## November 06 Research Article-Massage and Exercise Combined-Easy Reading Version By Ted Nissen M.A. M.T. Copyright © January 2007 Ted Nissen

## SUMMARY

This was a first of a kind study with lots of people in it to measure the effects of massage therapy and exercise combined to help people with chronic low back pain. The combination of exercise and massage was compared to exercise alone and massage alone and with no treatment. It turns out in the long run (One month follow-up) massage alone was about as good as massage and exercise. Massage about good as exercise alone but alone was as massage/exercise was better by some measures (function & Pain Intensity) than exercise alone. All three modalities (Massage/Exercise, Massage, and exercise) were better than no treatment. That at least tells the statistical story.

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/functional improvements but is both more expensive and time consuming than the other alternatives. Potential bias, questionable standards/fraudulent statistics, uncertain ethical practices, high drop out rate at follow-up makes for the somewhat superior massage/exercise results uncertain. Future studies should be carefully crafted to address these deficiencies.

Massage research studies should insure that those who pick people for the study (screener) and those who assign people to the groups are not the same person and or that steps are taken and detailed in the study to prevent foreknowledge of who will be assigned to which groups. Creative solutions should also be found to make it difficult or impossible for therapists/subjects (clients) to know who is giving/getting the measured treatment.

Statistics should be performed and the details included in the study on all participants even if these subjects dropped out before the completion of the research. Back up therapists should be available to provide treatment if primary therapists are unavailable. In no case should the researcher have direct contact or provide treatment to the subjects.

The researcher should insure that the research findings in the abstract summary are consistent with the measured variables and with the findings within the body of the research study. Researchers should avoid the appearance of "plugging" research institutions which provided funding for the project by providing "bogus" research findings just because it may gratify the funding institution. This erodes confidence in all of the other research findings and ultimately results in more costly and therefore fewer massage research studies.

Researchers should defend their research but readily admit are made. Misleading when mistakes arguments (spin=misleading interpretation of material facts and or introduction of irrelevant information to argue in support heavily of false conclusions and or biased characterizations) should not be used to deliberately deceive research evaluators and avoid responsibility for errors. The aforementioned practice further erodes the confidence in research findings.

All of the above difficulties were noted in this study (Summary of Difficulties) (Conclusion). In short, it may be that the results reported in this study cannot be trusted. Further independent investigation of the potential of a culture of deception in scientific community, at least those entities surrounding this study, could be conducted. This would include University Oversight of doctoral candidates, peer review/editorial process at the Journals, and Review of the College of Massage Therapists oversight practices. Perhaps this could be handled by an Ombudsman at these various organizations to determine if research fraud is evident in this study.

For a more detailed summary recap of this study click the following link (Recap)

#### RESOURCES

The following resources may be useful to open and keep open in a separate window while you are reading the text as a reference. These links are repeated in the section where they are most useful, if you haven't already opened them.

Research Article= http://www.cmaj.ca/cgi/reprint/162/13/1815 Questions to Author= Questions to Author Definitions of Technical Terms= Definitions Baseline Client Characteristics= Baseline Measures 1 Baseline Pre Treatment Scores= Baseline Measures 2 Outcome Post Treatment and Follow-up Scores= Outcome Measures Statistical Results from Research Study= Outcome Measures Results (Read the notes section for instructions) Matriculation (How many people completed the study) = Matriculation Research Conclusions Abstract Summary= Abstract-RDQ-PPI-PRI-Inaccurate Info Research Conclusions Body of Paper= 1.) Body of Research Paper-RDQ-Follow-up-No Statistical Differences

- 2.) Body of Research Paper-PPI-Post Treatment-Statistical Differences
- 3.) Body of Research Paper-PPI-Follow up-No Statistical Differences

## INTRODUCTION

The Story of the November Research Study (This is a bit long because the advantage of technical terms is that one word can be used to represent a whole mess of other wordsit is much like short hand)

This article does not contain a bibliography or endnotes to facilitate ease of reading. Endnotes would be numbered to reference sentences or passages. This is done in scholarly papers to show supporting evidence for the information contained in your writing. For your information, the endnotes for this paper can be viewed with the following link. (Endnotes) As you will notice, there are 79 endnotes in the analysis of this research paper. Because endnotes tend to repeat and are not alphabetized bibliographies are created as an alphabetical listing of the references. This makes it easier to find a reference rather than looking for the reference in the un-alphabetized endnotes which are ordered by where they were referred in the text. Also not all endnotes include all the references, as does the bibliography. You can view the bibliography with this link. (Bibliography) You will notice there are 57 references cited in the bibliography.

## ANALYSIS

The November research article was published in one of Canada's leading medical journals in June of 2000 but the preparation for the research study began well before that. It took 8 months to gather the clients for the study, 1 month to conduct the research, and about 10 months to write the research paper and get it published. This research project studies whether of not combining exercise/posture with massage is better than exercise/posture alone or massage alone and whether any of these modalities is better than no treatment at all. There are some interesting surprises to this study and nothing may be, as it seems. Here is the story of that research project.

Between November 1998 and July 1999 the author of the November research study, Michèle Preyde began soliciting subjects for this study. At the time of the study Michèle was a graduate student working on her PhD in Social Work and was also a registered massage therapist with the Canadian College of Massage Therapists. The College of Massage Therapists is a government institution that registers MTs in Canada and has funded this research project for \$38,000. During this initial period during 1998-99 Michèle sent out E-Mails to the local college faculty, advertised in the paper, sent out flyers to local doctors that she needed volunteers for a research study on low back pain. 165 people responded to the ad 107 (65%) were selected for the study (Matriculation). About 91 ended up completing the study. It is not clear whether she intended to pay these folks but often research subjects are paid for their time and gas mileage. In the ad the number screener was provided and interested subjects of a (clients) called the number. The screeners role was to determine whether the prospective subject qualified for the study based on the following criterion. 1.) Existence of subacute low-back pain (back pain of 1 week-8 months duration) 2.) Absence of significant pathology (bone fracture, nerve damage or severe psychiatric condition (clinical depression as physician diagnosed) 3.) No pregnancy 4.) Stable health 5.) Previous episode of lowback pain ok 6.) Positive radiographic finding of mild pathology ok.

About 104 people were recruited (3 dropped out before group assignment). After the research was published, there was some criticism that a physician should have examined all of the patients because you may not be able to trust people to self-report of their medical condition. What do you think?

You can begin to see why research is so expensive. Especially if you have to pay all of the subjects, the screener ect. That is why big businesses, institutions, or government funds a lot of research because it's so expensive for small clinics or individuals to afford. Turns out most people won't do the research unless they are paid. Problem is the deep pocket funding source may have an interest in the outcome. They could put pressure on the researcher to give them the results they paid for.

SIDE BAR=One of my friends tells the story that as an assistant to a corporate executive he was told to "get that ..... researcher on the phone, because I'm not paying out \$50,000 for this junk. Tell them if they ever want another grant they had better produce something I can quote. This research is going to make me look like an idiot to the board of directors"

To be more polite, when you favor a certain outcome that is not supported by the data its called research bias, because you may have, for example influenced the subjects to report the result your funding source wants or included a statement in the research summary which was not supported by the numbers. It's a tricky business. This problem may be widespread but the influence of the deep pockets may be much more subtle. Researchers just know how the game is played and no one talks about it. There are no smoking gun E-Mails or hard evidence. This is not talked about because it would be so embarrassing for everyone concerned. Some of the biasing influences may even be unconscious to the parties concerned. It's simply unclear how widespread this problem actually is. A good research project is designed so that cheating is next to impossible. Research design flaws usually have to do with loopholes where someone could cheat if they wanted to even if there is no proof that anyone did. Science does not trust human nature to do the right and honorable thing. Problem is covering all of the loop holes may cost more money and take more time than the

researcher or the funding source would allow. This makes it all the more important that the researcher goes out of their way as a model for ethical behavior, so that the research results can be trusted. That is if a loophole is found in the research the readers of the research paper are more likely trusting if the researchers behavior appears ethical in every other aspect of the research project. Because you can not always verify if a person is cheating by taking advantage of a loop hole this trust issue is very important. It is the basis for the trust of scientific conclusions. In this study as you will see the researcher evaded taking responsibility for errors and denied inconvenient truth.

