November Article Analysis

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1 Research Article Links

1.1.1 <u>http://www.anatomyfacts.com/Research/blog.htm</u>

2 Analysis

2.1 Brief Summary

2.1.1 This is a <u>novel</u>, <u>randomized</u> (<u>Alternate Definition-Random Sample</u>), and controlled research study (a study using a (<u>control group</u>) on comprehensive massage therapy combining soft tissue manipulation (trigger point, neuromuscular, and friction) with exercise/ postural correction in the treatment of <u>subacute</u> low back pain. The comprehensive massage group is compared with 3 other groups; soft tissue only group, exercise/postural group, and control group (fake laser treatments=The laser machine was not working-

this was a control group) (GROUPS). The comprehensive massage group does no better than the soft tissue only group, which is in a statistical dead heat (There was no difference between the treatments-that is the clients got about the same benefit from either treatment) with the exercise group at one-month followup. All of the 3 treatment groups do better than the fake laser group. Consumers would be advised to pick the treatment based on time and cost. The least time consuming option for clients would be soft tissue treatment and the least expensive would be exercise/postural correction. The comprehensive massage therapy may provide better pain relief (although potential bias and questionable statistics makes for an uncertain result) but is both more expensive and time consuming than the other alternatives.

2.2 Effectiveness of massage therapy for subacute low-back pain: a randomized controlled trial By Michele Preyde

2.2.1 Introduction

- 2.2.1.1 This <u>Peer reviewed</u>¹ article is according to its author, Michele Preyde "the first randomized controlled trial of the effectiveness of massage therapy for subacute lowback pain." ² Randomizing insures that researches can't pick clients that will prove their point and control groups allow researches to compare different treatments one with the other and with no treatment. This is a way to measure the effectiveness of treatment. This research would probably be considered more valid by statistical/research design type people because it follows good, acceptable scientific method.
- 2.2.1.2 Nearly 100 people, mostly overweight, college educated women in their mid to late 40's, who had chronic low back pain (1 week-8 months) (from bending or lifting), without significant pathology (No serious disease of the lumbar spine or other serious diseases, diabetes, Multiple Sclerosis ect) completed the study.

The large numbers of clients treated means the statistics are more accurate because this is a large sample. This study would have as they say street credibility (street creds), if your street is a research lab and your audience were research scientists.

2.2.2 Research Validity

- 2.2.2.1 Pedro rates this research as follows; 6 out of 10 possible (see <u>Pedro Validity Standards</u>). This study did have some significant flaws which are outlined below.
 - 2.2.2.1.1 "6/10 [Eligibility criteria: Yes; <u>Random</u> <u>Allocation</u>: Yes; <u>Concealed Allocation</u>: No; <u>Baseline comparability</u>: Yes; <u>Blind Subjects</u>: No; <u>Blind Therapists</u>: No; <u>Blind Assessors</u>: Yes; Adequate follow-up: Yes; <u>Intention to</u> <u>treat</u>: No; Between-group comparisons: Yes; Point estimates and variability: Yes. Note: Eligibility criteria item does not contribute to total score] * This score has been confirmed*" Pedro

2.2.2.2 Analysis of Weaknesses in this Research

- 2.2.2.2.1 Had the following criterion been met this research study would have gotten a perfect score of 10. The following attempts to explain the criterions, which were not met by this research study.
- 2.2.2.2.2 Concealed Allocation³
 - 2.2.2.2.1 This study does not clarify whether or not the screening person was unaware of which group the subject would be placed in. The screening person determines if a subject is eligible as participant in the research Allocation assignments, for example, should be sealed (opaque envelopes) to the screening person or allocation should be done by a person "off-site" to the research project, and by someone who has no association to the project personal. This would insure that the screening person's bias did not

influence which subjects were placed in what groups.

- 2.2.2.2.2When allocation is concealed from the researcher some studies (Schulz et al. (1995), JAMA 273(5): 408-412)) show more modest treatment effects. This can in effect reduce or nullify the positive effects of randomization in reducing researcher bias so that it has minimal effect on outcome.⁴
- 2.2.2.2.3 In this study people were assigned randomly using a <u>random number table</u> what is not clear is whether the allocation person knew who was being assigned to which groups.
- 2.2.2.2.2.4

2.2.2.2.2.5 Reference

- 2.2.2.2.5.1 <u>http://www.anatomyfacts.com/</u> <u>Research/allocationc.pdf</u>
- 2.2.2.2.2.5.2 <u>http://www.ncbi.nlm.nih.gov/en</u> <u>trez/query.fcgi?cmd=Retrieve&</u> <u>db=pubmed&dopt=Abstract&lis</u> <u>t_uids=11867132</u>
- 2.2.2.2.3 Blind Subjects
 - 2.2.2.3.1 This research did not insure that subjects in the study were unaware of whether they had received treatment. If subjects can't be sure whether they received treatment it is less likely they will be influenced by <u>Placebo Effects</u> <u>Hawthorne effects</u> or <u>Observer Effect</u>.
- 2.2.2.2.4 Blind Therapists
 - 2.2.2.4.1 The therapists in this study were aware of which groups they were treating and therefore were not blinded. Since one of the therapists had a family emergency the researcher who was also a registered massage therapist

provided treatment thus raising questions about Experimenter's Bias.

2.2.2.2.5 Intention to treat

- 2.2.2.5.1 In this study all of the subjects scores who were intended for treatment were not statistically analyzed together. If subjects dropped out or did not complete all of the treatments their scores were dropped from the statistical pool. This can reverse the good effects of randomization in eliminating bias according to some research.⁵⁶ It can result in an increasing the probability of what is known as Type 1 Error, which involves rejecting the null hypothesis when it should be accepted. Research usually begins with a Null Hypothesis, which is a statement that predicts the research will show no difference in the means between the treatment groups and control groups. A hypothesis then is a prediction about the outcome of the research. The null hypothesis predicts the null (null=not any) effect of the treatment.
- 2.2.2.2.5.2 In this case when all of the subjects scores even the ones that dropped out are not included it increases the chance of rejecting the null hypothesis when it should be accepted. This research may have shown treatment effects between the various groups when there were none.

2.2.2.2.5.3 Reference

- 2.2.2.5.3.1 Statistical Considerations
- 2.2.2.5.3.2 <u>http://www.bmj.com/cgi/conten</u> <u>t/short/319/7211/670</u>

2.2.2.2.5.3.3 <u>http://www.ncbi.nlm.nih.gov/en</u> <u>trez/query.fcgi?CMD=search&</u> <u>DB=pubmed</u>

2.2.3 Treatment Setting

2.2.3.1 "This study was conducted at the Health and Performance Centre, University of Guelph, Guelph, Ont., which offers multidisciplinary services such as sports medicine, physiotherapy and chiropractic manipulation. Treatments were provided and outcome measures were obtained at this centre." ⁷

2.2.4 Screening and Random Assignment

- 2.2.4.1 Prospective subjects were recruited via university E-Mail, flyers sent to family physicians and local newspaper advertisements. Were subjects paid and if so how much? Telephone screening of subjects (age range 18-81) determined the following;
 - 2.2.4.1.1 Existence of subacute (1 week-8 months) low-back pain
 - 2.2.4.1.2 Absence of significant pathology (bone fracture, nerve damage or severe psychiatric condition (clinical depression as physician diagnosed)
 - 2.2.4.1.3 No pregnancy
 - 2.2.4.1.4 Stable health
 - 2.2.4.1.5 Previous episode of low-back pain ok
 - 2.2.4.1.6 Positive radiographic finding of mild pathology ok

- 2.2.4.2 Although the information above was obtained as selfreported criteria along with their information regarding health history. (Medical conditions, medication use past history of serious injury) Doubts about a particular subjects inclusion in the study were discussed with their personal physician.
- 2.2.4.3 Random assignment using a random numbers table forming the 4 groups described below.
- 2.2.4.4 Upon the first appointment the following was completed;
 - 2.2.4.4.1 Patient characteristics and health information
 - 2.2.4.4.2 Informed consent
 - 2.2.4.4.3 Baseline measures (Function, pain, anxiety and lumbar range of motion) were recorded

2.2.5 Modalities

- 2.2.5.1 Introduction
 - 2.2.5.1.1 The treatment consisted of several modalities. were combined which and labeled comprehensive massage (Group # 1) by the researcher. Comprehensive massage consisted of soft tissue mobilization, exercise, and postural education. These modalities were also combined to form a total of 2 additional groups, which were compared statistically to a Sham laser group (Total of 4 groups). (See below) Subjects were also encouraged to increase their activity level between treatment sessions
- 2.2.5.2 Soft-tissue manipulation techniques
 - 2.2.5.2.1 Purpose
 - 2.2.5.2.1.1 Promote Circulation
 - 2.2.5.2.1.2 Relax Muscle Spasm
 - 2.2.5.2.2 Procedure

