

Title: Correlation of Trust and Outcomes Following Physical Therapy for Chronic Low Back Pain

NCT#: NCT03443401

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UNIVERSITY OF SOUTH DAKOTA
Institutional Review Board
Informed Consent Statement

Title of Project: Correlation of Trust and Outcomes following Physical Therapy for Chronic Low Back Pain

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Other Investigators: Louie Puentedura, Morey Kolber, Adriaan Louw

Purpose of the Study:

The purpose of this research study is to help understand how trust between the patient and physical therapist might have an effect on outcomes while receiving physical therapy care for chronic low back pain.

Procedures to be followed:

You will complete 3 trust measurement questionnaires at 3 different periods: 1) prior to your initial visit with your physical therapist, 2) immediately after your initial visit, and 3) again at the end of your physical therapy care. You will also be asked to fill out other measurement scales during those time periods. We will also be collecting outcomes information at the beginning of your care and again at discharge from your care. Your treating physical therapist will also be completing forms regarding your engagement and connection during your physical therapy care along with sharing information regarding number of visits, no shows/cancellations, and billing codes used during your episode of care. All questionnaire forms will be confidential and not shared with treating physical therapist or any other outside entity beyond the research team.

Risks:

The risks are small with potential psychological or invasion of privacy with use of questionnaire forms. These forms will be kept confidential and not shared with your treating therapist or anyone else at the clinic site. Every effort will be made by the research team to secure privacy of the information you share. Also, if you do not wish to answer any question on the questionnaire forms, please leave them blank. You are free to withdraw from the study at any point. In addition, your care will not be altered in any fashion if you partake or do not partake in this study.

Benefits

You may not benefit personally from participating in this research project however:

- This research might provide a better understanding of how trust might affect outcomes during physical therapy care. This information could help clinicians' provider better care for their patients in the future.

Exclusion

You will be excluded from the study if any of the following are present: younger than 18 years of age, unable to speak or read English, you need to be referred out at any time for different level of medical care, concurrent pregnancy or cancer diagnosis, or your back pain that has been present for less than 3 months. If any of these are present, please let the office staff know that you are not eligible for the study. If your initial treating physical therapist does not see you for 80% of treatments during episode of care you will not be eligible for the study, but you will not be penalized by not being allowed to receive the gift card for completion of the forms to that point.

Duration:

Prior to seeing the physical therapist the first time, it will take about 10-15 minutes to complete the series of forms needed for this study. At the conclusion of your initial visit, it will take about 5-10 minutes to complete the series of forms. When you see the physical therapist the last time (discharge by you and/or therapist) or after 6 months of care, it will take approximately another 10-15 minutes to complete the series of forms. Beyond your normal clinical treatment time for your physical therapy, you will need to provide a total of 40 minutes extra time completing forms for the study over the course of your care.

Statement of Confidentiality:

The questionnaires will be coded. The code and link will be kept secured by the PI and research team. The code and link will be destroyed upon completion of the study. Both your responses and the therapist responses are held in confidence and not shared with either party or any outside agency beyond the research team.

Right to Ask Questions:

The researchers conducting this study are Kory Zimney, Louie PuenteDura, Morey Kolber, and Adriaan Louw. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Kory Zimney at 605-658-6373 during the day.

If you have questions regarding your rights as a research subject, you may contact The University of South Dakota- Office of Human Subjects Protection at (605) 677-6184. You may also call this number with problems, complaints, or concerns about the research. Please call this number if you cannot reach research staff, or you wish to talk with someone who is an informed individual who is independent of the research team.

Compensation: You will receive a \$25 gift card mailed from the researchers if you complete all of the questionnaires for each of the 3 time periods. You may withdraw from the study at any time but will only be eligible for the gift card if you complete all 3 time periods of questionnaires.

Voluntary Participation: You do not have to participate in this research. You can stop your participation at any time. You may refuse to participate or choose to discontinue participation at any time without losing any benefits to which you are otherwise entitled.

You do not have to answer any questions you do not want to answer.

For this study you must be 18 years of age older to consent to participate in this research study.

Statement of Consent

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject Name (Printed)_____

Subject's Signature

Date