Anyway back to our discussion. Now we have about a hundred people ready for their free massage. They may even be waiting for a little extra cash for their time. It is often asked "Doesn't this bias the research." Perhaps but it's the only way to get subjects nowadays. It is not clear in the research how an assignment person is chosen for this task. Is this person paid and do they have any connection to the researcher? You can see a possible loophole if the assignment person knew the researcher they could influence the outcome. However the assignment person was chosen they are given the task of putting these folks into four groups. This is done randomly with the use of a random numbers table. The research paper does not tell us exactly how that was done. We will describe here the usual procedure. If you want a more detailed description of this procedure click this (Link)

The first step is to assign each person a number for the hundred or so study participants. Each group then has approximately 25 people. You could choose to fill each group and then move on to the next or fill the first slot in group 1, then 2 thru 4 and then back to group 1. A consistent method is what is required. The random numbers table is a table of 5 digit numbers for example with column and row headings. Take a finger and pick a starting number, decide on the first part of the five-digit number and start assigning people to groups based on these numbers, as they were pre assigned to people. This is called randomization because in theory you could not have predicted who was assigned to which group, thus the term random assignment.

There is a fly in the ointment of this particular study. It is not clear in this study if the screener and assignment person were the same person or independent of one another. This is because if the screener was the assignment person they could pick and choose who was going to be in the study and even though this is supposedly a random study this person could cheat and put people in the groups they wanted. They could select people based on their own prejudgment or bias. This is called selection bias when the assignment person knows who the people were who were assigned the numbers. This is a loophole that could result in selecting less severe people for the therapies you want to do better and more severe people for the therapies you want to do worse or for that matter excluding people from the study completely. If you know what group the next person will be placed in you can alter your selection accordingly.

This is not to say in this study there is any proof of this kind of cheating but as aforementioned is considered bad form and the study is therefore considered less valid. People have cheated in other studies and been caught doing so (We will talk about the statistical ways of catching a cheater later). When the opportunity is there, it is considered possible. It reverses the effects of random selection described above because since if you know the next person selected will be assigned to which group you can control the process even though a random number was assigned to each person and used in group selection.

This research study did not tell us enough to know whether any of these problems were real but in evaluating research, you should assume the worst when not otherwise indicated. This problem is called no concealed allocation because the allocation to group assignment was not concealed. There are several fixes to these problems; 1.) The screener should be independent of the assignment person, the assignment person should be independent of the researcher and the envelopes or file container which contain lists of who is assigned which random number and which numbers are assigned to which groups should be hidden (opaque envelopes). 2.) Allocation should be done by a person "off-site" to the research project, and by someone who has no association to the project personal. 3.) Whatever precautions are taken these precautions should be clearly outlined in the research paper to document the absence of selection bias. This paper did not mention any procedures to prevent selection bias and insure allocation concealment. The author was asked

about this problem, allocation concealment (see questions to author (References) under question # 8)

The four groups these people were placed in consisted of three treatment groups and one control group. The control group is set up so that people think they are receiving a treatment when surprise surprise they really aren't. In this case it was a laser that was made to look like it worked but it didn't (fake). That way you are controlling who receives what treatment and comparing the treatment groups with a group that didn't receive treatment. Calculating statistics compares these groups.

of the most important statistics is One the mean (MEAN=Average Score). Figure out what kinds of tests you will do on the clients add up the scores and divide by the number in the study and you have a statistic (one number that represents a lot of numbers). This is the very statistic that is used in baseball to calculate batting averages. If you have the following numbers; 6, 9, 2, 1, 8; Total these numbers Total=26 and divide by their number; MEAN= 26/5= 5.2. In this case the mean of these 5 numbers is 5.2. This one statistic is used probably more than any other in research. Here is why; no matter what you are measuring whether it is a drug treatment or talk therapy with a psychologist a number that can be added to other numbers is produced from that research. Usually these numbers are produced before treatment and after treatment. Various complicated formulas (WE WON"T GO THERE YET) are used to determine whether the mean score before treatment was significantly different from the mean score after treatment or whether the difference is due just to chance (Generally if you flip a coin you may get more heads for a while but eventually it's a 50/50 trick-These formulas help you determine whether your results are due to those chance occurrences-Pretty cool).

You can try flipping a coin yourself. For a long while you may get more heads, for example. If you were doing research and the heads was the positive result of your treatment you might think that the treatment was effective. In fact it might be due to chance fluctuations. That is, Coin flips normally result in more heads for awhile and then more tails, but these are just chance occurrences which with enough coin flips perhaps 10,000, the number of heads and tails would even out to 50% heads and 50% tails. In research the same is true. You don't want to have to take 10,000 ranges of motion measurements for example just to find out whether your result is due to chance or are because of the treatment you provided. The formulas figure out for you the probability that your differences between the means before treatment and after treatment, for example, are due to chance.

If the probability is 1 chance in a 1000 then you are pretty safe to assume that the differences you observe between the groups is due to the treatment you provided and not due to chance alone. If your formulas tell you that there is a 50 in 100 chance that your results are due to chance you probably can't count on your treatment's effectives. When you see p= or P-Value= that is the probability that your results are due to chance. That is that the probability that the significant difference between groups is due to chance alone.

Most research studies will have charts of numbers and in the right hand side of the chart will be that p or p value. If this value is under .05, which means 5 chances in 100 that your results are due to chance alone, then you can be fairly certain that your treatment was effective. <u>Outcome</u> <u>Measures</u> To put it another way, if significant differences between the groups have been found the P-Value tells what the probability is that these differences are due to chance alone.

If the difference wasn't due to chance your treatment is considered effective. When you have more than one group the formulas get a lot more complicated (ANOVA-Factor Analysis) (Don't even ask). These formulas help you determine whether the differences between the groups before, sometimes during, and after treatment are significant or just due to chance.

As I've said there are four groups to this study. There were approximately 25 people in each group give or take. The first group is the comprehensive massage group. This group received massage as well as exercise and postural correction. The soft tissue massage involved asking a subject where they hurt. Massage therapists performed the following soft tissue techniques on subjects. 1.) Friction (Used for Fibrous Tissue) 2.) Trigger points (Muscle Spasm) 3.) Neuromuscular therapy where no particular use was specified in the study. The soft tissue massage treatments lasted about 30-35 minutes.

# SIDEBAR-The author's view of Comprehensive Massage therapy (skip)

The author states that comprehensive massage technique and benefits of said technique as described in this study "are not generalizable to other form(s) of therapies that one might consider similar." Since this research study does not provide enough information to evaluate whether this is a correct characterization, the author was asked for further supporting documentation (see questions to author (References) under question # 2).

Unfortunately the author does not have these documents readily available and so this claim by the author can't be assessed. The author seems to want to make the case that comprehensive massage as practiced by experienced therapists with additional training is what makes this combination of exercise/soft tissue massage more effective. If you carefully read the analysis under question # 2 you may be tempted to characterize the authors above answer, as an attempt to spin a clever plug for the funding source the "College of Massage Therapists" without mentioning their name and further without doing the research to prove the claim since education and experience were not measured variables (a variable is the thing that is measured=pain rating, function, ROM ect) in this research study.

There is the additional fact that the exercise portion of the comprehensive massage was provided, in part, by a certified personal trainer/weight-trainer supervisor and not a massage therapist. The experience or education (did they graduate from a college of massage therapist approved school? Probably not.) of the personal trainer was not made clear in the research and so can not be considered as a factor that gives clear advantage and or makes dissimilar the comprehensive massage technique.

This may be an example of spin on the part of the researcher because it is a distortion of the material facts. It treats comprehensive massage as if it were just one technique provided by a massage therapist instead of two techniques provided at least in part by a massage therapist and a personal trainer each with possibly different educational backgrounds and experience. This supports the false conclusion that comprehensive massage is better due to education and experience of one massage therapist. The spin of the researcher also introduces irrelevant information (education & training) which distracts attention away from the important measured variable which is client function, pain levels, and lumbar ROM at pre treatment, post treatment, and at 1 month follow-up after 4 distinct therapeutic or sham therapeutic interventions.

## OTHER RESEACH GROUPS (BACK TO THE RESEARCH)

The soft tissue massage group consisted of only soft tissue massage and no other modality.

