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

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Study protocol

This dissertation was a non-experimental correlational quantitative analysis of multi-clinic site locations of consecutive patients referred to or coming via direct access for physical therapy care related to chronic low back pain. It was a collection of trust surveys, TA questionnaires, and patient reported outcomes related to their low back pain and function completed by the patient participant through an interrupted time-series of prior to initial evaluation, post-initial evaluation, and at discontinuation of the current episode of care. The physical therapist participants completed a patient connection and engagement questionnaire after the second visit and at discharge along with outcomes measurement data collect at the completion of the current episode of care. Data collection was at multiple outpatient physical therapy sites with multiple physical therapists and wide patient demographics to improve generalizability of the study findings.

The research project was conducted according to the Declaration of Helsinki. All the participants were fully informed of the study content before their participation in this study and completed informed consent. Institutional Review Board (IRB) at the University of South Dakota served as the IRB of record with joint approval from Nova Southeastern University IRB.

3.3 Procedures

3.3.1 Participant recruitment

Various clinic sites (AZ, CA, RI, VA, WA, and WI) were approached through email, phone, and direct contact and were provided general study protocol to investigate their interest in serving as a data collection site. Clinic sites interested in participating completed an IRB Location Site Application along with a clinic site consent agreement (Appendix A). Each clinic site had a point of contact person appointed, and that contact person ensured that all informed

consent forms were signed for those physical therapists willing to consent to participate in the study protocol. Once each clinic site and participating physical therapists at those sites were set up, new patients potentially meeting inclusion criteria of chronic low back pain (pain greater than 3 months) coming to the clinic were identified by front office staff scheduling the appointment. Upon arrival at the clinic, potential patient participants were handed regular clinic site new patient paperwork, but they were also given a participant recruitment flier. If the patient verbally expressed interest in participation, they were provided with an introductory letter with a PsychData link. This link had the informed consent and the participant was given a Health Insurance Portability Accountability Act (HIPAA) form as part of the IRB process. This method of recruitment was utilized to minimize any potential coercion.

Once patient participants completed the informed consent process they were directed to a second PsychData link in order from them to complete a participant demographics form (Appendix B) that further verified their eligibility into the study. Inclusion criteria consisted of greater than 18 years of age, able to read, speak, and write in English, and presence of low back pain for at least 3 months. Exclusion criteria were current pregnancy or active cancer diagnosis. Patient participants were also excluded from the study if at any point during the episode of care they required different medical attention beyond physical therapy and needed to be referred out for medical reasons and had to discontinue their physical therapy prior to achieving goals. Any patient participant that did not receive at least 80% of the treatments from the initial physical therapist participant were excluded from primary data collection. Physical therapist participant inclusion criteria were having a physical therapy license to treat patients and employed at a clinic site approved for the study.

The initial *a priori* was set for a total of 64 patient participants with the primary complaint of chronic low back pain that had lasted a minimum of 3 months prior to initiating the current physical therapy episode of care. The patient were consecutively enrolled in the study at the various clinic sites. An *a priori* achieves 79% power to detect a Pearson correlation of 0.400 using a two-sided hypothesis test with a significance level of 0.05 with an included 20% dropout rate. These results are based on 1000 samples from the bivariate normal distribution under the alternative hypothesis. The number of physical therapist participants was determined by the clinic site enrollment and treating at least one patient participant during the course of the study.

3.3.2 Instruments – Predictor variables

Various instruments were used to measure trust during the encounter. For the purpose of this study, three of the most well studied provider-specific trust measurement scales (Trust in Physician Scale,[29] Primary Care Assessment Survey (PCAS),[28] and Wake Forest Scale[38]) used in the physician and psychology literature were chosen that have items written that could easily translate to physical therapy practice and patient care. To date, none of these provider-specific trust measurement scales had been studied for use in physical therapy practice. General trust in the medical profession and physical therapy was assessed by the General Trust in Physician Scale.[37] A TA measurement scale (Working Alliance Inventory – Short Revised) was used and was the only predictor instrument previously used in the physical therapy literature.[126] The final instrument was developed as part of the dissertation process to assess the physical therapist's perception of their patient's connection and engagement (PT Survey of Patient Connection and Engagement) within the therapeutic process during the physical therapy encounter.

