INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Study title:

A Comparison of Two Body Awareness Training Methods for Maintaining Precisely Coordinated Movements and Optimal Control of Spinal Stability for the Improvement of both Symptoms and Activity Capacities in Daily Life:

Comparative Effects on Subjects with Chronic Non-Specific Low Back Pain in an Out-patient Clinical Setting

Purpose: The purpose of this research is to find out whether there are significant differences between two existing types of body awareness training methods for improved stability and control of the spine column and surrounding relationships through precisely coordinated muscle and movement activity. Both treatment interventions are specifically designed for persons who commonly relapse into episodes of chronic recurrent low back pain, have persistent pain, also known and diagnosed as *Chronic, Non-Specific Low Back Pain* (CNSLBP). This project is being conducted by Doctoral (Ph.D.) Research Student, Timothy J. Sobie, PT, of Saybrook University, Oakland, California, who directs various local intervention programs -- including the **Alliant Spine Project** at Alliant Physical Therapy, PLLC in Tacoma -Gig Harbor, and Olympia, Washington. His supervisor is Doctor Richard A. Sherman, who directs the Psychophysiology Doctoral Concentration Program at Saybrook University.

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Procedures: PARTICIPATION INFORMATION: You have been invited to participate in a research study conducted through Saybrook University and Alliant Continuum Care, PLLC. It is very important that you read and understand the following general principles that apply to all participants in our studies, whether healthy controls or patient volunteers: (a) your participation is entirely voluntary; (b) you may withdraw from participation in this study or any part of the study at any time; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled; (c) after you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

NATURE OF STUDY: You are being asked to participate in a clinical investigation trying to find out about comparative relationships between two types of patient education and training methods involving the awareness and experience of muscle control activities and coordinative movements designed to improve back and spine function and to decrease the debilitating effects of CNSLBP, including the attenuation (or reduction) of pain intensity itself.

We have discovered that for some people who have Chronic (CNSLBP) Low Back Pain, that there is a corresponding disruption of clarity for both the sensation of where your body is in space and how it moves, and in how muscles can both *under-contract* and *over-contract* as if they sometimes have a mind of their own. Also, there is a corresponding disparity of how to coordinate daily or novel movement (motor) activities with clear dexterity--especially for larger movements involving a balance throughout the whole body. We believe that these ordinary activates have become hampered or blocked over time by the predominance of pain pathways. Yet, we also believe that by training precisely coordinated movements with these newer methods, you can invoke 'competing pathways' in your brain and nervous system that are not compatible with usual, often misunderstood, pain-invoking pathways.

You are one of 30+ subjects having a medically verified diagnosis of CNSLBP -- Low Back Pain without Sciatica or radiculopathy -- of which there is no one clear cause that can be clearly pinpointed or ascertained. The good news is that, with this diagnosis, there are no findings that are significantly dangerous, immediately life threatening, nor which require emergency room visits or hospitalization. The not-so good news is that there are many interactive and mysterious factors that can create the ongoing experience of pain, and it is hoped that your participation in this study can aid in adding some understanding for new discoveries and new improvements to help remedy and better resolve this all too common modern day malady of a problem.

If you decide to participate, you will be interviewed about your demographic history, your pain-related history and general medical history, and be physically screened by a qualified physician prior to fully participating in the clinical trial phase of the project. This is necessary so we can be as certain as is possible about ruling out any immediate or serious medical pathology in any body system -- and deducing a clarifying exam that clarifies your status as a participant having a primary diagnosis of CNSLBP. You will not be able to participate if you have any important medical findings that would otherwise preclude your safety or expectant outcome.

As part of your participation, you will be asked to complete a number of standard practice intake questionnaires and rating scales that are commonly used in both the treatment and research of Chronic Low Back Pain. In addition, you will be assisted to perform, to the best of your ability, a series of three endurance postures being timed by a stopwatch just prior to your first treatment session, and again after 2-weeks, 4-weeks, 8-weeks, then once again upon your last follow-up appointment at 6-months later.

After the initial intakes, you will be informed about your status as a continued participant in the study and be assigned to one of two groups wherein a licensed physical therapist - specifically trained in one of the two methods-will conduct a brief screening exam before beginning to instruct you in their respective techniques and methods. They will provide you a written and visual summary of what you did during the session, and suggest some ideas and strategies on how to practice them at home and in daily life - and in addition, to engage yourself more often and for a bit longer in the usual activities of daily life. Since we want to know the relationship and effects between each day of each intervention session for each individual subject in each group of the study, you will be asked to complete a rating scale about your experiences and abilities from the prior session, to be submitted to the front desk of our facility before each new subsequent treatment visit - and to be reviewed by your therapist(s) at the start of each session.