The exercise group consisted of stretching exercises for the trunk, hips and thighs, including flexion and modified extension, Stretches were to be performed in a relaxed manner within the pain free range held for 30 seconds, Subjects were instructed to perform stretches twice one time per day for related areas and more frequently for affected areas. Subjects encouraged to engage in strengthening or mobility exercises such as walking, aerobics and to build overall swimming or fitness progressively. Postural education consisted of proper body mechanics instruction, particularly as they related to work and daily activities.

So to recap; Comprehensive massage included basically all of the modalities. Soft tissue, exercise/postural ed with daily home exercise such as walking encouraged but not mandated. The other two groups separated out these modalities. For example Group 2 consisted of soft tissue only and group 3 was exercise/postural only. The fourth group was the laser treatment that really didn't work.

You can <u>skip</u> the following if you are not interested in the details of who provided the treatment, how much they worked and how much they were paid. Scroll down until you get to the summary for a brief review or click the <u>skip</u> link. This study is a bit complicated from a staffing viewpoint, as you will see. For simplicity I've rounded the numbers.

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. 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.

In addition one massage therapist also 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.

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.

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.

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.

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.

One personal trainer/weight-trainer 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.

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.

FINACIAL SUMMARY- Soft Tissue Massage=50 patients 300 visits=\$12000 Exercise/Posture=50 patients 300 visits=\$4500 Treatment=25 patients 150 visits=\$2250 Sham laser 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.

A significant amount of money was paid to the massage therapists and the trainer who provided the treatments in this study. Care should be taken in any study to avoid competing interests of the treatment providers and researcher, which could affect the outcome of the study. That is, if the treatment providers/researcher have an investment in the outcome of the study they could affect response positive or negative to the subjects the treatments. If in other words there is some benefit or financial reward to the treatment providers for a positive study outcome then the therapists may even unconsciously bias the research.

A special relationship of touch and nurturing which may return many to their childhood where a trusted parent's suggestions had amplified potency. Subjects in this study were rating their own functioning and pain. The influence

of the therapist might be quite significant since the measure of progress is subjective. We cannot place a ruler inside a person's brain to measure their pain. If we could that would be an objective measure because we could all examine the object measured and the ruler used to measure it. That way if errors have been made these errors would be apparent to the group and could be corrected. In the case of objective measurement, although the personal interest of the therapist could affect how they measured an object it is less likely a problem for example when measuring range of motion. With subjective measures, there is no way to check the measurements because the object of measurement is not visible. In the case of this study the researcher or therapist had to ask the subjects about their functioning and pain. Subject's responses may be affected by their personal affection for a nurturing therapist who has expressed their own interest in positive outcomes. The therapist can in many subtle or perhaps not so subtle ways influence the subject's assessment of their functioning and or pain. Some people are more suggestible than others. We simply can not know for sure whether or not a therapist is influencing subjects self ratings and so precautions which blind therapists to whether or not they are providing therapy help eliminate some of the economically or other incentivized bias which may influence the outcome of the study. It might also be helpful to blind the subjects so that they wouldn't know whether they are in the treatment group being studied. There are clever and creative ways of doing this that don't necessarily cost a lot of money. In this study none of these blinding techniques were utilized. This is the meaning of double blinding in research. Neither the therapist nor the subject knows which of the groups contain the treatment being measured. If you also blind the screener as aforementioned that is a triple blinded study.

Care should also be taken to select therapists who have no connection to the researcher to avoid bias resulting from friendship, business or other relationship. The researcher claims the following with regards to provider selection

"At the time of the study, the study site was new and still in the process of becoming fully developed. The coordinator of the Centre had recently interviewed several people for the Centre, and this coordinator assisted with locating appropriate personnel for the study."

One of the massage therapists in the study had a family emergency and could no longer provide treatment to the

subjects. The researcher herself took over the treatment to the subjects. The researcher herself denies receiving any financial benefit for her work on subjects which she claims was minimal (1-2% of time). Although the researcher minimizes her contact with patients and denies financial reward she might have been incentivized to bias in other ways. The funding source was the College of Massage Therapists of which she was a member as a registered massage therapist. The benefits may include increased prestige of an organization to which she belongs and well as future funding grants for positive study outcomes. Since this was a doctoral, dissertation additional benefits may accrue from a research project with positive outcomes. It would probably have been wiser in retrospect to have back up massage therapists who could have provided treatment in case of emergencies like this.

This is also a peer-reviewed study, which simply means that this study was reviewed by experts in the field of massage therapy/exercise ect. These peer reviewers or referees are individuals who are widely recognized by the profession and or public as having special expertise in the field of massage therapy research. In this study, we are not told who these experts are which is normally not revealed in most studies. Perhaps we should be told.

In this case, the editor of the Canadian Medical Journal (CMAJ=Canadian Medical Association Journal), which published this research, would have chosen a person/persons to peer review this article but ultimately the decision to publish would be with the editor. The peer review process aims to make authors meet the standards of their discipline and of science in general. Articles which do not pass the peer review process are less likely to be accepted for publication. Again, it is up to the editor as to whether the article is actually published. Even peer reviewed (refereed) journals, however, have been shown to contain errors, fraud and other flaws that undermine their claims to publish sound science. So far, in the case of this article, we have found several questionable practices, which warrant further investigation. Why was this study accepted by such a well-respected Canadian Medical Journal? Is it normal accepted practice for example for the researcher to provide actual treatment to patients, falsely list research results in the abstract summary that are not supported by the data in the body of the research paper, and plug the institution that funded the research without

scientific cause? Was this a mistake in the peer review process? These and other questions may go unanswered.

So far, we have covered all of the essential elements of a research project except one important aspect. How will we measure whether or not our treatments are effective? As aforementioned, this study uses self-rating and objective measures. First let's discuss the self-rated measures. We've discussed that; you can't put a ruler into someone's head and rate pain. These self-rated measures are subjective, that is hidden within the person who must relate their personal inner experience. This makes it difficult to know whether measurements are accurate since we have to rely on estimation and can't verify.

However, in the field of psychology, for example, it would be impossible to do experiments unless these measures were treated as if they were objective. That is, we pretend that we can take a ruler and put it in your brain to measure pain for example. To do this, much research is done which establishes whether these self-rated measures predict a person's objective function. For example, research shows that IQ can predict academic success in school even though IQ scores do not technically have equal intervals between each number. What are these scales of measurement anyway? This gets a bit technical but it is important to understand so hang with this if you can. Click this link (it will open a separate page so you can easily refer back) and please read carefully. (Scales)

Scales like IQ and self-rating scales similar to the one used in this experiment are not technically supposed to produce statistics (a number that summarizes many other numbers) because the intervals between the numbers are not equal. Add two numbers together, for example, 2+3=5. When the difference between 1 & 2 is not the same as the difference between 2 & 3 you could not say for example that two equal measures plus 3 equal measures when summed together equals 5 equal measures since the difference between each number is not equal. Nor could you say where 2+2=4 that 4 was twice as many as 2 since the intervals between these numbers is not the same. If you added numbers with unequal intervals between them together to produce a statistic like the mean (add the numbers together and divide by their number=mean) you could not compare the means from two groups if the measures between the numbers were unequal for both groups. A mean of 3 in group 1, for

example, would not be the same as a mean of 3 in group 2 if the measures between the numbers in each group were different. This makes it technically impossible to compute statistics within and between groups.

Why are the differences between the numbers unequal? This is because as aforementioned we are assigning number values, which only indicate, greater of lesser value assignments (ordinal= ordered sequence). This is because we do not have a way to precisely measure, as previously mentioned, the difference between some things except to say that they are of a lesser or greater value. The first place winner in a race is not of equal measure better than the second place winner nor is the 3<sup>rd</sup> place winner 3xs slower than the first place winner. These ordinal (ordered) scales measure something that is not easily pinned down yet it is a convenient way to declare the winner of a race.

Similarly, we cannot measure the pain or anxiety a person experiences but we can say that there is more or less of this quality of pain or anxiety. This is a convenient way of ordering the greater or lesser intensity of subjective experience. Unequal differences occur in self-rating scales because clients will rate pain differently. Different clients, for example, may have a different idea of what 5 on a pain scale of 0-10 is or what the difference between 5 and 6 and 6 and 7 is. Even the same person may mean something different if their pain rating on one day is 5 and on the next day is 6. Since we cannot use a ruler, which does have, equal intervals that we can all agree upon we have to rely on self-reported measures of pain on a scale which we can not see. This scale has intervals between the numbers that may be different in each person.