- 2.2.5.2.2.1 Subjects were asked to identify the area that was bothering them. The appropriate technique was used for that area according to the criterion below.
- 2.2.5.2.3 Duration

2.2.5.2.3.130 and 35 minutes

2.2.5.2.4 Frequency

2.2.5.2.4.1 Six treatments over a one month period

- 2.2.5.2.5 Friction (Used for Fibrous Tissue)
- 2.2.5.2.6 Trigger points (Muscle Spasm)
- 2.2.5.2.7 Neuromuscular therapy
- 2.2.5.3 Exercise/Postural Correction

2.2.5.3.1 Initial Session

- 2.2.5.3.1.1 Exercise instruction demonstrates stretching exercises for the trunk, hips and thighs, including flexion and modified extension
- 2.2.5.3.1.2 Stretches to be performed in a relaxed manner within the pain free range held for 30 seconds
- 2.2.5.3.1.3 Subjects instructed to perform stretches twice one time per day for related areas and more frequently for affected areas
- 2.2.5.3.1.4 Subjects encouraged to engage in strengthening or mobility exercises such as walking, swimming or aerobics and to build overall fitness progressively
- 2.2.5.3.1.5 Subjects were given postural education and proper body mechanics

instruction, particularly as they related to work and daily activities

- 2.2.5.3.2 Each subsequent session
 - 2.2.5.3.2.1 Includes stretching exercises with review of proper mechanics, postural education and reinforcement of home practice and ancillary exercise activities

2.2.5.3.3 Duration

2.2.5.3.3.115-20 Minutes with therapist

2.2.5.3.3.2Self exercise 1 x per day 2 repetitions= 15- 20 minutes (?).

2.2.5.4 Sham Laser Group

2.2.5.4.1 "The control group received sham low-level laser (infrared) therapy. The laser was set up to look as if it was functioning but was not. The subject was "treated" lying on his or her side with proper support to permit relaxation. The instrument was held on the area of complaint by the treatment provider, so the subject was attended for the duration of the session (about 20 minutes) to control for the effects of interpersonal contact and support."

2.2.6 Modalities (Narrative from research)

- 2.2.6.1 "For subjects in the comprehensive massage therapy group various soft-tissue manipulation techniques such as friction, trigger points and neuromuscular therapy were used to promote circulation and relaxation of spasm or tension. The exact soft tissue that the subject described as the source of pain was located and treated with the specific technique indicated for the specific condition of the soft tissue (e.g., friction for fibrous tissue and gentle trigger points for muscle spasm). The duration of the soft-tissue manipulation was between 30 and 35 minutes.
- 2.2.6.2 For each treatment, stretching exercises for the trunk, hips and thighs, including flexion and modified

extension, were taught and reviewed to ensure proper mechanics. Stretches were to be within a pain-free range, held for about 30 seconds in a relaxed manner, and performed twice on one occasion per day for the related areas and more frequently for the affected areas. Subjects were encouraged to engage in general strengthening or mobility exercises such as walking, swimming or aerobics and to build overall fitness progressively. Education of posture and body mechanics, particularly as they related to work and daily activities, was provided. The exercise and education segment took about 15-20 minutes." "Each subject received 6 treatments within approximately 1 month." ⁹

2.2.7 Groups

- 2.2.7.1 Subjects (clients) were placed randomly in one of four groups.
- 2.2.7.2 Group # 1 Comprehensive massage therapy

2.2.7.2.1 Soft-tissue manipulation

2.2.7.2.2 Remedial exercise

2.2.7.2.3 Posture education

2.2.7.3 Group # 2 Soft Tissue Only

2.2.7.3.1 Soft-tissue manipulation

2.2.7.4 Group # 3 Remedial exercise/Posture education only

2.2.7.4.1 Remedial exercise

2.2.7.4.2 Posture education

2.2.7.5 Group # 4 Placebo

2.2.7.5.1 Sham laser treatment

2.2.8 Initial and Outcome Measurement

2.2.8.1 Outcomes were measured using questionnaires, which are well researched to provide reliable results (reliability, validity and internal consistency). These questionnaires measured activities of Daily Living (ADL)(functionality) and pain. Secondary measures were anxiety and lumbar range of motion. The anxiety test measures anxiety at the moment the lumbar range of motion test was taken. Often people who suffer pain will experience anxiety prior to movement in the direction of pain (?). This is a way to initially measure and then compare post treatment anxiety levels associated with movement.

- 2.2.8.2 Despite the fact that many of these self-rating tests are well researched for validity (still used by many researchers) mainstream science (<u>Oppel</u>) may be sceptical of non-objective functional assessment. ¹⁰ ¹¹ ¹² ¹³ For insurance purposes many carriers are increasingly demanding functional capacity examination as necessary justification for payment.
- 2.2.8.3 References
 - 2.2.8.3.1 <u>Quantitative functional Capacity Evaluation:</u> The Missing Link to Outcomes Assessment
 - 2.2.8.3.2 <u>Functional Capacity Evaluation and</u> <u>Chiropractic Case Management</u>
 - 2.2.8.3.3 Applying Outcomes Management into Clinical Practice
 - 2.2.8.3.4 Proving the Existence of Chronic Pain
- 2.2.8.4 "Post-treatment measures were obtained after 1 month of treatment, and follow-up measures were obtained 1 month after treatment ended." ¹⁴
 - 2.2.8.4.1 Post-Treatment Measures=After 6 treatments (1 Month)
 - 2.2.8.4.2 Follow-up Measures=1 month post treatment Termination.
- 2.2.8.5 Definitions
 - 2.2.8.5.1 Test Described
 - 2.2.8.5.1.1
 - 2.2.8.5.2 Usage

2.2.8.5.2.1

2.2.8.5.3 Reliability

2.2.8.5.3.1 Intra observer & inter observer reliability

2.2.8.5.3.2 Reliability

2.2.8.5.3.3

2.2.8.5.4 Validity

2.2.8.5.4.1 Validity

2.2.8.5.4.2

2.2.8.5.5 Sensitivity

2.2.8.5.5.1 Sensitivity

2.2.8.5.6 Internal consistency

2.2.8.5.6.1 Internal consistency

2.2.8.6 Tests used

2.2.8.6.1 Roland Disability Questionnaire (RDQ) (AKA Roland-Morris Questionnaire (RMQ) (2.5 or greater considered clinically significant)

2.2.8.6.1.1Test

2.2.8.6.1.1.1 <u>http://www.anatomyfacts.com/r</u> <u>esearch/roland.pdf</u>

2.2.8.6.1.1.2 Adaptations

2.2.8.6.1.1.2.1 <u>http://www.anatomy</u> <u>facts.com/research/roland</u> 2.pdf

2.2.8.6.1.2Test Description

2.2.8.6.1.2.1 The Roland Disability Questionnaire (RDQ) (AKA Roland-Morris Questionnaire (RMQ)) variously with 18, 23 and 24 point scale dependent

upon the edition (I assume) asks the patient to check off functional limitations the imposed back and or leg pain. The RDQ that the author uses in this study is based on 24 points and is an adaptation of the Sickness Impact Profile. The greater the number of items checked by the patient the greater the disability. Improvement can be calculated as a percentage of the total number of disabling attributes before and after a series of treatments. If, for example, at the beginning of treatment, a patient's score was 12 and, at the conclusion of treatment, her score was 2 (10 points of improvement), we would calculate an 83% improvement. (10/12=83%).

- 2.2.8.6.1.2.2 A score of 14 or more is considered a poor outcome. ¹⁵
- 2.2.8.6.1.3 Reliability & Usage

2.2.8.6.1.3.1 Test described ^{16 17} Reliability, validity and sensitivity ^{18 19 20 21} Usage ^{22 23 24}

2.2.8.6.1.4 Research References

- 2.2.8.6.1.4.2 <u>A study of the natural history of</u> low-back pain. Part II: development of guidelines for trials of treatment in primary care

- 2.2.8.6.1.4.3 <u>Measuring the functional</u> status of patients with low back pain
- 2.2.8.6.1.4.4 <u>Defining the minimum level of</u> <u>detectable change for the</u> Roland-Morris questionnaire
 - 2.2.8.6.1.4.4.1 Full Text Article
 - 2.2.8.6.1.4.4.1.1 <u>http://www.a</u> <u>natomyfacts.com/re</u> <u>search/definingmldc</u> <u>roland.pdf</u>
- 2.2.8.6.1.4.5 <u>Responsiveness and minimal</u> <u>clinically important difference</u> <u>for pain and disability</u> <u>instruments in low back pain</u> patients
 - 2.2.8.6.1.4.5.1 Full Text Article
 - 2.2.8.6.1.4.5.1.1 <u>http://www.a</u> <u>natomyfacts.com/re</u> <u>search/responsiven</u> <u>ess&minimal.pdf</u>
- 2.2.8.6.1.4.6 <u>A comparison of physical</u> <u>therapy, chiropractic</u> <u>manipulation, and provision of</u> <u>an educational booklet for the</u> <u>treatment of patients with low</u> back pain
- 2.2.8.6.1.4.7 <u>A benefit of spinal</u> manipulation as adjunctive therapy for acute low-back pain: a stratified controlled trial
- 2.2.8.6.2 McGill Pain Questionnaire (PPI (Present Pain Intensity)(Intensity) and PRI (Pain Rating Index)(Quality))

2.2.8.6.2.1Test

2.2.8.6.2.1.1 Introduction

2.2.8.6.2.1.1.1 The long form of this questionnaire was used in this study. The short form has been included for vour information. The scales for both these tests are ordinal (names attached to numbers which have greater than or less than values but lack equal intervals) for the purposes deriving statistical of calculations are treated as if they were interval (equal intervals between numbers).

