

Cover page for Informed Consent Documents

Study Title

Eastern Principles Acceptance and Commitment Therapy for Injury Prevention Among Nurses and Nursing Aides

NCT Number

011559

Date

October 13, 2024

Nurse Aide & Nurse Wellbeing Study

Informed Consent – Control Group

Description of the Study:

You are invited to participate in a research study, which will evaluate relationships between work, injury, and wellbeing among nurses and nursing aides who work in long-term care settings. This research study is being conducted by Drs. William O'Brien, who is a Professor of Psychology at Bowling Green State University. Sam Lim, Brooke Short, and April Xia are graduate students at Bowling Green State University who are helping out with the study. You must be at least 18 years old and currently employed as a nurse or nurse aide to participate in the study.

Summary of Involvement:

Your participation will involve attending one in-person meeting that will last 40 minutes and later completing two online surveys. The in-person meeting will involve completing a survey and measuring your heart rate as described below.

- Meeting 1: Arrive, complete informed consent form, complete a baseline survey and measurement of heart rate using a noninvasive recording device. The survey will ask questions about your thoughts, feelings, and experiences relating to your work and home life. Completing this survey takes about 40 minutes and your heart rate will be measured for 10 minutes while you are resting comfortably in a chair. Total meeting time 50 minutes.
- Survey 2: Four weeks after meeting 1, you will receive an email and text message with a link to complete the same survey that was conducted in meeting 1. Total time: 40 minutes.
- Survey 3: Three months after meeting 1, you will receive an email and text message with a link to complete the same survey again. Total meeting time: 40 minutes.

Your participation, from start to finish, is expected to take about 3 hours. In exchange for completing all participation requirements, meaning attending the meeting and completing the surveys described above, you will receive \$150 (\$50 after survey 1, \$50 after survey 2, \$50 after survey 3).

Confidentiality:

If you agree to participate, the researchers will carefully maintain your privacy. Only the researchers mentioned above will have access to your responses, which will be stored in a locked office at Bowling Green State University and on password-protected computers. Your responses will be assigned an alphanumeric code and identifying information will be deleted once your responses from each survey have been matched.

Just as the researchers will protect your confidentiality, it is important that you agree to honor the confidentiality of other participants. The first meeting might have other workers present. You should not disclose anything that you are uncomfortable with other participants knowing and not discuss anything that is disclosed by other participants.

Risks, Benefits, and Voluntary Status:

There are no major risks associated with this study, meaning that by participating in this study you will not encounter any more risk than you encounter in your regular workday. The benefit of this research is that it will help you learn about coping strategies that have been demonstrated to be helpful in managing work stress, preventing injuries, and improving wellbeing. Additionally, your participation will help us learn about ways to prevent injuries and improve wellbeing for nurses and nurse aides in long term care settings.

At some points completing surveys you will be asked to reflect on work experiences that may be distressing such as work stressors, injuries, patient aggression, and patient sexual behavior. These questions may create discomfort. Please be reassured that you are not required to participate in any group exercises that you find stressful nor discuss any personal reactions or experiences during group meetings. Additionally, you are free to not answer any survey question that creates discomfort."

Your participation in this study is voluntary. You are free to decline to participate or withdraw consent and end participation in the study at any time without penalty or any change in your relationship with your employer or any existing or future relationship with BGSU. You may skip any questions that you do not wish to answer. You have the right to have all questions concerning the study answered by the researcher and may request a copy of the results of the study.

Contact Information:

If you have any questions or comments about this study, you may contact Dr. William O'Brien by phone at (419) 372-2974 or by email at wobrien@bgsu.edu. If you have any questions regarding the conduct of this study or about your rights as a research participant, you may contact the Chair of Bowling Green State University's Institutional Review Board by phone at (419) 372-7716 or by email at irb@bgsu.edu.

Voluntary Consent: I agree to voluntarily participate in this study and I am at least 18 years old.

Participant's Name

Participant's Signature

Date

Researcher Name

Researcher Signature

Date

Nurse Aide & Nurse Wellbeing Study

Informed Consent – Intervention Group

Description of the Study:

You are invited to participate in a research study, which will evaluate an intervention based on Acceptance and Commitment Therapy (ACT). The ACT intervention is designed to reduce work related injuries and improve wellbeing for nurses and nursing aides who work in long-term care settings. This research study is being conducted by Drs. William O'Brien and Daniel Maitland, who are Professors of Psychology at Bowling Green State University. Brooke Short and April Xia are graduate students at Bowling Green State University who will be helping out with the study. You must be at least 18 years old and currently employed as a nurse or nurse aide to participate in the study.