Finally, this scale could change from day to day or even hour to hour. Yet as, aforementioned, many disciplines in political, social, psychological, and psychiatric professions rely on these scales or similar scales to advance their scientific research. This is because these scales are useful in measuring progress. As mentioned, much research has been done to establish whether these scales are valid. For example, do these self-rating scales actually predict improvement or lack of improvement in objective functional assessment? There is research to show that, for example, increased pain rating correlates with decreased objective measures of range of motion. It then may be possible take a self-rated pain rating and predict an objective measurement. This makes using these scales useful in evaluating the effectiveness of treatment.

The numbers from these self-rated scales, even though they are subjective measures, are treated statistically as if they were objective measures. This is only true though if care is taken not to influence clients. It is also well researched that provider influences result in sometimesdramatic differences in the way people rate their pain for example. If the therapist wants a certain outcome and transmits that to clients even subtly, self-rating scores can be affected both positively and negatively. We are all, to varying degrees, susceptible to suggestion. With selfrated measures, it would be impossible to tell whether influenced clients self-rated measures, suggestion had since we cannot examine the ruler or the object because it within the subject/client. This study as we have is detailed did not take reasonable precautions to insure that clients were not influenced by researcher bias, given that the researcher herself provided treatment and therapists were not blinded. As will be discussed the objective measures in this study were not statistically different between the groups. This in itself may be a statistical sign of problems. If self-rated measures in this study show improvement (which they did) then the objective measures should also (which they didn't). It could be argued that researcher bias was responsible for an over inflated level of improvement. It could also be argued that the objective lumbar range of motion measures were within the normal range pre treatment which might explain the lack of objective improvement. The research paper does not tell us whether patient ROM was within the normal range pre treatment. The schober measure has a norm of about 7 cm (SD 1.2) so just eyeballing the pre treatment data they all look to be a little low in the 5 cm range. This would mean we would expect some improvement in the objective measure which we didn't see.

The following sidebars discuss the topics of blinding therapists and a detailed explanation of spin. If you wish to skip to the main topic of self rating scales click the following (scales).

## SIDEBAR BLINDING THERAPISTS AND SUBJECTS

The researcher claims (see questions to author (<u>References</u>) under question # 8) the following;

## "It would be difficult if not impossible to blind subjects and therapists..."

It is difficult to blind subjects and therapists but probably not impossible. Difficulty does not exempt researchers from the attempt. The scientific community would not exempt this researcher from this research design criterion because it is difficult and because dood scientific research depends on it. After all in this particular study the author (who has full knowledge of treatment variables) actually made contact and provided treatment to research subjects. It would not have been difficult to have back up therapists provide treatment yet she provided direct treatment to subjects. The blanket claim that blinding is too difficult to do is not entirely valid. For example steps could be taken and documented in the study, which although far perfect would decrease therapist and subject awareness of whether they were in a treatment group. Essentially you could spin (most of us would probably approve of this kind of spin even though it is a lie) the research project to selected subjects and therapists. This would be a kind of "white lie spin" that doesn't hurt anyone and helps our profession by reducing the impact that therapists and subjects may have in biasing research.

For example you could develop a background story to share completely or in part with therapist/subjects. The purpose of this story is to make it difficult to know which measures are being evaluated and in what way. You could tell subjects and therapists that this study was about the affects of several treatment methods, low back pain, and personality types. The research question was whether pain perception and functionality are influenced bv inappropriate therapeutic interventions for the personality type of the person. Certain personality types for example may not respond well to exercise and how would the application of exercise affect their low back function and pain perception. This would explain all of the material facts of this particular study eq. They will receive some type of treatment to some area of their body and subjects will be asked about personality traits, low back pain, and function. Given this explanation you could add a sham soft tissue massage therapy and apply it to another part of the body far removed from the low back. This could be explained away as yet another inappropriate personality type therapy and its effect on function and pain. This is all a lie,

misleading both therapists and subjects about the true nature of the research.

These are just free association brainstorming ideas and may not be practical but do serve an example of creative research design which may be necessary in at least attempting to blind both subjects and therapists with therapies that require personal touch and are difficult to masquerade.

#### SIDEBAR END

## SIDEBAR (BEGIN) DEFINITION OF SPIN

Most people hear the word spin and just assume it's a lie. Perhaps spin is just a fancy way of saying that someone is lying. After all if we define lying as; to make an untrue statement with intent to deceive there is a close association between lying and spin. Spin is probably the more complex and nuanced version of lying including some facts and half truths and perhaps many little and big lies.

We can all claim some ready awareness of the difficulty of relating our experience accurately. It is apparent that we can not completely represent our world of infinitely complex experience with words or otherwise. Our experience is simply to complex for our brains to capture and beyond our verbal/writing skills to fully articulate. We selectively remember certain events and forget others usually with characterizations which favor the image we have of ourselves and or how we want to be perceived by others. The events we remember represent our interpretation of reality and not reality itself. Our recollections are a collection of self selected memories which is in part distortion, in part real, and in part forgotten/denied.

This becomes clear when friends or spouses see the same movie and realize their versions afterwards are some times so radically different that it is unclear to both that they even saw the same movie. The telephone game is another example of how selective perception alters the original experience. The telephone game works like this; you form a circle with several people and whisper a story around the circle. The story is written down in its original version. The first person whispers the story by reading it into the ear of the person to their left, for example. The next person just repeats the story they heard into the ear of the person to their left without the aide of a written version. After several repetitions this story is almost never the same as the original. Is everyone lying? Probably not but the concept of spin probably better describes what folks are doing.

The point is that all of us selectively choose from our infinitely complex experience certain material facts, which may also be distortions or even outright fantasies. This type of spin is largely unconscious and probably lacks internal consistency. Given this fact we are quick to forgive others for misstatements because we assume, as with ourselves, there was no conscious intent. We forgive others the little lies and exaggerations as long as there was no conscious intent or if there was it was not malicious (white lie). It is very difficult to prove conscious intent and so we give others the benefit of the doubt. One sign of conscious intent is a consistent pattern of deception in service of some false conclusion. The stronger the pattern of deception the more chance that the individual was conscious of their deception and therefore lying.

Professional political Spin (Spin Doctors) is much more conscious and consistent to a political strategy. Spin in research has probably not been studied enough but from this research study seems to be evident. How much conscious intent exists is hard to discern but some of the elements of professional spin seem to exist. You could envision though that as businesses and or institutions need research to support their various activities where accuracy is not crucial and spin could be used to cast a favorable impression without the extra cost of further research. Obviously businesses want consumer surveys to be accurate so that the product sells by incorporating improvements made by consumer input.

Institutions though may be looking to increase their credibility with the public may not need research to be so accurate. If they have developed relationships with Universities, in particular university professors, over time the funding source makes its intent known and researchers who are comfortable with spinning the research results are recruited.

The definition of spin again is; selecting true facts (cherry picking) which support a false conclusion, presenting inaccurate information, misleading information,

misleading interpretation and or denial of material facts that do not support false or misleading assertions, denial of indefensible assertions, Rejecting valid criticism as flawed and or even attacking the personal reputation of the critic, outright lying and or introduction of irrelevant information to argue in support of false conclusions and or heavily biased characterizations. If there is a pattern of deception as indicated by the aforementioned elements conscious intent can be deduced. We can then assume that the person was not telling the truth with conscious intent to deceive (lying).

