

Informed Consent

I understand that I have been asked to participate in a balance study that is being conducted by researchers who are graduate occupational therapy students at Brenau University under the direction of Dr. Mary Shotwell, Assistant Professor of Occupational Therapy at Brenau University.

PURPOSE

The purpose of the study is to determine the validity of the Bone Safety Evaluation (BSE) Balance Domain as a tool to assess functional motion in the osteoporosis population.

PROCEDURE

I understand that I will be participating in a study, which will include one balance testing session using three different evaluations. The balance testing session will last approximately one hour and will consist of a Bone Safety Evaluation (BSE), Computerized Dynamic Posturography (CDP), and the Modified Clinical Test of Sensory Integration and Balance (mCTSIB). Testing procedures focus on movements with functional activities and having ones balance challenged. In addition, I understand that I will be asked to fill out forms giving biographical information to aid the researchers in their data analysis.

RISKS

I understand there are no anticipated risks associated with this study and every attempt will be made to ensure safety throughout the testing process. All evaluations will take place in the controlled environment of a medical office. I will be closely monitored, wearing a gait belt for safety, and given opportunities to rest. I may experience physical discomfort when performing some of the functional tasks, but I may decline to participate or continue at any time. If evaluation results indicate that I am at risk for falls, I will receive appropriate referral information if I experience any psychological distress upon learning this information. In addition, I have been made aware that a copy of my evaluation results will be sent to me and my primary care physician.

BENEFITS

I understand that by participating in this study I will be provided with information regarding my performance during functional activities and whether or not I am at risk for falls. In addition, my participation will help to establish the Bone Safety Evaluation as a valid tool to more accurately identify patients whose functional movements put them at risk for falls and fractures. Providing this tool will support clinicians in their quest for evidence-based practice.

CONFIDENTIALITY/PRIVACY

Every effort will be made to protect my confidentiality throughout the study. I understand my participation is completely voluntary and I may withdraw from the study at any time without penalty. No information about me, or provided by me during the research, will be shared with others without my written permission, except if it is necessary to protect my welfare or if it is required by law.

PARTICIPATION

I understand that participation in this study is strictly voluntary, and if at any time I feel uncomfortable I am free to withdraw without any penalty. If I have any questions or concerns about my participation in this study, I may contact Dr. Mary Shotwell at (770) 534-6182. I also understand that I may contact the Brenau University Institutional Review Board at (770) 718-5304 if I have any questions about this research project.

My initials below mean that I give specific permission for:

_____ I agree to have my data available for analysis and comparison in future studies done by Brenau University and UOC

_____ I give permission for researchers to take photographs during my test participation. These photographs will be used during professional presentations.

_____ I realize that my data (with all identifiers removed) may be used in professional presentations and/or articles in professional publications

I agree to participate in this study.

Participant Signature

Date

Researcher Signature

Date