Trust in Physician Scale: The Trust in Physician Scale[29] is one of the first instruments developed to assess a patient's interpersonal trust in their physician. The original published work

of Anderson and Dedrick in 1990, detailed the development and validation of the Trust in Physician Scale. Three different dimensions of trust were assessed: dependability of the physician, confidence in the physician's knowledge and skills, and confidentiality and reliability of information between the physician and patient. The Trust in Physician Scale is a patient self-report tool with 11-items scored on a 5-point Likert scale. The labels for the Likert scale followed the later modified version by Thom, et al.[53] (1 = totally disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = totally agree). Raw scores can range from 11 to 55 with higher scores demonstrating higher trust. The scale was modified for the purposes of this study with the words "physical therapist" inserted any place the original version had the word "doctor". It has a combination of positively (questions #2, 3, 4, 6, 8, 9, and 10) and negatively (questions #1, 5, 7, and 11) worded questions. The Flesch reading ease score equates to 52.3 to provide a Flesch-Kincaid grade level at 9.6 according to Microsoft® Word 365 for Office (Redman, WA). This scale has been used in research in primary care physicians and specialty medical practice with a variety of patient populations.[29,53,59] (Appendix C)

Primary Care Assessment Survey: The PCAS[28] was developed to measure seven different domains of care through 11 different summary scales. The trust summary scale assesses the physician's integrity, competence, and role as the patient's agent. The trust summary scale is measured with eight different item questions with a lowest score of 8 and maximal score of 40, with the higher score demonstrating more trust. Seven of the item questions (questions #1-7) are measured by a five-point Likert scale (1 = strongly agree, 2 = agree, 3 = not sure, 4 = disagree, 5 = strongly disagree). Question #8 is scored on a 11-point scale with anchors (0 = not at all, 10 = completely) it requires recalibration to align with questions #1-7 (1 = 0-2 precoded item value, 2 = 3-4 precoded item value, 3 = 5-6 precoded item value, 4 = 7-8 precoded item value, 5 = 9-10

precoded item value). Four of the seven Likert scale items (questions #1, #3, #5, #8) are reverse score items and must be recoded for final scoring (5 = precoded item value 1, 4 = precoded item value 2, 3 = precoded item value 3, 2 = precoded item value 4, 1 = precoded item value 5). For purposes of this study, the word "doctor" was replaced with "physical therapist" from the original scale. The PCAS scoring algorithms calculate a score if a respondent answers at least 50% of the items on the scale (4 items on the trust scale), the missing whole values are inputted as the respondent's average score across all completed items for the scale. A transformed scale score can be computed as the product of the actual raw scale score minus the lowest possible raw scale score (8 on the trust scale) that is divided by the possible raw scale score range (32 on the trust scale) multiplied by 100. The Flesch reading ease score is 62.6, which equates to an 8.4 Flesch-Kincaid grade level according to Microsoft® Word 365 for Office (Redman, WA). The scale was originally developed and tested on Massachusetts state employees on their level of trust with their primary care physician. (Appendix D)

Wake Forest Scale: The third provider specific trust measurement scale used was the Wake Forest Scale[38] developed by Hall, et al. The Wake Forest Scale was developed to improve on the various trust measurement scales that currently had been published at that time (Anderson/Dedrick[29] with the Thom modification[53], Safran[28], and Kao[39,118]) and to be more generalized to other care providers, not just physicians. The Wake Forest Scale development was done by retaining or modifying questions from the existing scales that fit their conceptual model of trust measurement. To address areas of the trust domain that the study team did not think where fully covered, they, along with a group of experts developed additional items. After initial testing and screening of questions, it produced 26 candidate items for further testing, which ultimately produced the final 10-items that were accepted for the scale. The 10 items reflect

dimensions of trust (fidelity = #1-2, competence = #3-4 and #8, honesty = #6, global = #5, #7, and #9-10). The items cover question format consisting of a mixture of positive (#1, #4-7, and #9-10) and negative (#2, #3, and #8) statements in Likert categories (1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree). Trust is measured with a sum of the 10 item scores, with reverse scoring for negative items, to produce a range of scores from 10 to 50, with higher scores demonstrating higher levels of trust. For purposes of this study the questions with the words "your doctor" were replaced with "your physical therapist". The final Flesch reading ease is 54.0, demonstrating a Flesch-Kincaid grade level of 9.6 according to Microsoft® Word 365 for Office (Redman, WA). (Appendix E)

General Trust in Physician Scale: Patient general trust in healthcare providers has been shown to be different than interpersonal healthcare provider trust.[37] Thus general trust potentially has a strong influence on the formation of interpersonal trust and was measured prior to the initial visit for the purpose of this study with the General Trust in Physician Scale.[37] This scale was developed to test general trust in physicians in contrast to other scales that assess individual physician trust. An 11-item scale was formulated from the initial 25 candidate items that were based on five domains (fidelity, competence, honesty, confidentiality, and global trust). Five-point Likert scale categories were utilized for each question (1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree). The final 11-items have both positive (#1, #3-6, and #8-10) and negative (#2 and #7) worded questions, with reverse scoring for negative items. Scores can range from 11 to 55, with higher scores demonstrating higher trust. If one or two scores were left out, the missing values were imputed with the average score, if three or more scores were missing the total score was not be calculated and left out. The words "physical therapists" were inserted for the word "physician" for use with this study. The General Trust in