Several elements are used to make the spin work against objections from others and or close examination. The following is a brief discussion of some of the spin tactics and their particular application in this research study. You will probably need to open the following charts in (References); Baseline Measures 2, Outcome Measures, and Outcome Measures Results. Before reading the following make sure you are well rested, in a good mood, and ready for some serious mental concentration. This is made complicated and at times tedious because the author has demonstrated some intricate and sophisticated logic and wording. It also includes some statistical concepts you may not be familiar with. Hang on to your seat it is going to be a bumpy ride. If you get to frustrated just read past the material until you finish the whole paper. Many things maybe reinforced and or explained differently. Then re-read these passages as they may make more sense. You can always post a question to the group for clarification. To skip this passage partially (skip partially) and skip to the summary. To skip this passage completely for now click the following; (skip)

1.) Presenting Misleading Information, Inaccurate Conclusions, and or Using Factual Information to Deceive (Cherry Picking) - This is going to take carful concentration on your part. It is going to be hard to follow because it is complex and the author has couched her findings in clever and yet misleading wording. The research papers abstract summary incorrectly implies significant differences between comprehensive and soft groups on certain measures (RDQ). There are other incorrect conclusions in the summary between the Comprehensive and other groups but we will start with the RDQ measure of function. The incorrect conclusion is quoted as follows; "Statistically

significant differences were noted after treatment and at follow-up. The comprehensive massage therapy group had improved function (RDQ)...compared with the other 3 groups (this includes the soft group # 2)." For your convenience click the following link to view the yellow highlighted abstract summary as previously quoted. (Abstract-RDQ-PPI-PRI-Inaccurate The yellow highlighted phrase, although Info) carefully worded, implies statistically significant differences after treatment and at follow-up although it does not say that directly. In one sentence it mentions statistically significant differences and in another it says improvements. Although an improvement may be evident it may not be due to anything other than a chance fluctuation (probability). If there is only improvement between the comprehensive and soft groups it may be meaningless unless they are statistically significant. The comprehensive groups may have improvements over the other groups while these differences were not statistically different. This is subtle and tricky phrasing. The implication though is clear. This type of wording might allow the author deniability. More on that later. It would be easy to assume that the this use of words is accidental (ie the author may have used the words statistically significant and improvements interchangeably) except that it fits within larger pattern which looks more like calculated spin which we will examine. Given the facts you can then decide for yourself is it spin or something else. We do not have access to the actual statistical calculation of this study (the author claims no easy access). The author was contacted and states "I think the important statistically significant differences were noted in the article." There were no statistically significant differences between the comprehensive and soft post treatment for the RDQ measure mentioned in the article and so we can assume that significant difference between these groups no existed. The abstract summary both in the yellow highlighted abstract below (Abstract-RDQ-PPI-PRI-Inaccurate Info) implies that there are statistically significant differences post treatment between the comprehensive and soft groups yet no difference were mentioned in the body of the research paper and thus no statistical difference

noted by the author. This contradicts the author's implication of statistical difference in the summary. **NOTE-**Only the follow-up scores are reported in the abstract summary, which are highlighted the following with colors;

# turquoise=RDQ pink=PPI green=PRI

red=Percentage. Back to the RDQ measure. With the 1 month follow-up results on the same RDQ measure, the author implies, again in the summary, that there are statistical differences between comprehensive and soft groups. There is a contradiction between the authors claim in the summary (EG significant differences) and in the body of the paper. The body of the research paper states there are no statistical differences between these (comprehensive & soft) groups as inspection of the overlapping confidence intervals further reveals (this will be discussed later in this analysis). Ι have turquoise the passage highlighted in that contains the inaccurate information contained in the abstract summary regarding the RDQ score. (Abstract-RDQ-PPI-PRI-Inaccurate Info). You will have to look at the **turquoise** highlighted passage carefully to understand the following. The part of the passage we are interested in here refers to the RDQ (function measure). Specifically I will translate the following information cited in the passage so that you understand it; RDQ score 1.54 v. 2.86-6.5, p<0.001. 1.54 is the mean (average of all the measures) score for the comprehensive massage group at 1 month follow-up. If you go to the outcome measures chart (References) you will notice that under comprehensive massage column and under the row entitled follow-up (1 mo) and next to the row entitled RDQ score the number 1.54 appears. This is the 1.54 number cited in the abstract and turquoise highlighted. This represents the average score that the subjects in the comprehensive group had on the disability questionnaire 1 month after treatment had ended (this test has 24 disability items low numbers are better than higher numbers). We will explain this disability measure later in more detail. The before treatment mean for this measure for this group was 8.3 which is in the base line measures 2 chart (outcome measures)

(References). You will notice 8.3 in the 1st row RDQ score. The next number to look at is the 2.86 which is in the outcome measures chart under on comprehensive massage column and under the row entitled follow-up (1 mo) and second column next to the row entitled RDQ score. 2.86 is followed by the number 6.50. This represents the range of RDQ scores from the soft group thru the sham groups as you will note by looking at the outcome measures chart in the RDQ row. To repeat the summary implies that there significant differences "The comprehensive are massage therapy group had improved function (mean RDQ sore 1.54 v. 2.86-6.5 ...)." but in the body of the research paper the author states "Self-reported levels of function..., at follow-up there were no statistical differences between the comprehensive massage therapy group and the soft-tissue group". Comprehensive manipulation massage therapy....only marginally better than soft-tissue manipulation alone for improving function." (Body of Research Paper-RDQ-Follow-up-No Statistical Differences). There appears to be a contradiction between what the author wrote in the summary and what the author concluded in the body of the research paper at least with regards to the soft tissue group. The summary cherry picks the correct facts of mean differences 1.54 v. 2.86 but infers from these correct statistics a misleading and factually incorrect conclusion. It is carefully worded so that if these inconsistencies are noted by critics the author can deny implying statistical significance but only noting improvements 1.54 v. 2.86. This deniability clause is often used in spin so in case you have to defend you can appear innocent. The spin master then could claim that all you were trying to convey was that there was a clear improvement in some scores while others were significantly different statistically. This clever wording may be evidence of conscious intent. Certainly in and of itself it may not be meaningful but as you will see many other elements of spin are evident in this research paper and so increase evidence of conscious intent. The p < 0.001 in the abstract summary (Abstract-RDQ-PPI-PRI-Inaccurate Info) refers to the p value which does indicate significant differences between at least one of the groups but it does not tell you which one. Actually

significant differences were between the the comprehensive and exercise and sham groups but not between the comprehensive and soft groups as aforementioned. By including the P-value the author further implies difference between the comprehensive and soft when in fact none exists. Professional who are looking quickly researchers thru the summary may just that abstract assume the significant difference was between the comprehensive & soft tissue group especially if they did not bother to look in the body of the paper. The confidence intervals are further evidence that there significant differences between the are no comprehensive and soft both at post treatment and follow-up. We will talk about confidence intervals in more detail later. For now, look at the outcome measures chart. Look again at the RDQ score row and notice that next to the average score, 1.54 is the comprehensive, there is a range of scores that are in parenthesis. The comprehensive is (.69-2.4), for example. The rest of the scores for the RDQ measure summarized as follows; **POST** TREATMENT= are Comprehensive 2.36(1.2-3.5) Soft 3.44(2.3-4.6)6.82(4.3-9.3) Sham 6.85(5.4 - 8.2)Exercise The confidence interval in each case is in parenthesis. Although not always true it can be said that in general if the confidence intervals overlap between groups then there is no statistical differences between the groups. The more these intervals overlap the less significant difference. You will notice significant overlap there is between the comprehensive and soft groups indicating no statistically significant differences between these groups. You will also notice there was no overlap between the comprehensive exercise, and sham groups indicating that there were significant differences these groups. 1 MONTH between FOLLOW-UP= 1.54(.69-2.4)Comprehensive Soft 2.86(1.5-4.2)Exercise 5.71(3.5-7.9) Sham 6.50(4.7-8.3) There was significant overlap between the comprehensive and soft groups indicating no significant differences between these groups. There was no overlap between comprehensive, exercise, and sham groups the indicating significant differences between these groups. The next color highlighting is **pink** also in the abstract-Inaccurate Info chart whose link is above if you don't already have it open. This

reports PPI pain intensity score (0-5) which is better when lower. PPI score .42 v. 1.18-1.75 p< .001 As with the previous measure these scores are average scores for the groups at follow-up. If you look at the outcome measures chart, under the comprehensive column and under the 1 month follow-up row is the row for PPI where the .42 number appears. This is the average pain intensity rating for the comprehensive massage group at one month follow-up. The other groups are summarized in the range listing 1.18-1.75 which begins the range with soft group's scores and ends with the sham scores. As previously noted the author suggests that there were significant differences statistically between comprehensive and soft both post treatment and at follow-up. The statistical difference between the comprehensive and soft group noted in the summary for post treatment scores is reinforced in the body of the research paper and the non overlapping confidence intervals suggest. Comprehensive did better than in the soft post statistically treatment. This then is a correct statement by the author in the summary and the body of the research paper. (Body of Research Paper-PPI-Post Treatment-Statistical Differences) These significant differences between comprehensive and soft vanished follow-up. There were no statistically at significant differences between these groups at follow up. (Body of Research Paper-PPI-Follow up-No Statistical Differences) The abstract summary suggested that there were statistically significant differences between these groups at follow-up as is noted in the (Abstract-RDQ-PPI-PRI-Inaccurate Info) chart where the follow-up score of the comprehensive which is .42 is listed vs. the follow-up score of the soft group which is 1.18 with a previous were statistically implication that there significant difference between these score when in fact as stated in the body of the research paper there were not. The confidence intervals between these groups also supports the above analysis. The author was correct about the post treatment measures but deceived us with the conclusions about the follow-up treatements. The next color highlighting (Abstract-RDQ-PPI-PRI-Inaccurate Info) is in the **green**. The following PRI scores (Pain Quality) (Scale=0-79) are listed 2.29 v. 4.55-7.71, p=0.006.