You will be required to undergo and participate in scheduled 1-hour treatment sessions with corresponding and like-trained physical therapists and / or physical therapy assistants at 2x / week for the 1st 4 weeks (initial 8 visits), then reduced to 1 x / week for an additional 2nd set of 4 -weeks (4 visits) --for a total of 12 visits over an 8 -week long period. (i.e. a two-month commitment to yourself and for the advancement of science).

In addition, for further data collection, you will be required to complete the 2-rating scales and a single questionnaire, along with repeating the position / posture endurance physical exam at 2 weeks, 4-weeks, 8-weeks. Each data collection event in its entirety should take no more time than 15-minutes. And finally, you must be

available for a for long-term follow-up at 6-months after your last treatment date to complete one more set of scales, the questionnaire, and timed physical endurance tests to see how well your new skills and practice sets have taken effect over an extended term -- without being necessarily dependent on continued or added therapy directly.

Where applicable, participating human subjects are allowed to maintain their current or existing medication regimen (dosages and schedules) as intended for purposes of treatment of low back pain symptoms during and throughout the 8-week course of the study. However, you will not be permitted to *abruptly increase* nor *abruptly discontinue* (i.e. totally stop via 'cold turkey') your prescribed or existing medication regimen. Instead however, since there is strong possibility that you are likely to develop competing receptor sensitivities and newer reward differentiation pathways throughout and within the movement control centers of your brain during the course of the study, *you may instead feel, as so inclined, to gradually reduce* (titrate down) *your frequency of dosage to less numbers of times per day, as needed, week by week*; and this is recommended so as to re-cultivate and to gradually restore your natural endogenous (internal) pharmacy from a renewed and opportunistic inside place.

Other exceptions to medication changes due to interaction precautions with other drugs or other posed risk(s) will be approved but must be accompanied by explanatory rationale to us being documented by your physician. Where applicable, limit alcohol to 2 drinks / day. We will request and attain records of difference in your medication intake during the course the study, after the 8-weeks, and again at 6-month follow-up.

As part of your agreement for participating as a research subject in this study, you are asked not to seek any other form of physical, behavioral, and /or medical/surgical, new prescription drug or over-the-counter interventions for low back pain during the 8-week course of the study -- in order to retain your status as a participant in the study. This need for restraining controlled exposure to select variables requires that you do not seek or visit treatments for other physical therapy, massage & bodywork approaches, chiropractic, osteopathy, acupuncture, interventional pain specialists, injections, naturopathic interventions, counselors, hypnotherapists, biofeedback practitioners, Yoga, Pilates, personal trainers, energy healers, etc. , and *medical cannabis* – (unless already in use as a medical regimen). However, you are allowed to use pads or supports as needed for improving comfort while sleeping within your existing sleep arrangement –but must refrain from purchasing a new mattress or moving to a different room for an alternate sleep arrangement for and throughout the entire course of the 8 –month study. Likewise, you may certainly adjust your existing desk and dining furniture with supports or props for improving comfort (as informed through either each intervention and /or your own self-discovery), but you may not invest in a new ergonomic or customized piece of furniture for either work nor for reclining / nor for newly accommodative rest purposes during the entire 8-month course of the study. If by chance you spend more than 2-hours per day driving, you are also asked to refrain from purchasing a new vehicle during the 8-month course of the study.

If you become anxious about any aspect of the study or have questions, you can contact Alliant Spine Project's Research Coordinator, Kenny Li, at 253-572-4611 Ext 5, who in turn reports to the Principle Investigator. You can, of course, cease participation at any time. If we find out anything which would affect your decision to continue participating in the study, we will tell you immediately.

As a health plan insured beneficiary of treatment, there are no budget provisions requiring subjects to be paid a stipend or cash reward for their participating in this study. There will otherwise be no cost to you other than usual and customary co-pays and deductibles where applicable under private health plans, plus time required to meet with the investigator staff for filing out assessment scales and the questionnaire, and to undergo successive treatments and the positional endurance assessments. No experimental devices are involved in the study and you are not taking any major risks by participating.