Physician Scale according to Microsoft® Word 365 for Office (Redman, WA) has a Flesch reading ease of 42.4 providing a Flesch-Kincaid grade level of 10.8. (Appendix F)

Working Alliance Inventory-Short Revised: The Working Alliance Inventory-Short Revised (WAI-SR)[127] is one of the most commonly used instruments to measure the alliance between patients and therapists in physical rehabilitation.[55] A 12-item short form was originally developed in 1989[128] from the original 1986 36-item Working Alliance Inventory[129] and revised in 2006[127] into the current WAI-SR. The WAI-SR has been developed to assess Bordin's Task, Goal, and Bonds dimensions.[18] The scale is measured on a 5-point Likert scale (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always). All items are positively worded and higher scores reflect higher levels of therapeutic alliance. Flesch reading ease score is at 63.0, producing a Flesch-Kincaid grade level of 8.0 according to Microsoft® Word 365 for Office (Redman, WA). (Appendix G)

PT Survey of Patient Connection and Engagement: This survey questionnaire was developed for use during this dissertation study. An original 10-question survey was developed and created based on current literature[48,52,93,130,131] in the area of TA along with personal conversation with experts in the field of physical therapy and patient care management. After original survey item creation was completed, it was sent to a panel of five clinicians throughout the US that have experience in research and the study of patient involvement and psychosocial aspects of clinical care from both practice and academic settings. After review of the questionnaire and the comments made by the panel, it was revised into its current consensus form. This questionnaire is aimed to evaluate the physical therapist's perceptions of the patient's engagement and connection with their physical therapist during the therapeutic encounter. No measurement tool such as this exists based on the review of the current literature. The scale

contains 10 positively worded items scored on a 5-point Likert scale (1 = very poor, 2 = below average, 3 = average, 4 = above average, 5 = excellent). The score contains two sub-scores connection (questions 1, 3, and 7) and engagement (questions 2, 4-6, and 8-10). The questionnaire scores a 62.0 on the Flesch reading ease scale, making it at an 8.5 Flesch-Kincaid grade level according to Microsoft® Word 365 for Office (Redman, WA). (Appendix H)

3.3.3 Instruments – Outcome measurement variables

The outcome measurements chosen for this study assessed the patients' progress during their physical therapy episode of care on various levels. Patient reported outcomes assessed clinical pain and functional progress by utilizing the Oswestry Disability Index 2.0 (ODI), Numeric Pain Rating Scale (NPRS), and a Global Rate of Change Scale (GROC) as these have been shown to be more responsive than physical impairment measurements.[132,133]

Oswestry Disability Index 2.0: Improvement in function is a key outcome measurement for clinical conditions and the ODI has shown to have some of the best responsiveness when it comes to patients with low back pain.[134] The ODI has been an extensively used measurement tool to evaluate function and how back pain affects an individual's ability to do daily activities.[135-138] The ODI assesses function in 10 categories (pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sexual activity, social life, and traveling). Version 2.0[135] was utilized for the purposes of this study. Each of the 10 categories has six statements that are scored from 0 to 5, the statement with the least disability is scored a 0 and the greatest disability scored with a 5. If more than one statement is marked, then the highest score is recorded. The overall score (index) is calculated by taking the total points added up for items answered and dividing by the total possible score (number of categories answered x 5). This number is then multiplied by 100 and rounded to a whole number. Overall index scores can be interpreted for

the range of 0-20% for minimal disability, 21-40% for moderate disability, 41-60% for severe disability, 61-80% for crippled, and 81-100% for individuals bed bound or exaggerating their symptoms.[139,140] (Appendix I)

Numeric Pain Rating Scale: The NPRS is a unidimensional measurement of pain intensity in adults.[132,141-147] It consists of an 11-point ordinal scale measuring pain from "0" = no pain to "10" = worst pain imaginable. The respondents were asked to report on current, best and worst pain in the last 24 hours. All three scores (current, best, and worst) were recorded along calculation of the average of all three being reported. This scale has been used across various diagnoses and age ranges.[132,143-145,148] (Appendix J)