2.29 is the average PRI score for the comprehensive group v. the average score of 4.55 of the soft group and the range thru the sham group of 7.71. The pvalue is listed is .0006 higher than the other groups but still below the .05 minimum accepted level. The summary scores for the PRI scores are as follows; **POST TREATMENT**= Comprehensive 2.92(1.5-4.3) 5.24(2.9-7.6) Exercise 7.91(5.2-10.6) Soft Sham 8.31(6.1-10.5) 1 MONTH FOLLOW-UP= Comprehensive 2.29(.5-4) Soft 4.55(2-7.1) Exercise 5.19(3.3-7.1) Sham 7.71(5.2-10.3) The summary incorrectly suggests significant differences exist between comprehensive and soft at both post treatment and follow-up while the body of the research paper reports no statistical differences between these groups at follow-up and does not mention any differences post treatment. The significant overlap between confidence intervals both at post treatment and follow-up suggest no statistically significant differences between these groups exist. The summary also suggests significant differences between comprehensive and exercise both at post treatment and follow-up. This difference was reinforced in the body of the research paper only for the post treatment and not for the follow up where no mention was made. The non overlapping confidence intervals for post treatment scores between comprehensive and exercise support the congruent observation (between the summary & body of paper statements) that there were significant differences between comprehensive exercise post treatment. The statistical and difference between comprehensive and exercise is no longer apparent at follow-up as confidence intervals overlap significantly. The implication in the summary that comprehensive and exercise were significantly different at follow-up was incorrect. The **red** highlighted passage in the summary reports results which are misleading. This same passage is found in the body of the research paper which restates the same results. The research paper does not contain any description as to how these statistics are derived but we can assume the 0 pain scores were simply added and a percentage derived. The author was asked if she had any references citing the validity of using the McGill pain scale ratings (ordinal scale) as a ratio scale

(percentage). I could find no references and she had

no further references either stating "I am sorry, I do not have other references." There is no support in the scientific literature, as far as I or the author can discern, on the reliability of drawing ratio (percentage) conclusions using the McGill pain scale. In addition the author excluded a significant P-Value of .04 at one month follow-up for the ROM (Schober) group stating "While it appears that the participants in the comprehensive massage therapy group had the greatest range of motion at one-month follow up, you might note that due to scheduling difficulties, not all the participants in the soft tissue manipulation group underwent this test. I therefore did not have confidence in this finding especially since the sample sizes were somewhat small." If this is true for the ROM group why not then exclude the percentage improvement statistics using the McGill pain scale for which no research validity has been established. It is likely that the differences between the comprehensive and the other groups although significant is not dramatic. The summary scores with confidence intervals for the ROM groups are as follows; Comprehensive 6.47(6-7) Soft 5.93(5.3-6.6) Exercise 5.39(4.8-6) Sham 5.50(4.8-6.1). There was slight overlap between all of the groups indicating that if there were statistical differences between any of the groups is would have been slight with a higher than normal probability of error. These results if used would have been less dramatic than the apparently large percentage differences between the groups with regards to no pain scores. Although these percentage statistics may have been correct using them was misleading for the very reasons the author stated. There was an unusually high drop out rate in the soft group before the 1 month follow-up measure could be taken and none of the follow-up measures could be trusted because not all of the participants scores could be measured. Yet the author used statistics without scientific validation to mislead her readers into accepting false conclusions which follow. This may be further evidence of conscious intent. The author states her reservations, aforementioned, and yet used the statistics anyway because they better and dramatically support the following false more conclusions (see # 2 & 3 below) **SUMMARY**= The author used the summary abstract to present a spin version

of the research results. The author cherry picked correct factual statistics (mean RDQ sore 1.54 v. 2.86-6.5 ect) and correct conclusions (statistical differences between some groups did exist= р <0.001), to present inaccurate conclusions (significant statistical differences between comprehensive, soft & some other groups) by using misleading information (improved function ect) while drawing accurate conclusions in the body of the research study (No significant statistical differences between comprehensive and soft). There appears to be conscious intent on the part of the researcher to deceive us. The author's carful wording of the results in the summary is an example. Many readers of research simply don't have time to read the entire research study or look carefully at the charts. Most folks just read the summaries. Conscious intent to deceive would place any misinformation in that summary where it would likely be read quickly where a p value of less than .001 would justify the author's positive findings. People simply don't bother with greater depth. Knowing this if you wish to deceive your readership the abstract summary is the place to include spin. That is exactly where the author put it. The aforementioned, makes a stronger case for conscious intent to deceive on the part of the author.

Denial of Indefensible Assertions 2.) æ Irrelevant Information Introduction of to Support False Conclusions - The abstract summary contains a false conclusion and what appears to be a blatant plug for the institution which funded this research study. The author was asked why she mentioned the "College of Massage Therapists" in her summary conclusion when regulation of massage technique & the experience of the massage therapists are not measured variables in this research (irrelevant information to support false conclusion)? The author denied having done so even though a copy of the research study was attached for the authors review. The author states "I do not see College of MT in the summary conclusion. It is important to note that the effectiveness suggested in this study is only associated with comprehensive massage therapy by experienced therapists with additional training, and so forth as noted in the article. The findings are not generalizable to other

form of therapies that one might consider similar." The following link yellow highlights the college of therapist massage reference. http://www.anatomyfacts.com/research/abstractlb.bmp discussion of this is included in the questions to author assessed with this link. (Blatant Plug) The authors carful placement of this information under the summary with a subheading of interpretation is curious and then her denial disingenuous (appears honest but is not). It is difficult to believe that with her memory of detail on other questions intact why this one was such a stumper, especially given the referenced attachment. As aforementioned, the inclusion of irrelevant information in support of a false conclusion would suggest a conscious intent to deceive and is a sign of crafted spin. The authors "can't remember defense" is weak but a strategic necessity given that blatant advertising plugs, and irrelevant information were used to support false conclusions. This practice on the part of the researcher would be difficult to defend. Although it may be true that these therapists were registered by the college of massage therapists and were experienced these were not research variables. Let's discuss this because it does require a deepening understanding of the concept of variable and the distinction between independent, dependent, confounding variables. A variable is something that varies or has the potential to vary and can be identified or measured. Experimental research identifies variables to be measured in the study. Even though in a complex study such as this there are many variables which could be measured it is only the ones that are identified in the research that actually are measured. For example, as aforementioned, the education of the therapist, years of experience, and registration status of therapists (College of massage therapists regulates standards and competencies (ability to effectively combine remedial exercise and soft tissue for example)). The variables of therapist education, experience, registration status were mentioned in the study. These variables (education, experience ect) were identified but not measured as part of the experiment. The purpose of any experiment is to determine how one factor affects another factor. Research questions help determine the purpose of the

study. One such question would be to ask whether there is a difference in disability, pain intensity, pain quality, and ROM with different types of therapy or combinations of therapy such as soft tissue mobilization, exercise. To determine whether any of these therapies work you would then compare them with each other and with no treatment. That is exactly what was done in this experiment. The independent variables are the types of treatment and the dependent variables are the disability/pain measures and the potentially confounding variable are the education ect. Independent variables are usually treatments or medications and remain the same and dependent variables are measured for any changes which may occur as a result of that treatment. The experiment attempts to control all other possible influences except for the influence of the independent variable on the dependent variable. A confounding variable is not an experimental measure but rather a factor which may affect the outcome of the research but is generally controlled to reduce its influence. For example in this study we are not measuring whether the experience of the massage therapists affects our dependent variables disability, pain ect. We would want to minimize the influence of therapist education as a factor affecting those dependent measures (pain ect). If we select therapists with roughly the same experience level (in this case over 10 years) you can minimize any differential effects on the subjects disability or pain ratings. The reason for this is that experience may affect the treatments effectiveness. If you did not select therapists with roughly the same experience and it did influence outcome it would confound or confuse the treatment results. For example a massage therapist in one group with 15 years experience may get better results than a therapist in another group who has only 2 years experience. This would make it hard to tell whether it was the independent variable or the confounding variable that was producing any treatment effects such as reduced pain ect. By keeping the confounding variables relatively equal you are less likely to produce a differential treatment effect. That is a different effect between the therapist with 10 years and the therapist with 2 years. That is since both therapists have 10 or more