2.2.8.6.2.1.1.2 Reference

- 2.2.8.6.2.1.1.2.1 <u>http://www.a</u> <u>natomyfacts.com/M</u> <u>uscle/statsdisc.htm</u> <u>#scales</u>
- 2.2.8.6.2.1.2 McGill Pain Questionnaire (SF-MPQ) Short Form ²⁵
 - 2.2.8.6.2.1.2.1 Test

2.2.8.6.2.1.2.1.1 <u>http://www.a</u> <u>natomyfacts.com/re</u> search/mcgill.pdf

- 2.2.8.6.2.1.2.1.2 <u>http://www.a</u> <u>natomyfacts.com/re</u> search/mcgill3.pdf
- 2.2.8.6.2.1.2.2 Test Description Short Form
 - 2.2.8.6.2.1.2.2.1 The short form of the McGill pain questionnaire, copyrighted by Ronald Melzack in 1984, correlates well with the long

form, which was used in this study. The short form has several components e.g. Pain Rating Index (PRI), Present Pain Intensity (PPI)/Visual Analog Scale (VAS). 26 2.2.8.6.2.1.2.2.2 The Pain Rating Index (PRI) 11 sensory has components (Throbbing, shooting, stabbing, sharp, cramping, hotgnawing, burning, aching, heavy, tender, & splitting), and 4 affective components (tiringexhausting, sickening, fearful, punishing-cruel) Under each component the subject is asked to rate degree of that attribute using (none=0, mild=1, moderate=2, severe=3) These 15 components spanning two areas (sensory & affective) are scored separately and then added together in a total sum.

2.2.8.6.2.1.2.2.3 The PPI score measures intensity on a 0-5

scale (0=no pain,1=mild, 2=discomforting, 3=distressing, 4=horrible, 5=excruciating). A visual analog scale (VAS) also allows the subject to place a mark between the continuum extremes of (no pain-worst possible pain). Some practitioners ²⁷ have devised a scale which is 10 centimeters long which once the patients have marked the scale a centimeter ruler can be placed and the centimeter millimeter score can be calculated а used as a statistic; e.g Beginning score 5 centimeters 5 millimeters=5.5. A review of the literature does not reveal that this practice has been validated.

2.2.8.6.2.1.2.2.4 The VAS on the short form is exactly 10 centimeters long so that by have the client make a mark between or on the two extremes you can place a 10centimeter ruler to determine the

score. The bold numbers are the centimeters and the numbers between are the millimeters with the final score as illustrated above (5 centimeters 5 millimeters=5.5).

- 2.2.8.6.2.1.3 McGill Pain Questionnaire (LF-MPQ) Long Form
 - 2.2.8.6.2.1.3.1 Need a copy
 - 2.2.8.6.2.1.3.2 <u>http://www.anatomy</u> <u>facts.com/research/mcgill2</u> .pdf
 - 2.2.8.6.2.1.3.3 Test Description Long Form
 - 2.2.8.6.2.1.3.3.1 The earlier (long form version of the McGill pain questionnaire, copyrighted by Ronald Melzack in 1970, includes four groups of descriptors (Sensory, affective, evaluative, & miscellaneous). Each of these descriptors has several attributes. which in descending order represent increased discomfort rated with the number of the tick mark in the category. For example the first number has flickering, quivering,

pulsing, throbbing, beating, & pounding. If you selected pounding your rating would be 6. There are 20 descriptors each with varying numbers of attributes. Each category is totaled and the grand total is the PRI score. The score range is 0-79.

2.2.8.6.2.1.3.3.2 The PPI score is tabulated in the same way as form the short which measures intensity on a 0-5 scale (0=no pain, 1=mild, 2=discomforting, 3=distressing, 4=horrible, 5=excruciating). The visual analog scale is not included but an anterior/posterior body chart with descriptors is provided. A front and back body chart with suggested markings is also provided but no score is provided in the final totals.

2.2.8.6.2.2 Reliability and Usage

2.2.8.6.2.2.1 Usage ²⁸ Test Described ^{29 30} ³¹ reliability and validity.^{32 33 34} ^{35 36 37} Visual Analog Scale ³⁸ 2.2.8.6.2.3 Research References

- 2.2.8.6.2.3.1 <u>http://www.chcr.brown.edu/pco</u> <u>c/Physical.htm#McGill%20Pain</u> %20Questionnaire
- 2.2.8.6.2.3.2 <u>The short-form McGill Pain</u> <u>Questionnaire in chronic</u> cancer pain
- 2.2.8.6.2.3.3 <u>Relationship between MPQ</u> and VAS in 962 patients. A rationale for their use
- 2.2.8.6.2.3.4 <u>The McGill Pain</u> <u>Questionnaire: major</u> <u>properties and scoring</u> methods
- 2.2.8.6.2.3.5 <u>The short-form McGill Pain</u> <u>Questionnaire</u>
- 2.2.8.6.2.3.6 <u>Transcutaneous electrical</u> <u>nerve stimulation for low back</u> <u>pain</u>
- 2.2.8.6.2.3.7 <u>The language of low back</u> pain: factor structure of the McGill pain questionnaire
- 2.2.8.6.2.3.8 Principal dimensions of the pain experience and psychological disturbance in chronic low back pain patients
- 2.2.8.6.2.3.9 <u>Factorial validity of the short-</u> form McGill pain questionnaire (SF-MPQ)
- 2.2.8.6.3 State Anxiety Index (SA) (State-Trait Anxiety Inventory Form Y (STAI))

2.2.8.6.3.1Test

2.2.8.6.3.1.1 Need to get a copy

2.2.8.6.3.2 Description

- 2.2.8.6.3.2.1 Consists of 40 questions 20 to assess the current anxiety state and 20 to assess the personality traits of the individual. The test takes about 10 minutes to complete. This instrument assesses the level induced by stressful experimental procedures and by unavoidable real-life stressors such as imminent surgery, dental treatment, job interviews, or important school tests. The State-Trait Anxiety Inventory Form Y (STAI) is the definitive instrument for measuring anxiety in adults. The STAI clearly differentiates the temporary between condition of "state anxiety" and the more general and longstanding quality of "trait anxiety." The essential qualities evaluated by the STAIS-Anxiety scale are feelings of apprehension, tension, nervousness, and worry. Scores on the STAIS-Anxiety scale increase in response to physical danger and psychological stress, and decrease as a result of relaxation training." 39
- 2.2.8.6.3.2.2 So far I could find no research directly linking orthopedic movement with this test. Nor did the author cite research.
- 2.2.8.6.3.2.3 The State Anxiety Index(SAI) comprises separate self-report scales to measure state (at this moment) anxiety. Scores can range from 20 (minimal anxiety) to 80 (maximum). The norms of state anxiety for working adults are considered

to be 35.7 (standard deviation [SD] 10.4) for men and 35.2 (SD 10.6) for women.

2.2.8.6.3.3 Reliability & Usage

2.2.8.6.3.3.1 Reliability, validity and internal consistency ⁴⁰ ⁴¹ ⁴²and widely used in research ⁴³ in a variety of disciplines, psychology and medicine. ⁴⁴ ⁴⁵ ⁴⁶ ⁴⁷ ⁴⁸

2.2.8.6.3.4 Research References

- 2.2.8.6.3.4.1 <u>http://www.mindgarden.com/pr</u> oducts/staisad.htm
- 2.2.8.6.3.4.2 <u>http://www.cps.nova.edu/~cpp</u> help/STAI.html
- 2.2.8.6.3.4.3 <u>Biofeedback and relaxation</u> training with three kinds of headache: treatment effects and their prediction
- 2.2.8.6.3.4.4 Failure to complete treatment for headache: a multiple regression analysis
- 2.2.8.6.3.4.5 <u>Psychometric properties of the</u> <u>Portuguese version of the</u> <u>State-Trait Anxiety Inventory</u> <u>applied to college students:</u> <u>factor analysis and relation to</u> <u>the Beck Depression Inventory</u>
 - 2.2.8.6.3.4.5.1 Full Text Article

2.2.8.6.3.4.5.1.1 <u>http://www.a</u> <u>natomyfacts.com/re</u> <u>search/statetai.pdf</u>

2.2.8.6.3.4.6 <u>Does experience influence</u> perception of dyspnea?