CONFIDENTIALITY: The information gained about you because of your participation in this investigational study will not identify you individually in any way which could permit people to easily determine who you are. The information may be discussed as an educational model and used generally in the furtherance of medical science. Information gained from this protocol may be used as part of a scientific publication in medical or professional journals, but you will in no way be personally identified. Complete confidentiality cannot be promised because information bearing on your health may be required to be reported to appropriate medical authorities in compliance with federally mandated HIPPA Regulations. As a standard of usual care, all patients as participants will be provided a HIPPA Policy fact sheet privacy statement - as appended to this document – prior to any data intake, assessment or treatment.

Possible Risks, Re-directing the Fluctuating Nature of Pain, and Other Safeguards:

Interventions and assessments for individual subjects in either or both groups pose minimal risks that are no different from the usual and customary scope of physical therapy practice - of which both applications are deemed minimally invasive.

All procedures occur within usual scope of Physical Therapy practice within The State of Washington. This study is designed to minimize as much as possible any potential physical, psychological, and social risks to you. Although very unlikely, there are always risks in research, which you are entitled to know in advance of giving your consent, as well as the safeguards to be taken by those who conduct the project to minimize the risks. Those risks include the possibility of:

The occasional phenomenon of latent or spontaneous pain flares occurring anywhere in the body after or during the course of treatment, or at any time… as a normative and common finding in new or uncertain activity situations involving an amplified background sensitization of signaling processes within the nervous system that have, over time, become involuntarily conditioned to anticipate possible threats and to trigger a state of chronic pain -even if during a delayed onset occurring within hours or days later.

- Here it is important to note that the size and magnitude of movements encountered in these therapy sessions are actually and very likely much gentler than that which occurs in everyday common life activities for most people. However, these movements and muscle recruitments do demand a quality of attention that requires you to move, and in some cases, to think different, in manners that may be conceptually challenging to your initial experience of learning to coordinate and to practice them. Confusing pain flares, background muscle tension, spasms, worry, and feeling lost in your body are real and possible events. Though these phenomena can be quite normal for all new learning, and that feelings of anxiety or inadequacy might occasionally surface up, it is important to know that no one is expected to get it right the first time--or even the second time. We all learn at our own pace, and something is better than nothing.

Again, the movements and muscle recruitments in this study are sub-maximal - and sometimes only imagined and only mentally rehearsed --and in some cases without actually generating any actual physical movement at all.

- In this, **the most important thing to know** is that if an episodic pain flare (hurt state) should occur, it is **not** likely due to 'tissue damage' or 'muscular strain' or to 'joint inflammation,' nor attributed to normal age-appropriate arthritis or 'connective tissue breakdown' but rather instead through the brain and nervous systems' inadvertently mis-matching a hyper-sensitized and guarded over-response output to newly unfamiliar movements being introduced against an acquired history of withdrawn or over-protective patterns and restricted attention --as is the basis of which modern neuroscience research is now just finding out. On the other hand, other new and unfamiliar movement patterns of muscle recruitment can equally bring welcome and sustained relief to your usual state! This is why it is so important to explore the variations provided by your therapist -- rather than to conclude something is unhelpful.

- Again, just remember that **within the context of slow, gentle, and graded movements** via the subtle muscle recruitment activities being taught in this study, "**tissue damage is not at all likely, and that in most cases, hurt does not equal harm**" and you will need to consider how to pause, re-adjust, and re-settle yourself as you review how to approach or coordinate the desired muscle activation and movement pattern all over again, each time from a fresh slate of opportunity.

- Finally to reduce any other added worry–it is also likely that pain flares, or any other strange sensations that occur --are not likely due to any serious medical condition --as can and will be further evidenced by your complete medical work-up and screening for pathology prior to entering this study.

These ideas will be briefly reviewed and re-assured *prior to* or *during* each intervention should the topic come up. Furthermore, you will be supported by pads, props, and substitutive variations and adaptations to facilitate comfort and reduce unnecessary strain during most training activities to the extent possible via the judgment of your individually trained and qualified therapist.

Alternatives to Participation in the Study and Safeguards to Privacy and Data Protection:

I understand that:

[1] My participation shall in no way have any bearing on my clinical care, or alter or deprive me of any or all services presently received in the institution and setting in which I participate, as well as those provided by the institutions sponsoring, funding, and providing oversight, inclusively, for this research project.

[2] Although my identity shall be known to the Principal Researcher and through Research Coordinator, and any in-facility staff-supervised research assistant(s), all identifying information shall be removed at the time that individual and group data are analyzed, and shall in no way have any bearing on my social recognition or reputation, my insurance eligibility, my employment, or my applicable social program status.

