CONSENT TO PARTICIPATE IN RESEARCH

Title: Test Retest Reliability of the Head Control Scale

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Summary and Key Information about the Study

You are being asked to participate in a research study conducted by Jane Doe, an Assistant Professor at Texas Woman’s University. The purpose of this research is to determine the reliability of an assessment tool called the Head Control Scale (HCS). You have been invited to participate in this study because you have a condition that affects physical abilities, which is the population for which the HCS was designed. You will be asked to take part in a brief interview to collect demographic information (e.g. age and diagnosis). You will then be asked to take part in two 15-20 minute sessions in which the HCS will be administered. The HCS is mainly an observational tool, though researchers will interact with you. The time commitment for this study will be about 45 minutes total, over two sessions that take place between 3 and 7 days apart. Following the completion of the study, a $20 gift card will be given for participation.

The greatest risks of this study include potential loss of confidentiality and mild physical discomfort, such as fatigue. We will discuss these risks and the rest of the study procedures in greater detail below. Your participation in this study is completely voluntary. If you are interested in learning more about this study, please review this consent form carefully and take your time deciding whether you want to participate. Please feel free to ask the researcher any questions you have about the study at any time.

Description of Procedures

If you participate in this study, you will be asked to answer a few questions that allow researchers to collect demographic information about you. These questions will include (but are not limited to) your age, diagnoses, and your current rehabilitation program (e.g. type, frequency, etc.). The demographic information will be collected only once, at the first session. You are being asked to participate in this study so that a researcher can administer the HCS, which rates head control on a scale of 0-4 in each of four positions (on stomach, on back, pull to sit, and sitting). The researcher(s) will primarily be observing you. However, the researcher may need to interact with you to a) assist movement among the test positions (e.g. from on stomach to on back); and/or b) provide physical support as needed (e.g. in sitting, if you are unable to do independently). Upon completion of the first session, a second session will be scheduled. The second session will be the same as the first with regard to the administration of the HCS. The second session will take place between 3 and 7 days from the first session. The study will take place in a quiet lab space within the PT department at Texas Woman’s University, Dallas.

Potential Risks

A possible risk in this study is mild discomfort you may feel due to fatigue and/or being around unfamiliar people. If you become tired or upset, you may take breaks as needed. The data collection can be discontinued at any time. Sessions can be rescheduled or you can withdraw consent for your participation at any time.

Another risk in this study is loss of confidentiality. Confidentiality will be protected to the extent that is allowed by law. The administration of the HCS will be done in a private area (e.g. physical therapy treatment room). Codes will be used to identify you from one session to the next as well as during data analysis. Data will be stored in a locked filing cabinet in the researcher’s office. The master code sheet will be stored in a password protected computer in the researcher’s office.

Initials
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The signed consent form will be stored in a separate filing cabinet, away from all collected information and will be destroyed three years after the study is closed. The results of the study may be reported in scientific magazines or journals, but no names or any other identifying information will be included. There is a potential risk of loss of confidentiality in all email, downloading, electronic meetings and internet transactions.

The researchers will remove all personal or identifiable information (e.g. name, date of birth, contact information) from the demographic information collected. After all identifiable information is removed, any personal information collected for this study may be used for future research or be given to another researcher for future research without additional informed consent.

If you would like to participate in the current study but not allow de-identified data to be used for future research, please initial here .

In the event of a research-related injury or if you experience an adverse reaction, please contact the principal investigator immediately; her contact information is at the top of this consent form. You will also be advised to consult your regular doctors.

The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will try to help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

Participation and Benefits

Your involvement in this study is completely voluntary and you may withdraw from the study at any time. Following the completion of the study, a $20 gift card will be given to you for your participation. If you would like to know the results of this study we will email or mail them to you.\*

Questions Regarding the Study

You will be given a copy of this signed and dated consent form to keep. If you have any questions about the research study, you should ask the researchers; their contact information is at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the TWU Office of Research and Sponsored Programs at 940-898-3378 or via e-mail at IRB@twu.edu.

Name of Participant

Signature of Participant Date

\*If you would like to know the results of this study tell us where you want them to be sent:

Email: or Address:

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