2.2.8.6.3.4.6.1 Full Text Article

2.2.8.6.3.4.6.1.1 <u>http://www.a</u> <u>natomyfacts.com/re</u> <u>search/statetai2.pdf</u>

2.2.8.6.3.4.7 Literature Reviews

- 2.2.8.6.3.4.7.1 <u>http://www.ncbi.nlm.</u> <u>nih.gov/entrez/query.fcgi?it</u> <u>ool=pubmed_DocSum&db</u> <u>=pubmed&cmd=Display&d</u> <u>opt=pubmed_pubmed&fro</u> <u>m_uid=9621742</u>
- 2.2.8.6.3.4.8 <u>Test-retest reliabilities of State-</u> <u>Trait Anxiety Inventory in a</u> <u>stressful social analogue</u> <u>situation</u>
- 2.2.8.6.4 Modified Schober test (lumbar range of motion) 49 50

2.2.8.6.4.1 Description

- 2.2.8.6.4.1.1 This is a simple but reliable objective measure of lumbar spinal range of motion, which has been extensively researched as an accurate predictor of pathology (e.g. ankylosing spondylitis) of the lower spine.
- 2.2.8.6.4.1.2 The test is a simple objective measurement of the distance between two points at mid distance 10 cm superior and 5 cm inferior to the PSIS midpoint during flexion and extension activities with the centimeter result recorded for both measurements. Norms have been established.
- 2.2.8.6.4.1.3 The Schober test has a norm of about 7 cm (SD 1.2).

2.2.8.6.4.2Test

- 2.2.8.6.4.2.1 Need to get a copy
- 2.2.8.6.4.2.2 <u>http://www.anatomyfacts.com/r</u> esearch/activities.htm#schober
- 2.2.8.6.4.2.3 <u>http://moon.ouhsc.edu/dthomp</u> so/namics/labs/standing.htm

2.2.8.6.4.3 Reliability & Usage

2.2.8.6.4.3.1 Test Described 51 52 Norms 53 Validity, Intra observer (r = 0.99) & inter observer reliability (r = 0.97) 54 55 56 57 58 59 usage

- 2.2.8.6.4.4 Research References
 - 2.2.8.6.4.4.1 <u>Reproducibility of nine tests to</u> <u>measure spinal mobility and</u> trunk muscle strength
 - 2.2.8.6.4.4.2 <u>Defining spinal mobility in</u> ankylosing spondylitis
 - 2.2.8.6.4.4.3 <u>Association between</u> radiographic damage of the spine and spinal mobility for individual patients with ankylosing spondylitis: can assessment of spinal mobility be a proxy for radiographic evaluation?
 - 2.2.8.6.4.4.3.1 Full Text Article
 - 2.2.8.6.4.4.3.1.1 <u>http://www.a</u> <u>natomyfacts.com/re</u> <u>search/associationb</u> <u>et.pdf</u>

2.2.8.6.4.4.4 Literature Review

2.2.8.6.4.4.4.1 Keywords (modified schober)

2.2.8.6.4.4.4.1.1 <u>http://www.n</u> <u>cbi.nlm.nih.gov/entr</u>

ez/query.fcgi?CMD =search&DB=pubm ed&cmd=Display&d opt=pubmed_pubm ed&from_uid=1714 3634

2.2.8.6.4.4.2 Keywords Keywords=Moll JM, Wright V. Normal range of spinal mobility. An objective clinical study Related Articles

> 2.2.8.6.4.4.4.2.1 <u>http://www.n</u> <u>cbi.nlm.nih.gov/entr</u> <u>ez/query.fcgi?db=p</u> <u>ubmed&cmd=Displa</u> <u>y&itool=abstractplus</u> <u>&dopt=pubmed_pu</u> <u>bmed&from_uid=55</u> 57779

2.2.8.6.4.4.5 No Keywords Specified

2.2.8.6.4.4.5.1 <u>http://www.ncbi.nlm.</u> <u>nih.gov/entrez/query.fcgi?</u> <u>CMD=search&DB=pubme</u> <u>d_DocSum&db=pubmed&</u> <u>cmd=Display&dopt=pubm</u> <u>ed_pubmed&from_uid=81</u> 84354

2.2.8.6.4.4.5.2

2.2.8.6.4.4.6 <u>Spinal mobility in ankylosing</u> <u>spondylitis: reliability, validity</u> and responsiveness

2.2.8.6.4.4.6.1 Full Text Article

2.2.8.6.4.4.6.1.1 <u>http://www.a</u> <u>natomyfacts.com/re</u> <u>search/spinalmobilit</u> <u>y.pdf</u>

2.2.8.6.4.4.7 <u>A randomized, double-blind,</u> placebo-controlled trial of

sclerosing injections in patients with chronic low back pain

2.2.8.6.4.4.7.1 Full Text Article

2.2.8.6.4.4.7.1.1 <u>http://www.a</u> <u>natomyfacts.com/re</u> <u>search/arandomize</u> d.pdf

- 2.2.8.7 Remarks on statistics
 - 2.2.8.7.1 With a level of significance of 0.05 and a power of 0.80, minimum samples of 20 subjects per group ⁶⁴ (JL., 1981) were required to detect a proportional reduction of pain of 50%. Outcome data were analyzed by intention to treat and group means compared with ANOVA, and subsequently Scheffé (post hoc). Minimal, insignificant differences between groups at baseline with near normal distributions permitted analysis without adjustment.
- 2.2.8.8 Measures (Dependent Variables)
 - 2.2.8.8.1 RDQ Score (Function)
 - 2.2.8.8.2 PPI Score (intensity of pain)
 - 2.2.8.8.3 PRI Score (quality of pain)
 - 2.2.8.8.4 State Anxiety Index Score (SA)
 - 2.2.8.8.5 Modified Schober Test, cm (Lumbar Range of Motion)(ROM)

2.2.9 Treatment/Assessment Providers

- 2.2.9.1 Two registered massage therapists, with more than 10 years experience, provided treatment, which was monitored by the principal investigator (also a registered MT) for consistency in application.
 - 2.2.9.1.1 "Two treatment providers were hired to deliver treatments, but it became necessary for the principle investigator, who is also a registered massage therapist, to provide treatment when

the other providers experienced personal distress (e.g., death of a family member)." ⁶⁵ We do not learn when the primary treatment provider drops out of the study and the author replaced her.

- 2.2.9.2 Certified personal trainer and certified weight-trainer supervisor (this was one person?) who along with one of the massage therapists, provided treatment for the remedial exercise and sham laser groups provided additional treatment.
- 2.2.9.3 Three physiotherapists provided the range of motion test (Schober) and were blind to which group each subject was allocated.
- 2.2.9.4 Calculation of pay to providers

2.2.9.4.1 Massage Therapists

2.2.9.4.1.1 Soft tissue Massage

2.2.9.4.1.1.1 Two massage therapists were hired to provide the soft tissue treatments and paid \$40 for each 30-35 minute session for 6 sessions. Each massage therapist then handled approximately 25 clients for 6 visits each or 150 visits over about a month's period (37.5/clients/week or about 18.75-21.88 hours/week) to the tune of \$6000 (50 x 6= 300 x 40=12000/2=\$ 6000). This works out to a total of 75-87.5 patient hours in a month. At that rate the massage therapists were paid between \$68.57-\$80 per hour.

2.2.9.4.1.2 Sham Laser

2.2.9.4.1.2.1 Sham Laser (20 minutes) 6 sessions \$15 per session=\$90

2.2.9.4.1.2.2 One massage therapist and a trainer provided sham laser

treatments 25 patients received sham laser treatments

- 2.2.9.4.1.2.3 The massage therapist saw about 12 sham laser patients for 6 visits with a total of 72 visits at about 20 minutes for each session and made \$15 per session or \$1080 or about 24 hours of sham treatment in a month. This works out to about \$45 per hour for sham laser treatment.
- 2.2.9.4.1.2.4 One certified personal trainer/weight-trainer supervisor (I assume this is just one person) was hired to provide sham laser treatment for 13 patients (I guessing they gave the extra client to the lone trainer). The 13 sham laser patients were seen for 6 visits of 20 minutes per session for a total of 78 visits for a total of 26 hours for the month or 6.5 hours per week, receiving \$15 per session for a total of \$ 1170.