[3] My responses to the questions will be pooled with others and all identifiers, such as names, addresses, employers, and related information that might be used to identify me, will be given a code number.

[4] This informed consent form will be kept separate from the data I provide, in a locked file for five years, known only to the Principal Researcher, after which it will be destroyed unless the local authorities at an affiliating, partnership, or government / legislative institution require it to be kept longer.

[5] The data collected in their raw and transcribed forms will be kept anonymous, stored in a locked container accessible only to the Research Coordinator for the first 2-months, then the Principal Investigator thereafter for five-years, after which it will be destroyed.

[6] Transcribed, anonymous data in the form of computer disks, will be kept indefinitely for future research.

[7] All the information I give will be kept confidential to the extent required by law. The information obtained from me will be examined in terms of group findings, and will be reported anonymously.

[8] DEBREIFING: At the end of your participation in the study, you can be advised as to whether or not you were involved in which arm of the comparative study that engendered better results. . You will also be given an opportunity to have your name put on a list of those receiving reports and publications resulting from the study. Only general findings will be presented in a Summary Report of which I am entitled a copy, and my individual responses are to remain anonymous.

[9] None of the personal information I provide associated with my identity will be released to any other party without my explicit written permission.

[10] I have the right to refuse to answer any question asked of me.

[12] I have the right to refuse at any time to engage in any procedure requested of me.

[13] I have the right to withdraw from participation at any time for any reason without stating my reason.

[14] I have the right to participate without prejudice on the part of the Principal Researcher and other persons assisting the Principal Researcher.

[15] It is possible that the procedures may bring to my mind thoughts of an emotional nature that may upset me. In the unlikely event that I should experience emotional distress from my participation, the Principal Researcher, Research Coordinator, [*and relevant research assistants*] present shall be available to me. They shall make every effort to minimize such an occurrence. However, should an upset occur and become sufficiently serious to warrant professional attention, as a condition of my participation in this study, I understand that a licensed mental health professional will be made available to me. If I do not have such a person, the Principal Researcher will refer me and reasonable costs up to the first two visits will be paid by the Principal Researcher.

[16] By my consent, I understand I am required to notify the Principal Researcher at the time of any serious emotional upset that may cause me to seek therapy and compensation for this upset.

[17] I will receive a copy of this signed consent form for my records.

Regarding any concern and serious upset, you may contact the Principal Researcher and/or Research Coordinator at: 253-572-4611 and /or Faculty Research Supervisor, Dr. Richard Sherman, Ph.D. at 800 530 6658. Should you have any concerns regarding the conduct and procedures of this research project that are not addressed to your satisfaction by the Principal Researcher, you may report and discuss them with Dr. M. Wilson Williams (SIRB@Saybrook.edu), the Director of the Saybrook Institutional Review Board.

Possible Benefits:

I understand that my participation in this study may have possible benefits.

[1] I may obtain a greater personal awareness, knowledge, and understanding of the relationships between my pain and muscle tension, along with improved body awareness, muscle control, and quality of movement.
[2] Through future communications and possible applications of the findings of the research, indirectly my participation may bring future benefits to others who have the same problem.
[3] My participation may enable the Principal Researcher and others working in the topic area to contribute to knowledge and theory of my pain problem.

Summary Report:

Upon conclusion of this study, a summary report of the general findings will become available. If you would like a copy of the report, please check the box below and provide the address to which you would like it sent (your email or postal address):

☐ I would like to receive a copy of the Summary Report

Postal or Email Address:

_____

Phone Number: _____

Emergency Contact Name and Phone Number: _____

Consent of Research Assistant Staff Member working directly with the subject

I have explained the above procedures and conditions of this study, provided an opportunity for the research participant to ask questions, and have attempted to provide satisfactory answers to all questions that have been asked in the course of this explanation.

_____

Research Coordinator's Signature Date

Research Coordinator's Name: _____ (Assistant to Principle Investigator)

_____

Principle Investigator's Co-Signature Date

Principle Investigator's Name: _____ (Supervisor to Research Assistant)

Consent of the Participant

If you have any questions of the Principal Researcher and / or Research Coordinator at this point, please take this opportunity to have them answered before granting your consent. If you are ready to provide your consent, read the statement below, then sign, and print your name and date on the line below.

"I have read the above information. I have received a copy of HIPPA Privacy Protections Fact Sheet from Alliant. I have had an opportunity to ask questions about any and all aspects of this study, and give my voluntary consent to participate."

Participant Signature Date

Participant Name