Global Rate of Change scale: The GROC scale, as stated in its name, is global rating of improvement and satisfaction over the course of treatment.[149] It does not measure a specific dimension such as pain or function, but allows the patient to decide what they consider important. The GROC is a commonly used outcome tool in clinical research, especially as it relates to musculoskeletal care.[150,151] The most common formats of the GROC is typically a 7, 11, or 15 point scale on a number line with 0 in the middle and moving out one integer in the positive and negative numerical direction. The end anchors also contain the negative and positive words of "very much worse" and "very much improved" or "completely better" with "no change" being in the middle at the zero.[152] Evidence shows that scales with 7 or 11 points offer the best mix of patient preference, appropriate discrimination ability, and test-retest reliability.[153,154] For purposes of this study the recommended 11-point scale was used (-5 = very much worse, 0 = unchanged, 5 = completely recovered).[152] (Appendix K)

3.3.4 Instruments – Demographic collection

Demographic data was collected on both the patient along with the treating physical therapists involved in providing care. Each patient provided information regarding age, gender, race, and educational level. The patient's birth order was recorded, as first born or only child have been shown to accept treatment more readily and stayed in treatment longer.[155] Questions related to whether the patient had been seen in physical therapy previously, at this specific site, or by this specific therapist was enquired upon during the initial demographics screening. Lastly, the choice of why the patient participant selected physical therapy, the specific clinic, and physical therapist was asked. (Appendix B) Each of the participating physical therapists also completed a demographics form providing their age, gender, race, level of physical therapy education, specialty certifications (if any), and years practicing as a physical therapist. (Appendix L)

3.3.5 Procedural process

Clinical sites across the US were recruited to be data collection sites. These sites were chosen based on interest in participating with research design and availability to be a data collection site. Physical therapists at each location were given the option to opt in or out as a participating physical therapist. If the physical therapist opted in, they signed an informed consent and completed a physical therapist participant demographic information form and were provided a coded ID#.

At each clinical site, front office staff that recognized potential patients for the study (patients being seen for initial evaluation of low back pain or equivalent diagnosis by a physical therapist that had consented to partake in the study) gave the patient a research study recruitment flier. Those patients interested in participating were provided a link to an online PsychData link to complete the informed consent and a HIPAA form. Once the patient participant provided

informed consent, they progressed to additional PsychData questionnaires to be filled out by the patient participant prior to their initial evaluation with their physical therapist. Information collected consisted of: baseline demographic information sheet, General Trust in Physician Scale, Trust in Physician Scale, PCAS, Wake Forest Scale, ODI, and NPRS. The online participant data collection allowed for blinding of the physical therapist throughout the study to the trust measurement scores. Patient participants received normal physical therapy evaluation and treatment as directed by the physical therapist. Upon completion of the initial visit, the patient participant completed the WAI-SR, Trust in Physician Scale, PCAS, and Wake Forest Scale through a second PyschData link. After completion of the second physical therapy visit, the participating physical therapist completed the PT Survey of Patient Connection and Engagement. Patient participants were blinded to the physical therapist's responses on this instrument. Patient participants continued to receive normal physical therapy as directed by the physical therapist working toward discontinuation of the current episode of care. The majority of the physical therapy encounters (80%) needed to have the initial physical therapist directly involved with the care of the patient participant to be eligible for data collection. If less than 80% of the visits have the direct care delivered by someone other than the initial physical therapist, that data was excluded from primary analysis. Upon discontinuation of the current episode of care or the end of 6 months of care, the patient participant completed the Trust in Physician Scale, PCAS, Wake Forrest Scale, WAI-SR, ODI, NPRS, and GROC. The participating physical therapist completed a second PT Survey of Patient Connection and Engagement at the conclusion of care. (Figure 1) Patient participants that complete all three series of forms (pre-initial visit, post-initial visit, and discontinuation episode) were eligible for a total of $25 in Walmart gift cards to be mailed to an address of their choice.

Statistical Analysis Plan (SAP)

All data was coded and entered into SPSS version 27.0 (IBM Corp., Armonk, N.Y., USA) for statistical analysis. Patient participant and physical therapist participant demographic data was reported with means, ranges, and standard deviations. The primary correlational statistics was the Spearman rho to assess the various individual trust measurement scores and changes in scores over time and individual scores with the primary outcome measurements of pain, function, and global change. The individual trust measurement scores, that have not been used in physical therapy, were be analyzed for correlation to WIA-SR, which has been used in physical therapy research, with Spearman's rho. Friedman's analysis of variance looked at changes in individual trust measurement scores over time from pre-initial visit, post-initial visit, and discharge. The non-parametric analysis was used due to the ordinal nature of the outcome variables. The PT Survey of Patient Connection and Engagement was analyzed for correlation with outcomes and the individual trust measurement scales with the Spearman rho. Linear regression analysis was done with the individual trust measurement scales and outcomes variables for predictive modeling of trust and outcomes assessment.