2.2.9.4.1.3 Exercise/Postural Correction

2.2.9.4.1.3.1 One personal trainer/weighttrainer supervisor and one massage therapist was hired to provide "remedial exercise" for 25 patients each, which I assume included postural education although the study does not specify. In addition the study does not tell us which of the massage therapists provided the remedial exercise and so I will assume that it was the one who didn't provide sham laser

treatments. Each session was 15-20 minutes long and the therapists were paid \$15 per session for 6 sessions totaling \$90 per patient. There were 50 patients who received "remedial exercise" and the trainer/massage therapists were paid a total of \$4500 or \$2250 each for their services. There were a total of 300 visits or 150 visits per trainer and a total of 75-100 hours or 37.5-50 hours of training per trainer per month. This works out to about 9.38-12.5 additional hours per week at a rate of \$45-\$60 per hour.

2.2.9.4.1.4 Combined Treatment

- 2.2.9.4.1.4.1 One massage therapist then worked upwards to 27.88 hours per week or for a total of upwards of 111.5 hours total making about \$7080 for their combined services providing both soft tissue massage and sham laser treatments. This averages out to about \$63.50 per hour for the combined treatment.
- 2.2.9.4.1.4.2 The other massage therapist received just \$6000 for a month of soft tissue massage as aforementioned but then received additional monies for remedial exercise of \$2250 totaling \$8250. This massage therapist worked upwards to 34.38 hours per week of upwards to 137.5 hours in a month. This works out to about \$60 per hour for the combined treatment.

2.2.9.4.1.4.3 One certified personal trainer/weight-trainer supervisor worked upwards of 19 hours per week, 76 hours total for a total of \$ 3420 for combined exercise and sham laser treatments making a total of \$ 45 per hour of combined treatment.

2.2.9.4.1.5 Objective Measurement

2.2.9.4.1.5.1 The one objective measure, the range of motion test, was conducted by 3 physiotherapists who were blind to which group each subject was allocated. The study does not tell us, however, how much the physical therapists were paid or how much time they spent completing their tasks.

2.2.9.4.1.6 Summary

2.2.9.4.1.6.1 Soft Tissue Massage=50 patients 300 visits=\$12000 Exercise/Posture=50 patients 300 visits=\$4500 Sham laser Treatment=25 patients 150 visits=\$2250 Total=\$18750 for all of the treatments provided in this research project. Massage Therapists received an average bulk payment of \$ 7665 for their combined treatments working an average of 124.5 hours in a month at an average of \$61.57 per hour of work with an average workweek of 31 patient hours for 4 weeks. The trainer worked upwards of 19 hours per week, 76 hours total for a total of \$ 3420 for combined exercise and sham laser

treatments making a total of \$ 45 per hour of combined treatment.

- 2.2.10 College of Massage Therapists Ontario (Registered Massage Therapists for this Study)
 - 2.2.10.1 "The College of Massage Therapists Ontario (the College), one of this province's health regulatory bodies, exists to protect the public interest and to regulate the profession of massage therapy." The word college in this case doesn't refer to a school but to an organized body of persons engaged in a common pursuit or having common interests or duties.
 - 2.2.10.2 "As part of its responsibility to the public, the College sets minimum entrance to practice requirements, administers the certification examinations and promotes continuous quality improvement of massage therapist's knowledge, skills and abilities through the Quality Assurance Programme."
 - 2.2.10.3 "The College also promotes research and development of expertise in the massage therapy profession."
 - 2.2.10.4 It does not appear that the college actually regulates schools.
 - 2.2.10.5 The College of Massage Therapists of Ontario regulates the massage therapy profession through the administration of the Regulated Health Professions Act (RHPA) and the Massage Therapy Act, (MTA) as they pertain to the classification and practice of massage therapy in Ontario. The College of Massage Therapists of Ontario exists to protect and serve the public by ensuring the competency and quality of care provided by Massage Therapists through the maintenance of Standards and Regulations. Through its activities and programmes the College provides quality assurance and continuing education for Massage Therapists.

2.2.10.6 Reference

2.2.10.6.1 <u>http://www.cmto.com/about/cmto.htm</u>

2.2.11 Results

- 2.2.11.1 Most of the clients that started the study completed it. Roughly 25 people completed the treatments in each of the four groups with a total of 100 subjects.
- 2.2.11.2 Findings
 - 2.2.11.2.1 Post Treatment
 - 2.2.11.2.1.1 Note
 - 2.2.11.2.1.1.1 RDQ=2.5 or greater is considered clinically significant.
 - "Massage therapy group (Group 2.2.11.2.1.2 # 1) had significantly better scores than the remedial exercise (Group # 3) (4.2) and sham laser groups (Group # 4) (5.0) on measures of function (RDQ), intensity of pain (PPI) quality of pain (PRI) and in addition with group 4 on State Anxiety (SA) Group 1 also had significantly better scores than the softtissue manipulation group (Group # 2) the PPI." 66 No significant on differences were reported by the author between Group # 1 and Groups 3 on state anxiety. The author reported no differences between Group # 1 & 2 on any of the following measures; RDQ, PRI, & State anxiety.
 - 2.2.11.2.1.3 At the end of treatment (Posttreatment) the soft-tissue manipulation group (Group # 2) had significantly better scores than the remedial exercise (Group # 3) (2.8) and sham laser groups (Group # 4) (3.6) on the RDQ and significantly better scores than the sham laser group (Group # 4) on the PPI. This implies no significant differences between Group # 2 and between Groups 3 & 4 on PRI, & State anxiety and no differences reported between group 2 and 3 on PPI (these

measures were not mentioned in the study).

- 2.2.11.2.1.4 There were no statistical differences reported by the author at post treatment on RDQ PPI PRI SA between Group 3 and Group 4.
- 2.2.11.2.1.5 There was no post treatment significant difference in the lumbar range of motion between the groups. ⁶⁷

2.2.11.2.2 Follow-up

- 2.2.11.2.2.1 "At follow-up the comprehensive massage therapy group (Group # 1) continued to have significantly improved scores over the sham laser group (Group # 4) on the RDQ, PPI and PRI and had significantly better scores than the remedial exercise group (Group # 3) on the RDQ and PPI." ⁶⁸ No statistical differences were reported between group 1 and group 3 on PRI SA.
- 2.2.11.2.2.2 Whether the comprehensive massage therapy group (Group # 1) had significantly improved scores at follow-up compared with the soft-tissue manipulation group (Group # 2) is unclear. These findings seem to conflict.
 - 2.2.11.2.2.2.1 At the 1-month follow-up, 63% of the subjects in the comprehensive massage therapy group reported no pain, as compared with 27% in the soft-tissue manipulation group, 14% in the exercise group and 0% in the sham laser group.⁶⁹
 - 2.2.11.2.2.2.2 "At follow-up there were no statistical differences between the comprehensive massage

therapy group and the soft-tissue manipulation group." ⁷⁰

2.2.11.2.2.2.3 One possible interpretation is that scores from the McGill Pain Questionnaire (LF-MPQ) Long Form PPI (5 point scale for intensity-0=No Pain) were added together forming a mathematical ratio between the total number of responses with a no pain rating divided by the total responses in the group. The quotient is the percentage of respondents who reported a "No Pain" rating. This is an ordinal scale, which is treated as if it were a ratio scale. These self-rated scales are especially sensitive to bias because they are essentially subjective reports. The likelihood of a possible negatively skewed distribution given the under 30-sample size is uncertain but possible if the population is skewed (Central Limit Theorem). If Sedergreen is correct а skewed population is possible with self-reported screening. Since there was no Concealed Allocation in this study selection bias is possible as the groups were formed. Given that the researcher herself may have received monies for providing Soft-tissue manipulation to subjects. economically incentivized bias may have also been present negatively skewing the post treatment and follow-up scores of both the comprehensive massage group and the soft tissue manipulation group. The scores may have been less

negatively skewed in the soft tissue manipulation group, which would mean fewer extreme no pain, scores and thus a lower percentage of subjects reporting no pain in the soft-tissue group.

- 2.2.11.2.2.3 At follow-up the soft-tissue manipulation group (Group # 2) was not distinguishable from Group 3 (exercise group); both group means were statistically better than the mean for the sham laser group (Group # 4) on the RDQ. If this is true how can Group 1 be statistically superior to group 3 since there are no statistical differences between group 1 and group 2?
 - 2.2.11.2.2.3.1 One possible explanation is that Group 1 scores were more negatively skewed than group 2 scores but statistically equal to group 2. Group 3 scores were less negatively skewed than group 2 scores but statistically equal to group 2 but unequal to group 1.
- 2.2.11.2.2.4 No statistical difference was reported between group 2 and group 4 or with group 3 and group 4 PPI PRI SA.