years experience any effect from the experience variable would be the same across groups. Since both therapists were also registered, probably by the College of Massage Therapists, they both had to take some type of test, prove educational training standards ect and so presumably provided similar treatments to the subjects of this study. Since these treatments would be relatively similar the advantage of superior training would be neutralized across the groups in the same fashion. The variables of education and experience when controlled do not confound or confuse the measurements of the dependent variables the researcher wishes to measure. If education and experience were to be studied this research project would ask a different research question and be designed differently. The research question might be; Does education and experience improve the effect of soft tissue treatments for chronic low back pain. For this research study we might want to have a group of massage therapists with more or less experience and measure whether there are differences between the groups. We might want to do the same with education varying registered vs. non registered massage therapists who provide treatments to different groups. As you can hopefully see this is quite a different study than the one Ms. Preyde has done. We cannot determine in Ms Preyde's study if education or experience make any difference unless we could compare the effect of these factors with different groups. Ms Preyde's study did not compare these factors with different groups. The authors claim simply is not valid. Ms. Preyde variously state that "the effectiveness suggested in this study is only associated with comprehensive massage therapy by experienced therapists with additional training ... " Ms. Preyde further states in the summary under interpretation "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." Hopefully it is clear that Ms. Preyde's study did not demonstrate the aforementioned. The training and experience of massage therapists were confounding variables, to be controlled (equalized) but not measured in this research study. The fact that both massage therapists and the researcher who

provided treatment to the subjects were registered by the College of Massage Therapists are also confounding variables to be controlled and equalized but not measured. This means we cannot say that this study proved that getting registered by the College of Massage therapists or having years experience makes any difference whatsoever in the effectiveness of treatment as measured by the dependent variables. These factors then are irrelevant to the findings of this research and the author used this irrelevant information to support false conclusions namely that regulated massage therapy by experienced therapists had anything to do with the measured treatment effects. The fact that the author did this and attempted to deny it, is further evidence of a pattern of behavior suggestive of conscious intent to deceive. This researcher, Michèle Preyde, was a PhD student at the time of the research and currently has earned her PhD in social work PhD, RSW Assistant Professor Department of Family Relations and Applied Nutrition University of Guelph. It is inconceivable that she is not aware that these conclusions are faulty given her training and experience. PhD programs in Social Work have extensive course work in Research Design and Methodology and Statistics which refutes any claim of ignorance. Indeed it is unlikely that she could have gotten her PhD without this knowledge. What is more difficult to understand is that this research paper was published in a peer reviewed magazine and accepted without revision by the funding source given their own Guiding Principles and Values of honesty. http://www.cmto.com/about/mission.htm This research study has the appearance of being dishonest. It is difficult to tell if this is a wide spread problem with just one case study example, but surely the journal that published this paper and the funding source either did not read the paper or choose to ignore the error. It is again difficult to understand how these rather obvious errors were just missed like some misspelling or grammatical misstep. SUMMARY The author with, apparent intent to deceive, cited irrelevant information (College of Therapists regulated education Massage and experience) to support a false conclusion (that treatment effect was due to education and experience). The author then denied citing the

College of Massage therapist reference even though a copy of the research article was provided to the author. This paper was peer reviewed by one of Canada's leading medical journals and the research was funded and presumably reviewed by the College of Massage Therapists one of Canada's Ontario province's health regulatory bodies. Yet these publications and governmental regulatory bodies allowed the publication and or promotion of this paper. This at the very least would suggest a carful examination of these institutions review procedures.

3.)

substantive discussion of valid No criticism, Avoidance (Skirting) & confusionresearch paper was evaluated by Pedro This (Physiotherapy Evidence Database) using 10 validity standards which are widely accepted measures of good research. This research paper was criticized for the following problems; no Concealed Allocation, no Blind Subjects or Therapists, and no Intention to treat analysis documented in the research. In a very brief response to a question citing these standards when applied to this research the author did not openly discuss Pedro's evaluation factors. Her response and the analysis is detailed with this link. (Validity Standards) In this section is a discussion of the tactical necessity of denial as a technique of spin. In the broad sense allowing for the validity of any criticism the defender of a spin version of events or in this case a research outcome is carful to protect and minimize acknowledgement of error. It is similar to protecting a house of cards (a fragile structure) against the wind. If you allow the wind to blow on it the whole thing could fall. Since the author knows that her conclusions as cited in # 1 & # 2 above have serious flaws if discussion of error is permitted it permits acknowledgment of vulnerability. For example, the author could have acknowledged the no concealed allocation in her research. This is where the screener is blinded to which groups the people will be assigned to. She instead confuses the term concealed allocation with blinding therapists and subjects to treatment groups. These terms are separate and given that the author of this study is now a seasoned researcher (7 years since the 2000 study) she should know the separate meaning of the terms concealed allocation, Blind Subjects or Therapists. Just in case though a

link to Pedro was provided to the author. Still it is easier to defend the difficulty in blinding therapist and so she choose to conflate all of the terms and use the "to difficult" defense for all of the terms. This is yet another sign of spin and yes adds to the mounting evidence for this author's conscious intention to deceive. SUMMARY-Pedro's analysis of this research identifies 4 areas that needed improvement, discussion of which could facilitate understanding the problems in implementing good research and design criterion. The was perfunctory, that author's response is superficial. The author appeared to skirt or avoid amplifying and discussing problem areas by confusing terms (concealed allocation with concealed treatment) or not discussing the whole issue. In responding to Pedro's evaluation that there was no intention to treat analysis the author responded "This is not entirely correct. Data were analyzed by intention to treat". The author implies that some of the criticism was valid but did not discuss. We can only surmise which aspect of critical evaluation was correct. In any case, the intention to treat analysis was not included in the research paper and so the author is essentially asking us to trust that it was done when trust is in an ever shortening supply.

Pattern of 4.) Deceptive Practices-Ιt is impossible to know whether or not someone intends to lie by looking in their brain. Conscious deception can be deduced by examining the person's behavior to see if there is a pattern of deception. The stronger the pattern the greater the chance that the person was consciously lying with intent to deceive. That is this person knew they were putting one over on you. They knew that they were trying to get you to believe something that was untrue. Most people are offended by this behavior and consider it unethical, fraudulent, and in some cases illegal. Since this is a serious charge it is best that a group of people examine the behavior and more or less vote, like a jury on whether a pattern exists. This is how the legal system determines whether someone is lying. Although a group of people may widely disagree on what constitutes a pattern of deceptive practices it is the only way minimize the bias of an individual evaluator. The argument for a pattern of deception
on the part of the author in this research study is summarized from above as follows; **SUMMARY-**The author placed information regarding the outcome of this research which was either partially true but misleading or factually incorrect in the summary of paper while generally providing accurate the information in the body of the research paper. This selective placement of information suggests a deceptive practice in that most readers will only read the summary abstract due to time or other constraints and will assume the information is accurate without looking carefully at the body of the research paper. The author suggests in the summary that comprehensive massage is statistically superior both at post treatment and follow-up to the other three modalities. In fact comprehensive massage was superior to soft at post treatment on only one measure, PPI and statistically identical on all the other measures both at follow-up and post treatment. Comprehensive was superior to exercise and sham on several measures post treatment (RDQ, PPI, PRI) but retained statistical superiority to exercise on only RDQ PPI while continuing its superiority all measures. to sham on The aforementioned contains misleading or inaccurate information suggesting that comprehensive is superior to all 3 groups on all 3 measures both post treatment and follow-up when in fact comprehensive was superior to soft at post on one measure but not superior to soft at follow-up on any measures. Further comprehensive was superior to exercise and sham on 3 measures at follow-up, retained superiority to exercise on 2 measures and sham on 3 measures at follow-up. This amalgam of part factually correct, part inaccurate information which misleads the reader into assuming that comprehensive massage is superior to all of the groups both at post treatment and follow-up on all measures. This misleading wording is another example of a deceptive The next deceptive practice is the practice. author's use of percentages (ratio statistics) to report differences between groups on the percentage of subjects who reported no pain ratings at followup. This is because these statistics would be especially vulnerable to the drop out rate at follow-up which was especially high in the soft tissue group. The author herself had concerns about

