The Effects of Mindfulness Meditation on Psychoneuroendocrinoimmunology in Nursing Students

Consent Form

Date: September 09, 2019

NCT number: Not yet issued

Consent Form

Study Title: Effects of mind-body modalities on health outcomes in Jordanian Nursing Students

Principal Investigator: Hossam Alhawatmeh

You are being invited to participate in this study. This consent form will provide you with information on the research project, what you will need to do, and the associated risks and benefits of the research. Your participation is voluntary. Please read this form carefully. It is important that you ask questions and fully understand the research in order to make an informed decision. You will receive a copy of this document to take with you.

Purpose:

The purpose of this study was to examine and compare the effects of three mind-body connection modalities, including progressive muscle relaxation (PMR), guided imagery (GI), and mindfulness meditation (MM) on stress and health outcomes in Jordanian nursing students.

Procedures:

You are being invited to participate in the study because you are undergraduate nursing students studying at Jordan University of Science and Technology. If you have any muscle injury, practice any stress-reduction technique, or take certain medications such as anxiolytic, sedative, antidepressant, or anti-hypertensive drugs, you may not be eligible. If you are eligible and agree to take part, you will be asked to sign this consent form.

In the study protocol, nursing students will be randomly assigned to 4 groups at a large university in Jordan. The 3 experimental groups (PMR, GI, and MM) will participate in 5 30-minute sessions (one session/week for 5 weeks) led by experienced trainers, in a private room during their clinical days. The control group will stay calm for 30 minutes during introducing the study interventions in another room at the university. The health outcomes will be measured at baseline and end in each group using different physical and self-report measures classified into different health categories such as cognitive health outcomes (executive brain function, stressful appraisal, mindfulness), physical health outcomes (e.g. physical symptoms, heart rate, blood pressure, neurobiological markers such as dopamine, serotonin, cortisol, adrenaline, and noradrenaline), and psychological health outcomes (e.g. depression, anxiety).

Risks and Discomforts

Physical or psychological harm or risks that might be associated with the measurement activities or intervention employed in the current study will be minimal. One risk that might have resulted from the study was making demands on your and venipuncture-related pain. Thus, you

will be provided with compensations (10 Jordanian Dinars) for your times spent in the study and ELMA cream will be used before blood sampling to decrease venipuncture-related pain. Moreover, trained nurses will draw blood from you, following the Blood Sampling Guideline of the European Federation of Clinical Chemistry and Laboratory Medicine, 2017. You may experience slight discomfort during blood pressure, heart rate measurements and taking blood samples. However, you can ask the researchers to stop the procedures anytime.

Benefits

Potential benefits of the measurement activities and intervention to you as study participant included increased knowledge and awareness about their health and mind-body modalities. For society, potential benefits included a greater understanding of the effects of mind-body modalities on stress reduction and the potential improvement of the study population's health. In this study, potential benefits are believed to exceed risks.

Privacy and Confidentiality

Identifiable data (your name) will be used to match your data over time and will not be used in research findings. You will be assigned a specific number. A separate sheet withyou're your name, and number will be created and saved on a password protected laptop computer accessible only by you. This sheet will be deleted from the computer after completion of data collection. Research findings will be presented in an aggregate manner. No one will be able to identify you

Compensation

You will receive 10 Jordanian Dinars (JDs) if you participate fully in this study. If I find that you have abnormal blood pressure or heart rate, I can refer you to the University Health Center for further evaluation and treatment. You or your medical insurance will be billed for this service.

Voluntary Participation

Taking part in this research study is entirely up to you. You may choose not to participate or you may discontinue your participation at any time. Your decision to refuse to participate in the study or discontinue your participation will not affect your academic achievements and benefits to which you are otherwise entitled. You will be informed of any new, relevant information that may affect your health, welfare, or willingness to continue your study participation.

Contact Information

If you have any questions or concerns about this research, you may contact me *Hossam Alhawatmeh* at *(+962 797 41 32 44*). This project has been approved the Jordan University of Science and Technology Institutional Review Board (JUST IRB). If you have any questions

about your rights as a research participant or have complaints about the research, you may call the JUST IRB at +962 2 720060.

Consent Statement and Signature

I have read this consent form and have had the opportunity to have my questions answered to my satisfaction. I voluntarily agree to participate in this study. I understand that a copy of this consent will be provided to me for future reference.

_____	_____	_____
Participant Name Printed	**Participant Signature**	**Date**

_____	_____	_____
Person Obtaining Consent Name Printed	**Person Obtaining Consent Signature**	**Date**