2.2.11.2.3 General

2.2.11.2.3.1 None of the groups showed significant post treatment difference in Lumbar range of motion (ROM) (Schober) but no difference between the groups (ROM) was reported by the author at follow-up. <u>P-Values</u> listed in Table 3 (<u>Outcome Measures</u>) of the research paper indicate <u>P-Values</u> of .04 for the groups at one-month follow-up. Because this is less than the

significance level of .05 a significant difference between the ROM groups at follow-up appears to exist.

- 2.2.11.2.3.2 Both the comprehensive massage therapy group and the softtissue manipulation group showed clinical significance for the improvement of function.
- 2.2.11.2.3.3 At the end of treatment and at follow-up the comprehensive massage therapy group had significantly better scores than the sham laser group on state anxiety, whereas no other group did.
- 2.2.11.2.3.4 The mean scores on the pain indexes for all of the groups were lower at the end of treatment than at baseline.
- 2.2.11.2.3.5 At posttest 8% of the subjects in the sham laser group indicated that they had no pain as compared with 5% in the exercise and education group.
- 2.2.11.2.3.6 All subjects' reported levels of pain in the comprehensive massage therapy group decreased in intensity from baseline to post treatment, which did not occur in any other group.
- 2.2.11.2.3.7 Comprehensive massage therapy seemed to have the greatest impact on pain scores but was only marginally better than soft tissue manipulation alone for improving function.

2.2.12 Cost & Time

2.2.12.1 Comprehensive Massage Therapy= \$50/session 6 Sessions=\$300 Time; Soft tissue=30-35 minutes Exercise/Postural=15-20 Total=45-55 minutes Total time=4.5 hrs-5.5 hrs Daily exercise=Self exercise 1 x per day 2 repetitions of exercises/stretches = 15- 20 minutes (?=not specified) 7 days a week (?=not specified)=1.75 hrs per week for 4 weeks=7 hours Undisclosed time spent on strengthening or mobility exercises such as walking, swimming or aerobics and to build overall fitness progressively. Total hours in one month=12.5 hours with additional time spent on strengthening/mobility.

- 2.2.12.2 Soft-Tissue Manipulation= \$40/Session 6 sessions=Time 30-35 minutes per session= \$240 Total Time=3.5 hours
- 2.2.12.3 Exercise/Postural (15-20 minutes) \$15/Session 6 sessions=\$90 Total=2 hours Daily exercise=Self exercise 1 x per day 2 repetitions of exercises/stretches = 15- 20 minutes (?=not specified) 7 days a week (?=not specified)=1.75 hrs per week for 4 weeks=7 hours Total=9 hours with additional time spent on strengthening/mobility.
- 2.2.12.4 Sham Laser (20 minutes) 6 sessions \$15 per session=\$90
- 2.2.13 Limitations
 - 2.2.13.1 Single setting
 - 2.2.13.2 Specific soft tissue techniques by only two therapists
 - 2.2.13.3 Unmeasured provider effects on the validity of outcome measures
 - 2.2.13.4 Limited protocol; set number of treatments regardless of severity or complexity of the problem and short term follow-up

2.2.14 Contact Information

- 2.2.14.1 Michele Preyde, Faculty of Social Work, University of Toronto, 246 Floor St. W, Toronto ON M5S 1A1;
- 2.2.14.2 E-Mail
 - 2.2.14.2.1 <u>mailto:preyde.shafir@sympatico.ca</u>
- 2.2.14.3 At the time of the research
 - 2.2.14.3.1 Michele Preyde was a PhD student in the Faculty of Social Work, University of

Toronto, and a member of the College of Massage Therapists of Ontario, Toronto, Ont.

- 2.2.14.4 Currently
 - 2.2.14.4.1 Michèle Preyde, PhD, RSW Assistant Professor Department of Family Relations and Applied Nutrition University of Guelph N1G 2W1 519-824-4120 Ext. 58599 Fax: 519-766-0691

2.3 Letters (Summarized Comments) to the Editor re: Effectiveness of massage therapy for subacute low-back pain: a randomized controlled trial By Michele Preyde

- 2.3.1 Is massage therapy genuinely effective? ⁷¹
 - 2.3.1.1 Lloyd Oppel Emergency physician Vancouver, BC
 - 2.3.1.1.1 Would the less expensive form of massage therapy (Is there a less expensive version in Canada) performed by non-registered therapists be as effective as the \$50 version performed by registered massage therapists?
 - 2.3.1.1.2 Sham massage would have been a better control treatment because there is no way of knowing whether touch from a caregiver only would reproduce the treatment effects.
 - 2.3.1.1.3 Volunteer subjects may be predisposed to believe in the positive effects of massage therapy and since the subjects were not blinded to the treatment.
 - 2.3.1.1.4 Although Preyde states that massage improves the patient function it would be more accurate to say that massage improved subjects perception of improved function.
 - 2.3.1.1.5 Self-rating scales (self-reported measures of function, pain and state anxiety) may be less informative for the reasons cited above than the objective range of motion study conducted by blind assessors. The outcome

indicates no difference between groups, perhaps the more true and accurate assessment of treatment result.

- 2.3.1.2 Chris Sedergreen, M.D. Family physician Coquitlam, BC
 - 2.3.1.2.1 Dr Sedergreen points out 6 flaws in this research
 - 2.3.1.2.1.1 Self-reported criteria are unreliable. (How do you know this?) This was done in the screening process to determine eligibility. Apparently Sedergreen thinks to subjects should all receive a physical examination.
 - 2.3.1.2.1.2 Significant pathology (metastatic or metabolic disease) was not excluded. Given the rarity of this and the increased cost and budget limitations of the research project is this really necessary?
 - 2.3.1.2.1.3 Ages undefined (Only mean or average score). Approaches to back pain vary with age.
 - 2.3.1.2.1.4The patient of the sham laser treatment did not know the laser machine was turned off. The operator should also have been blinded to avoid unconscious communication of its ineffectiveness.
 - 2.3.1.2.1.5 Analgesic use was permitted, thus creating subsets of patients whose distribution were not randomized.
 - 2.3.1.2.1.6 Subjects who may have secondary gain (compensation or avoidance behaviors) were not screened
 - 2.3.1.2.2 Since the interaction between massage therapists and patient is especially vulnerable to placebo it is the researchers doubled duty to rule out these effects.

2.3.1.3 Michele Preyde's response

2.3.1.3.1 Lloyd Oppel's Letter

- 2.3.1.3.1.1 Oppel's suggestion of substituting sham massage for sham laser treatment was according to Preyde good but impractical due to financial & time limitations. Why would this take more time and cost more? Subjects were told in the advertisements they might receive "one or more modalities" This according to Preyde might dilute their expectations. Expectations of what? That comprehensive massage was the therapeutic treatment.
- 2.3.1.3.1.2Drop out rates were consistent with expected rates cited in other research papers. ⁷² Each group had approximately the same dropout rate (1 or 2 per group) What does this have to do with Oppel & Sedergreen comments?
- 2.3.1.3.1.3 Preyde acknowledges the limitation of self-rated measures and provider influences and so states in the research article. She further notes in her literature review "no study that employed a truly objective measure of subacute back pain (e.g., laboratory investigations).

2.3.1.3.2 Chris Sedergreen's letter

2.3.1.3.2.1 Staff physicians approved the screening criterion. Preyde states that history taking and physical examination (was this by a physician other than the subjects physician) helped rule out both contraindications to massage therapy as well as exclusion criteria. She seems to be implying a greater physicians role than was apparent in the research. It seems poorly worded.