Summary of Involvement:

Your participation will involve attending two intervention meetings that last approximately 2.5 hours each and two follow-up online assessments that will last about 40 minutes. The intervention meetings will focus on developing skills to manage work related stress, prevention of injuries, and improving wellbeing. The intervention meetings will take place in a meeting room at your place of employment. The specific activities in each meeting are described below:

- Meeting 1: Arrive, complete informed consent form, complete a baseline survey, measurement of heart rate using a noninvasive recording device will be obtained, you will then participate in a 2-hour group-based intervention session. The survey will ask questions about your thoughts, feelings, and experiences relating to your work and home life. Completing this survey takes about 30 minutes. Your heart rate will be measured for 10 minutes before the intervention session and during the intervention session while you are resting comfortably in a chair. At the end of the intervention session, you will be asked to complete a brief (5 minute) survey about your experiences. Total meeting time: 2 hours, 40 minutes.
- Meeting 2: One week after meeting 1, arrive and participate in a 2-hour group-based intervention session. Your heart rate will again be measured during the session. At the end of the intervention session, you will be asked to complete a brief (5 minute) survey about your experiences. Total meeting time: 2 hours
- Survey 2: Two weeks after meeting 2, receive an email and text message with a link to complete the same survey that was conducted in meeting 1. Total time: 40 minutes.
- Survey 3: Three months after meeting 2, receive an email and text message with a link to complete the same survey again. Total time: 40 minutes.

Meeting 1: Arrive, complete informed consent form, complete a baseline survey, measurement of heart rate using a noninvasive recording device will be obtained, you will then participate in a 2-hour group-based intervention session. The survey will ask questions about your thoughts, feelings, and experiences relating to your work and home life. Completing this survey takes about 30 minutes. Your heart rate will be measured for 10 minutes before the intervention session and during the intervention session while you are resting comfortably in a chair. At the end of the intervention session, you will be asked to complete a brief (5 minute) survey about your experiences. Total meeting time: 2 hours, 40 minutes.

• Meeting 2: One week after meeting 1, arrive and participate in a 2-hour group-based intervention session. Your heart rate will again be measured during the session. At the end of the intervention

session, you will be asked to complete a brief (5 minute) survey about your experiences. Total meeting time: 2 hours

Your participation, from start to finish, is expected to take about 6 hours. In exchange for completing all participation requirements, meaning attending intervention sessions and completing the surveys described above, you will receive \$150 (\$50 after meeting 1, \$50 after survey 2, \$50 after survey 3).

Confidentiality:

If you agree to participate, the researchers will carefully maintain your privacy. Only the researchers mentioned above will have access to your responses, which will be stored in a locked office at Bowling Green State University and on password-protected computers. Your responses will be assigned an alphanumeric code and identifying information will be deleted once your responses from each survey have been matched and the study is completed.

Just as the researchers will protect your confidentiality, it is important that you agree to honor the confidentiality of other participants. Because the sessions feature group discussion, you should (a) not disclose anything that you are uncomfortable with other participants knowing and (b) not discuss anything that is disclosed by other participants outside of the session. If you feel that you cannot commit to maintaining confidentiality, we request that you not participate in the study.

Intervention sessions will be audio-recorded for quality assurance purposes. Content from the sessions, including quotes from participants, may be used in any reports based on these sessions, but will always be anonymous.

Risks, Benefits, and Voluntary Status:

There are no major risks associated with this study, meaning that by participating in this study you will not encounter any more risk than you encounter in your regular workday. The benefit of this research is that it will help you learn about coping strategies that have been demonstrated to be helpful in managing work stress, preventing injuries, and improving wellbeing. Additionally, your participation will help us learn about ways to prevent injuries and improve wellbeing for nurses and nurse aides in long term care settings.

At some points in the group meetings, you will be asked to reflect on work experiences that may be distressing. Additionally, some questions in the surveys ask about work stressors, injuries, patient aggression, and patient sexual behavior. These questions may create discomfort. Please be reassured that you are not required to participate in any group exercises that you find stressful nor discuss any personal reactions or experiences during group meetings. Additionally, you are free to not answer any survey question that creates discomfort.”

Your participation in this study is voluntary. You are free to decline to participate or withdraw consent and end participation in the study at any time without penalty or any change in your relationship with your employer or any existing or future relationship with BGSU. You may skip any questions that you do not wish to answer. You have the right to have all questions concerning the study answered by the researcher and may request a copy of the results of the study.

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Voluntary Consent: I agree to voluntarily participate in this study and I am at least 18 years old.

Participant's Name

Participant's Signature

Date

Researcher Name

Researcher Signature

Date