in clinical setting. Most patients requiring HD have ESRD and the number of ESRD patients depending on HD in Asia have been increasing at a higher rate than anywhere else in the world, where Malaysia has an annual growth of more than 10%.² As ESRD is usually an irreversible chronic condition unless a kidney transplant is performed, patients would have to undergo HD for the rest of their life severely impacting their quality of life. HD patients faced many stressful and disruptive issues dealing with their chronic illness and a strict treatment regimen.³ (Evans RW). HD patients typically have several complaints after a haemodialysis session including tiredness, weakness, fatigue and possibly some depressive symptoms as well.^{4,5} Persistence of these symptoms leads to a decrease in capacity to perform daily task and it takes a few hours for a patient to recover from it which have a negative impact on their quality of life (QOL).^{6,7}

Dialysis recovery time (DRT) is the time needed for a patient to recover from post-dialysis distress after a HD session. DRT can be measured by the patient's response to a simple question "How long does it take you to recover from a dialysis session?", which is easily interpreted and simple for the patient to respond. 8 Globally, 27% of patients have reported 6 hours and longer DRT while 68% of patients reported taking longer than 2 hours to recover from a dialysis session. In a recent study, majority of patients which accounts for 68% have a recovery time of more than 2 hours while 27% of patients reported to have a recovery time of more than 6 hours. 9 There are studies that shows longer DRT is associated with patient variability such as older age, higher BMI, diabetes or psychiatric disorder that results in increased risk in mortality. However, there are research studies that shows the comorbidities above shows little association with the patient's DRT. 10 As a result, studies were done to investigate the possible interventions to reduce the DRT by increasing the ultrafiltration rate. 11 However, there are conflicting studies about effectiveness of altering the ultrafiltration rate.¹² Furthermore, there are multiple studies attempting to reduce post-dialysis fatigue and DRT such as decreasing dialysate temperature, doing physical exercise sodium modelling, increasing dialysis glucose, haemodialysis biofeedback technologies, and hemodiafiltration. 13-20 However, there is no effective solution currently to help HD patients to

deal with the post-dialysis complaints and reduce the DRT, resulting in the need for physicians to explore new methods to treat this issue.

There are different approaches to deal with recovery time including through invasive methods, non-invasive methods and psychosocial intervention. However, no studies were done on the effect of psychosocial intervention about how mindful breathing is related to decreasing the DRT. Mindfulness can be defined as consciously paying attention in a distinct way: on purpose, in the present moment, and nonjudgmentally.²¹ The idea is that mindfulness can shift the patient's attention away from the HD and the distress associated with it by focusing on something else such as breathing. The practice of mindfulness results in stress reduction through mechanisms including (1) paying attention purposely to disrupt negative thoughts; (2) paying attention to the present moment to reduce rumination and anxiety; and (3) paying attention nonjudgmentally to minimizes negative appraisals of the situation.²² 20-minutes Mindful Breathing is chosen from a series of mindful practices because it contains the core practice of mindful practices.²³ A previous study about mindful breathing therapies have shown it to be a simple and fast therapeutic option to produce a swift reduction of stress in terminally ill cancer patients.²⁴

The primary objective of the study is to determine the efficacy of 20-minutes mindful breathing on reducing the dialysis recovery time (DRT) among haemodialysis patient. The secondary objective is to improve sleep and symptoms (QOL) of patient. The foresee outcome is that multiple 20-minutes mindful breathing sessions will be able to significantly reduce the DRT and improve patient's QOL.

Methods

A multiple, non-blinded and randomized controlled trial study will be conducted from 5th November 2018 to 5th December 2018. The study is conducted in University Malaya Medical Centre (UMMC) a tertiary hospital, and its affiliated centres in Kuala Lumpur, Malaysia.

The inclusion criteria for all participants includes (1) Patients 18 years of age and older, (2) history of ESRD, (3) currently undergoing haemodialysis (HD) on a 3 times per week basis under the care of the haemodialysis team in UMMC and UMMC affiliated centres, (4) patients has been undergoing dialysis treatment for more than 3 months, (5) patients with a DRT of more than 2 hours long, (6) patients able to understand and follow basic instructions, (7) Consented. The exclusion criteria include (1) patients with delirium or confusion, and (2) Patient decline to participate. Patients in the dialysis unit will be approached and screened for eligibility. Those who satisfy all the criteria will be recruited into the study. Their sociodemographic background information will be collected. The relevant clinical data (history of disease, other medical comorbidities and medications) will be obtain from the medical records.

Participants will be allocated randomly into either "mindful breathing + standard care" or "standard care + control". A computer will be used to generate a table of random numbers from 1 to 40. The allocation ratio was 1:1. Participants allocated to the "mindful breathing + standard care" group will receive a 20-minute mindful breathing session guided by a trained research assistant in mindfulness. The session includes instructing participants to relax their body, close their eyes and focus all their attention on their breathing. If they are distracted by anything such as sounds, body sensations, thoughts, or feelings, they will be told to redirect their attention back to their breathing. The research assistant trained in mindfulness will sit and practice mindful breathing together with the participant during the 20 minutes. The participants in this group will be required to complete at least 6 sessions of mindful breathing in 6 dialysis session. Participants allocated to the "standard care + control" group will receive the standard care only.

Outcome will be assessed by the same research assistant trained in mindfulness. There are 3 aspects of outcome assessed namely dialysis recovery time (DRT), sleep, and health related quality of life (QOL). The DRT outcome will be assessed each day after intervention in the following haemodialysis session. DRT is determined by asking the participants 3 questions around the 2nd or 3rd hour of their 4 hours dialysis session, including (1) Do you feel tired after dialysis? (2) How much time do you need to recover after dialysis? (3) Give a range of DRT i.e. <2hours, 2-6 hours, 7-12 hours, >12 hours. The QOL and sleep quality assessment will be assessed in the first and the last session. The questions will be asked in 3 main languages including Malay, English and Chinese depending on patient preference to show stability by testretest. Sleep is assessed by a questionnaire based on Pittsburgh Sleep Quality Index. Heath related quality of life is determined by the changes in severity of symptoms before and after intervention through an assessment form based on visual analogue scale (EQ-VAS).

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