- 2.3.1.3.2.2 Preyde doesn't think ancillary tests are appropriate. I assume she is referring to ruling out cancer. Can't be sure cause this passage is vague. But she does cite the following research.⁷³
- 2.3.1.3.2.3As aforementioned due to funding and time limitations this was not reported or conducted as a double-blinded study and according to the author it was not feasible. Why? Even still, despite the fact that the providers of both the sham laser and exercise treatment groups believed that the exercise to be an effective remedy, at posttest 8% of the subjects in the sham laser group indicated that they had no pain as compared with 5% in the exercise and education group. If some unconscious communication about the sham laser's ineffectiveness was communicated by the provider it was not evident in this research.
- 2.3.1.3.2.4 Medication use was not considered during randomization however as it turns out patients who were using analgesics were evenly distributed and among the groups and within the 95% <u>Confidence Interval</u> of their group mean. That is to say, the scores of the subjects using medication were not above or below the expected sampling parameters for other members of the group.
- 2.3.1.3.2.5 None of the subjects of this study were receiving any disability payments/compensation for their lowback pain and thus would have no cause to disavow or declare treatment effects (no secondary gain).
- 2.3.1.3.2.6The author calls for more research to provide conclusive evidence for treatment effectiveness. A quick

search does reveal some additional research in this area. $^{\rm 74\ 75}$

2.4 Recap

- 2.4.1 This peer reviewed, randomized, and controlled trial of the effectiveness of massage therapy for subacute lowback pain is the first of its kind in the literature of massage therapy research. The research study compared 3 treatment groups with a control group. The groups were as follows; Group # 1=Comprehensive (soft tissue, exercise/postural ed), Group # 2=Soft tissue (soft tissue only), Group # 3=exercise (exercise/postural ed) and Group # 4=one control group (sham laser). Patients were recruited from college campus via E-Mail, local advertisements, and physician flyers and then screened according to self-reported criterion (subacute low-back pain (1 week-8 months), no significant pathology, no pregnancy, stable health, previous lb pain history ok, Positive X-Ray mild pathology ok.). Nearly 100 people, mostly overweight, college educated women in their mid to late 40's with non complicated low back pain participated in the study. Subjects were, then, randomly assigned to one of 4 groups aforementioned. The research was conducted at a multidisciplinary facility.
- 2.4.2 The soft-tissue therapy was provided by two registered massage therapists. The author of the research paper was also a registered massage therapist who provided patient treatment when one of the other registered massage therapists dropped out of the study due to a family emergency. The exercise and postural education was provided by a certified personal trainer, and certified weight-trainer supervisor. Three physiotherapists provided the range of motion test (Schober) and were blind to which group each subject was allocated.
- 2.4.3 The funding source for this project was not declared.
- 2.4.4 Modalities included; Soft-Tissue manipulation (friction, Trigger points, & Neuromuscular), Exercise/Postural

Correction (Lumbar/hip/thigh stretches, waking/swimming/aerobics, postural education) Sham Laser (Non-functioning laser)

- 2.4.5 Patients were evaluated on several outcome measures including; Self reported function (RDQ), intensity (PPI) and quality (PRI) of pain, State anxiety (pre movement anxiety)(SA), and objective lumbar range of motion (modified Schober)(ROM).
- 2.4.6 Approximately 25 subjects in four groups (100 total approximately) completed the study. Initial baseline measures were completed pre-treatment, Post-treatment measures after 1 month (6 sessions) of treatment and follow-up measures 1 month after treatment ended.
- 2.4.7 Results Summary
 - 2.4.7.1 References
 - 2.4.7.1.1 Worksheet
 - 2.4.7.1.2 Groups
 - 2.4.7.1.3 Modalities
 - 2.4.7.1.4 Variables
 - 2.4.7.1.5 Baseline Measures
 - 2.4.7.1.6 Outcome Measures
 - 2.4.7.2 At one month follow-up there was no statistical difference between mean scores of group 1 & 2 although the author notes that patients in Group 1 reported a greater pain reduction than any other group. No statistical differences, post treatment, were found between any of the groups on the only objective ROM measure (Schober) which was also the only measure evaluated by blinded assessors. At follow-up, <u>P-Values</u>, (probability that the difference between groups is due to chance alone. If the p value is lower than .05, for example there is significant differences between two or more groups) reveal significant differences between

the groups for the ROM (Schober) measure (<u>Outcome</u> <u>Measures</u>) but the author does not reference or explain this result. Group 1 was superior to all of the groups post treatment for PPI and remained so at follow up compared to groups 3 & 4. Likewise Group 1 was superior to groups 3 & 4 both post treatment and follow up on RDQ and superior on PRI post treatment to groups 3 & 4. Group 1 continued to remain more effective than group 4 on PRI at follow up.

- 2.4.7.3 Group 2 was superior post treatment to both groups 3 & 4 on RDQ but only to group 4 on PPI. At follow up group 2 continued to be more effective than group 4 on RDQ but there was no statistical difference between groups 2 & 3 at follow up. As aforementioned no statistical difference between groups 1 & 2 was present at follow up. Does it not follow that there is no statistical difference between group 1 and 3 at follow up? As previously stated group 1 was found to be statistically superior to group 3 at follow up. The author does not explain this apparent anomaly.
- 2.4.7.4 Group 3 was superior to group 4 on RDQ at follow up.

2.5 Critical Analysis

- 2.5.1 The comprehensive massage therapy group was statistically indistinct from the soft tissue group, which was statistically matched with the exercise group at follow up. All three groups were better at follow-up than the control group. More comprehensive massage therapy subjects reported no pain at follow up than in any other group. It remains unclear how the aforementioned pain/no pain ratings were calculated while overall statistical differences (including pain rating PPI PRI) were statistically indistinct. None of the treatment groups improved objective range of motion at post treatment. It remains unclear if this was also true at follow up.
- 2.5.2 These findings may inform prospective therapists and clients when considering various treatments for low back pain. Certainly any of these treatments would be more effective than doing nothing. Given that any of the

three treatments would provide relatively equal relief from pain and improved perceived function (RDQ) other evaluative factors such as <u>time and cost</u> may be considered.

- 2.5.3 Comprehensive Massage costs \$300 for 6 sessions over a month period totalling 12.5 hours with additional time spent on strengthening/mobility self exercise. Soft-Tissue Manipulation costs \$240 for 6 sessions over a month period totalling 3.5 hours without additional time commitment. Exercise/Postural costs \$90 with a total of 7 hours with additional time spent on strengthening/mobility.
- 2.5.4 The least time consuming option for clients would be soft tissue treatment and the least expensive would be exercise/postural correction. The comprehensive massage therapy may provide better pain relief, 1 month after treatment, but is the most expensive and time consuming of the treatment modalities. The comprehensive massage group provided neither statistically significant different results than soft tissue manipulation on either self-rated function or pain indexes (PPI PRI).
- 2.5.5 The validity of this research is compromised by several factors. The author of the research study was herself a registered massage therapist who provided some of the treatments to subjects in the study. Registered massage therapists in this study were hired to provide soft tissue treatments to subjects. It may be that the author of the study also received monetary compensation for her soft tissue therapy. The author of the study was herself a member of the College of Massage Therapists of Ontario Canada (College of Massage Therapists) which has as its mission statement "All qualified massage therapists are registered and proud to be associated with the College" In her summary conclusion the author states "Patients with subacute low-back pain were shown to benefit from massage therapy, as regulated by the College of

Massage Therapists of Ontario and delivered by experienced massage therapists." ⁷⁶ This is seems inconsistent with the authors own conclusions within the body of the research study namely;

- 2.5.5.1 "At follow-up there were no statistical differences between the comprehensive massage therapy group and the soft-tissue manipulation group." ⁷⁷
- 2.5.5.2 "by follow-up there was no statistical difference between the soft-tissue manipulation group and the remedial exercise group." ⁷⁸
- 2.5.6 Why did the author find it necessary to mention "College of Massage Therapists" in her summary conclusion when regulation of massage technique & the experience of the massage therapists are not measured dependent variables in this research?
- 2.5.7 Did the College of Massage therapists register the registered experienced massage therapists in this research study? It is unknown what the source of funding for the study was. If the college of massage therapists funded this study, obvious bias would be more evident. Similar emphasis of place of educational certification was not placed on the other providers of treatment in this research study e.g. personal trainer, weight-trainer supervisor & physiotherapists. We do not example that learn for their training/registration/certification/schooling benefited the outcome of the research. It might be noted that this study does not examine relative effectiveness of massage training programs and the author does not provide citations as to the increased relative effectiveness of programs endorsed by the College of massage therapists. Is there bias in this research which may have been transmitted to the subjects (subjects use self-rating of pain and function which may be influenced by therapeutic bias) by the proud registered massage therapy providers (the author included) who at least in the case of the author were a member of the college of massage therapists? Since the author herself

performed some of the massage treatments the appearance of bias is certain whether or not its effect of subjects self-rated symptoms can be statistically proven. If the author received only part of the compensation due her primary therapist for treatment to the subjects it still might have been a sizable sum of the $6000 \text{ due} (50 \times 6= 300 \times 40=12000/2=\$ 6000)$ Future studies would benefit by having standby therapists who can provide treatment to avoid the appearance of economically incentivized bias and easy dismissal of the results by the scientific community.

