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

Consent Form

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Application form for approval to participate in scientific research

Effects of Mind-Body Connection Program on Health Outcomes in patients receiving Hemodialysis

Introduction: You are invited to participate in scientific research that will be conducted by researchers at Jordan University of Science and Technology/College of Nursing. I will explain the study information in this form to you in detail. If there are some words that you do not understand, you have the right to ask me to stop and re-explain any detail during the presentation of the information. If you have questions after you have submitted the information or at a later time, you can ask for answers and clarification through the researchers' information attached with the information document that will be provided to you if you agree to participate in the study.

Objective of the study: End-stage renal disease (ESRD) has been reported to be a major cause of disability and increased mortality worldwide. Hemodialysis treatment is usually associated with various sources of stress, such as dialysis complications, adherence to time-consuming treatment schedules, restriction of diet and fluid intake, prescribing of various medications, reduced health-related quality of life and exaggerated morbidity and mortality rates. Despite the high physical and emotional burden of stress, stress reduction strategies have not been adequately used in patients undergoing hemodialysis. Thus, the current study aims to examine the effects of mindfulness meditation on perceived stress, mindfulness, emotion regulation, and quality of life in ESRD patients receiving hemodialysis.

The basis for the selection of study participants: All patients with end-stage renal disease (renal failure) undergoing hemodialysis, who are treated and followed up at Jahra Governmental Hospital in Kuwait.

Voluntary participation: Your participation in this research is completely voluntary. Whether you choose to participate or not, all services you receive at this hospital will continue and nothing will change. You can also change your mind about participating at any time during the study, and you have the right to provide or not provide a reason to stop participating.

Study procedure: The study examines the effects of mindfulness meditation on mindfulness perceived stress, mindfulness, emotion regulation, and quality of life in ESRD patients receiving hemodialysis. Participants will be allocated into two groups: the experimental group, where participants will receive mindfulness meditation with usual hemodialysis treatment, and control group receiving only usual hemodialysis treatment. Each participant in the study has an equal chance of being in one of the two groups, as they will be randomly distributed using a lottery. Participants in the experimental group will receive 30-minute sessions mindfulness meditation three times a week for five weeks. They will get free access to the software, a self-contained intervention that provides instructions via mobile. Participants will first be required to complete a foundation course, which teaches participants the basics of the program by an accredited study investigator. 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

Measurements: The quality of perceived stress, mindfulness, emotion regulation, and quality of life will be measured for the two study groups three times using self-report questionnaires: the first time on the day the participant agrees to participate in the study (during the first phase), and after the third week of intervention, and at the end of intervention. The experiment begins on the first day of participation in the study. It is also important not to take psychiatric or alternative pharmacological treatments to improve sleep or mood and to inform the researcher if necessary.

Duration of the study: The study will continue for 6 consecutive weeks (3 times a week for 30 minutes per session during dialysis days) starting from the first day of agreeing to participate in the study and signing the declaration.

Risks and how to avoid them:

1- The mindfulness meditation does not have any known side effects. However,

- If you feel discomfort, nausea, headache, muscle tension or any other uncomfortable symptoms, you must stop and inform the researcher or seek the nearest medical help.
- If you hear any beeps from the dialysis machine, you must stop and inform the researcher or seek the nearest medical help.

Privacy: The study data will be maintained confidential, as the personal data of participating patients will be listed and stored with the researchers alone. Each participant will have a code number to indicate anonymously, as this code number is used in all patient data collection tools. Furthermore, this list will be kept in a closed place and disposed of upon completion of the study.

Sharing Results: The results of this research will be shared with each study participant through text messages before they are widely available to the public. The results of the study will be presented as aggregate and not individual data to represent all participants together (there are no names or information indicating the identity of the results' owners).

After informing the participants of the results of the study, the results will be published for the benefit of a larger number of people interested in the subject of the study.

Researchers' information: If you have any questions later, after the start of the study or if you have finished it. You can contact any of the researchers involved in the study:

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Part Two: Certificate of Approval

I, the undersigned Mr. / E _____, have read to me the previous information related to a research study titled “The effects of mindfulness meditation on health outcomes in patients receiving hemodialysis” within sufficient time. I also had the opportunity to ask questions about this subject, and all the questions I asked were answered with precision and clarity. I voluntarily agree to participate as a participant in this research.

Participant’s signature _____ Date _____

Witness's name _____ Witness's signature _____