- 2.5.8 Several other factors affect the <u>validity</u> of this research, which received a total of 6 out of 10 by Pedro's rating scale. The following problems were noted;
 - 2.5.8.1 The assignment person should be unaware of which groups subjects are assigned to. (Concealed Allocation)
 - 2.5.8.2 The subjects should be unaware of whether or not they were placed in a therapeutic group (<u>Blinded subjects</u>)
 - 2.5.8.3 The therapists should be unaware that they are providing the therapeutic treatment. (Blinded therapists)
 - 2.5.8.4 All the subjects should be statistically analyzed whether they dropped out of the study or not. (Intention to Treat)
- 2.5.9 The author herself acknowledges limitations of this study (<u>Limitations</u>); varied settings, varied therapists, blind therapists, protocol to fit problem severity/complexity with long term follow up.
- 2.5.10 Other authors have also noted problems with this study
 - 2.5.10.1 <u>Lloyd Oppel M.D.</u> questions the effectiveness of registered massage therapist vs. non-registered therapists, advises the use of sham massage instead of sham laser as a control, advises blinding subjects, self rated function is not the same as actual function, ultimately this study failed to demonstrate any

improvement in actual function which implicates the result of not blinding subjects/therapists.

- 2.5.10.2 Chris Sedergreen, M.D. Improper screening which should have included physician examination (selfreported criteria unreliable), Significant pathology should be ruled out (cancer), Vary treatment to age appropriate, blind the operator of sham laser, analgesic use nullified randomization, disability compensated patients with secondary gain not screened, massage therapist/client relationship especially vulnerable to placebo effects which this study did not seek to dilute.
- 2.5.10.3 Michele Preyde
 - 2.5.10.3.1 <u>Oppel</u>
 - 2.5.10.3.1.1 Sham massage good idea but impractical, subjects were told they would receive one or multiple modalities which would dilute expectations, Drop out rates consistent with other studies, no previous studies used truly objective laboratory investigations.
 - 2.5.10.3.2 <u>Sedergreen</u>
 - 2.5.10.3.2.1 physicians developed Staff criterion/independent screening ancillary examination. tests inappropriate, not intended or reported as a double blind and control group had higher no pain ratings thus dispelling placebo, patients using analgesics were evenly distributed and their scores statistically similar to nonmedicated, none of the subjects were receiving disability payments, and more research is needed.
- 2.5.11 All of the statistics of this study are based on 4 self-rated/subject-rated measures (<u>RDQ (RMQ)</u>), <u>PPI, PRI, & State Anxiety</u>) and one objective measurement (<u>Schober</u>). As <u>Lloyd Oppel M.D.</u> cautions, these self rated measures are "very prone to non-specific provider influences." ⁷⁹

and as <u>Chris Sedergreen, M.D.</u> reminds "interaction between a massage therapist and a patient is particularly vulnerable to producing a placebo response, in which case the obligation of researchers in this field to disprove such bias is substantially increased. (e.g., laboratory investigations)." ⁸⁰ <u>Michele Preyde</u> notes "Oppel's concerns about the accuracy of reporting the self-rated measures and the possible provider influence on subjects' perceptions are valid" "In my review of the literature I found no study that employed a truly objective measure of subacute back pain (e.g., laboratory investigations)." ⁸¹ The following measures are discussed in more detail;

- 2.5.11.1 Roland Disability Questionnaire (RDQ) simply measures self reported disability caused by back and or leg pain on a 24 point scale which as more items are checked indicates greater disability or as fewer items with progressive treatment can determine progress in simple percentage terms. This instrument is widely used and researched for reliability, validity and sensitivity the results of which indicate its effectiveness as a sensitive accurate measure.
- 2.5.11.2 <u>McGill Pain Questionnaire (LF-MPQ) Long Form</u> measures self reported quality of pain over four categories; Sensory, affective, evaluative, & miscellaneous with descriptors giving a grand total PRI score. Also included is an intensity of pain score on a 0-5 scale. This test is also widely used and well researched for reliability, internal consistency, reproducibility, validity, responsiveness, and interpretability.
- 2.5.11.3 <u>State Anxiety Index (SA)</u> measures the current anxiety state (20 questions), which in this study is used to determine whether a person is anxious prior to lumbar movement. As treatment progresses the anxiety prior to low back movements should decrease as pain and discomfort with lumbar movement decreases. This psychometric instrument also measures a person's trait anxiety (20 questions), which is part of their personality. Both scores (40 questions) are used in this research study. Although the State-Trait Anxiety Inventory Form Y (STAI) is one of the most widely used

and validated instruments, nothing appears in the literature supporting its use to measure anxiety prior to orthopedic movements.

2.5.11.4 <u>Modified Schober test</u> is an objective measurement of spinal flexion and extension recorded in centimetres. The three physical therapists that were hired to record these measurements did not know which subjects were in which groups and therefore were blinded and thus less likely to influence the test which involved the actual measurement of spinal movement. This particular test is well-researched and reliable objective measure of lumbar range of motion.

2.6 Conclusion

- 2.6.1 This study found that Comprehensive massage therapy was no better than soft tissue massage at follow-up and soft tissue about the same as exercise/postural education. All of the groups were better than sham laser. Consumer decisions regarding treatment selection should be based on time and cost. The least time consuming option for clients would be soft tissue treatment and the least expensive would be exercise/postural correction. The comprehensive massage therapy may provide better pain relief (although potential bias and questionable statistics makes for an uncertain result) but is both more expensive and time consuming than the other alternatives.
- 2.6.2 Validity problems were evident in this study when the researcher herself provided and may have been paid to provide direct treatment to subjects and then reported unusual results in the summary conclusion, which did not fit the data (details). The researcher included what appeared to be a "plug" to an institution she was a member of and which may have funded the research. The author has been contacted to verify the source of the funding along with other questions. (Questions to Author)

- 2.6.3 Other validity questions include no concealed allocation which means that the subject assignment person was not blinded from knowing which subjects were assigned to which groups (details). Since both therapists and subjects were also not blinded along with the aforementioned author actually treating the patients this study had the appearance of bias. Since self-rated measures of function, pain and anxiety are especially susceptible to bias (Oppel)(Sedergreen) the results of this study are questionable. The statistical analysis the researcher may have used to justify the summary "plug" involved treating a subjective selfrating ordinal scale as if it were a ratio scale (Scales). I could find no research to verify the validity of the McGill PPI scale used as a ratio scale. The author has been queried on this matter. (Questions to Author)
- 2.6.4 Given the possibility of bias introduced into this study it also possible that although the distribution of the population of subjects for this study may have been normal (Central Limit Theorem) the group distributions may be skewed if their was selection bias by the assignment person (choosing less severe cases for some groups). In addition the researcher herself provided direct treatment to subjects and may have biased subjects responses. This might explain how a greater percentage of subjects in the Comprehensive Massage group selected no pain rating on the PPI McGill Scale (Details). Although all of the groups, including the exercise/postural group had a registered massage therapists (including the author) providing treatment but the exercise/postural group had the lowest percentage of no pain ratings.
- 2.6.5 If it turns out that the funding source was the College of Massage therapists the "plug" the author placed in the summary invites further question. Does this reflect the realities of "doing business" in producing research for institutions and businesses that pay a lot of money for the results they want. Does doing business as a

researcher mean you have to at least provide a gratuitous "quotable quote" in the summary abstract? How would you like to be the person (in the business/institution) who approved the research grant only to get back a negative research finding for your project? Your judgement would be questioned. Likely pressure would be placed on the researcher to give some positive findings. Future research grants may depend on the researchers willingness to bend and spin the results into a positive project "Plug". This is a tough problem to assess because much of this influence may be unwritten, unspoken, but well understood in the research community. This is the big elephant in the room no one wants to talk about. More study should determine how widespread this practice is because it does erode at public trust if research becomes only an extension of marketing. As for this research it gives the appearance of just such a "Plug".

2.6.6 If all this is true it may be necessary to go beyond reading just the abstract summary when reviewing research and doubly important to establish the funding source. In addition, an understanding of basic statistical concepts would be necessary to separate truth from spin. Research, if funded, by independent organizations such as the <u>Massage Therapy Foundation</u> may be less inclined towards this bias. This may be less about the unethical behavior of individuals but rather a system, which encourages and rewards this behavior. It might be counter productive, for example, to single out the author of this study, if the problem is wide spread. As for this particular study more information is needed before a final judgement can be reached, but the questions raised may be worth asking in any case.

3 Research References

3.1 Research Literacy (Summary of Concepts)

3.1.1 <u>http://www.anatomyfacts.com/research/literacy.htm#references</u>

3.2 Baseline Data (Initial pre-treatment measures)

3.2.1 Baseline Measures

3.3 Outcome Measures

3.3.1 Outcome Measures

3.4 Work sheet Results

3.4.1 <u>http://www.anatomyfacts.com/Research/Massage</u> Journal <u>Club/November06/outcome.htm</u>

9061/300= 30.20

Reviewed article 1815-1820=5

Words=4607 Citation apa = (Author, |Year|, p.^pp. Cited Pages|) start each ref Bibliography Number. Massage

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