the high drop out rate especially in the soft group and did not report ROM significant differences between groups stating "I therefore did not have confidence in this finding especially since the sample sizes were somewhat small." Yet the author used percentages to report differences in the McGill intensity scale (PPI) even though the author could not cite research to support such a use. Percentage measures with such small groups 20 or so would be extremely sensitive to a drop out rate of three for example 3 people dropped out of the soft group before follow-up so instead of 27% no pain ratings in the soft tissue groups the rating could jump up to 41% no pain rating if those three had all rated pain. If those that dropped out of the no comprehensive group had been added it could make the statistics in favor of comprehensive much less impressive. The author used these statistics because they appear impressive yet upon close examination are deceptive in that high drop out rates invalidate the results, and there is little research to validate interpretation to the McGill scale in this manner. This is then another deceptive practice. The final but in some ways most eqregious (best example) deceptive practice involved a blatant plug of the College of Massage therapists which funded this research study. The author places this in the abstract summary under a heading labeled interpretation. The College of Massage therapists (CMT) is a Canadian government institution which regulates the massage therapy standards in Ontario. To be a registered massage therapist, CMT, probably tests knowledge and skills and may require certain educational and experience requirements be met. The author is implying in this summary that the massage therapy in this study that most benefited patients with chronic low back pain was the type regulated by CMT. This would probably be some combination of soft tissue manipulation and exercise in as the Comprehensive group. Further in the same passage the author implied that the good benefits were also as a result of the comprehensive massage as delivered by experienced massage therapists. To state this succinctly the author is suggesting that patients with subacute low back pain benefited from massage therapy (same as provided to the Comprehensive massage group) from experienced massage therapists

who were CMT registered. On the surface this sounds like a reasonable assumption until you begin to think about what this research project didn't measure. It didn't tell us whether or not the experience of the massage therapist benefited subjects on any of the rating scales that were measured disability, pain ect. To measure the experience factor we would have to include more groups with inexperienced therapists vs. experience therapists to determine if there was improved benefit from more experience. This research project didn't measure whether CMT registration benefited subjects in any way. To do this you would have to have additional groups also eq registered vs. non registered therapists. Neither the experience of the massage therapists or the CMT regulated techniques (CMT registration) were studied in this research project and so the inclusion of these factors in the summary were further examples of deceptive practice. The author is asking us to draw false conclusions (CMT registered experienced therapists benefited subjects) from irrelevant information (experience & registration status of therapists). When the author was asked why she found it necessary to mention CMT at all in the summary she denied having done so. Further part of the exercise therapy was not even provided by CMT registered therapists but rather by certified personal trainers. CONCLUSION-The author utilized several deceptive practices which suggest conscious intent to mislead the reader into accepting false conclusions. In particular, she implied statistical significance when there was none especially between the comprehensive and soft groups by using deceptive and targeted statistical reporting. This included placing misleading information in the abstract summary where hurried readers could be easily mislead. The author also used percentage of no pain reporting as a follow-up scientifically unproven statistic knowing that this measure was probably invalid due to high drop out rates and small sample sizes. The author blatantly plugged the research institution which funded the research by suggesting the study showed that experienced massage therapists registered by this institution (CMT) benefited subacute low back pain. This interpretation by the researcher is an untruth because this research project did not determine

whether experience, education, or institutional registration status benefited subacute low back pain. The combined accumulation of several deceptive practices does not suggest that these were random clerical errors or oversights but rather reveals a pattern of conscious intent to deceive on the part of the author of this study. Further it seems likely that those who reviewed this study must have known or should have known that these unethical research practices were evident and these same reviewers should have forced revision of the study. None of the reviewers of this study which may have included University Personnel (University of Toronto), Peer Reviewers (CMAJ), and editors of Canada's leading medical journal (CMAJ) forced revision. Further the College of Massage Therapists, the source of funding with its pledge to honesty should also have caused revision of this study. As far as can be determined none of these unethical practices were challenged or changed. This seems to at least in the case of this study imply a system of checks and balances which is broken and or hijacked by business interests over science.

References

http://en.wikipedia.org/wiki/Political spin#Spin

http://www.m-w.com/cgi-bin/dictionary

http://www.aicpa.org/PUBS/JOFA/oct2004/lawrence.htm

## FRAUD DISCUSSION

Is this research fraud though? We have made the argument for a pattern of deception which implies conscious intent but are these fraudulent practices, that is do they harm anyone. The following is a discussion of harm. We are not necessarily talking about the penal code version of fraud but rather from a non-legal perspective. We may have to rely though on the more criminally defined fraud because there does not appear to be a lot of literature on research fraud. This does not appear to be an area which has been carefully studied.

#### Legal Definition of Fraud

"All multifarious means which human ingenuity can devise, and which are resorted to by one individual to get an advantage over another by false suggestions or suppression of the truth. It includes all surprises, tricks, cunning or dissembling (to hide under a false appearance), and any unfair way which another is cheated."

Source: Black's Law Dictionary, 5th ed., by Henry Campbell Black, West Publishing Co., St. Paul, Minnesota, 1979.

As you see from the above legal definition the distinction between fraud and spin/lying is that in the case of fraud there is harm done to someone who has been cheated. Fraud shares many similar qualities with spin tactics eg statistical tricks, cunning and dissembling. It may become a legal issue when actual monetary damage can be assessed. Certainly by the legal definition above this research would share many of the attributes.

#### Research Fraud

Caltech (California Institute of Technology) Ombuds (Ombudsman= one that investigates reported complaints (as from students or consumers), reports findings, and helps to achieve equitable settlements) office defines fraud as;

"serious misconduct with the intent to deceive, for example, faking data, plagiarism (coping others work), or misappropriation (stealing) of ideas"

In the case of research fraud the Caltech definition requires that data be faked. There is no evidence that the statistics were faked in this research project nor any evidence of plagiarism, and or stealing others ideas. By this definition the research paper is not fraudulent although the above definition is probably a brief summary and does not include the Caltech ombuds office full definition.

### Harm Analysis

The following will offer some of the arguments that this research study constituted a fraud at least with regards to harm analysis.

First was there harm done to any persons or to the Profession of Massage.

To the extent that prospective students give credence to research findings there may have been financial harm. After all education can be expensive and following the lead of this research students may pay for and complete a costly educational program as well as pay for and obtain registration with the College of Massage therapists. That is to the extent that this research influences students to unnecessarily spend money this could be assessed as monetary damage.

Consumers may be harmed to the extent that they base their choice of treatment modalities on research findings. This research study plugs comprehensive massage therapy which is both more expensive and time consuming than the other treatment modalities which in fact were as effective or nearly as effective. Folks may spend more money and time than they have to. People could get basically the same results with less cost and less time spent in treatment for the relief of their low back pain.

Science itself is damaged along with the profession of massage when it becomes apparent that research results can not be trusted and further that business concerns trump all else. Once a professional code of ethics is broken all of the loopholes in research will be seen by the general public and the scientific community as a probable opportunity for fraud. Much research that might be trusted won't. In other words, it will be more expensive to do massage research because in order to earn trust more research controls against fraud translate to higher research cost. That means less massage research.

## Conclusion

By the incomplete and summarized definition of fraud offered by just one university source (Caltech) this research study is not fraudulent. That is there is no evidence of "faking data, plagiarism (coping others work), or misappropriation (stealing) of ideas". It would probably be considered fraudulent though by most university sources if you include misleading the reader to false conclusions which may be equally harmful to the public and science in general. By the legal definition of fraud this study is probably fraudulent. That is, "...false suggestions or suppression of the truth", for the purpose of fooling or cheating people to the advantage of the perpetrator. In this case the researcher wants us to become registered massage therapists by the College of massage therapists and go to schools that teach some form of comprehensive massage therapy (combine soft tissue and exercise) and wants clients to pay for more expensive therapy. The harm here is financial, in that, prospective students may pay out money for education they don't need and clients may spend more money and time than needed on unnecessary therapy. Science is harmed since massage research may not be trusted unless more expensive research and design measures are employed thus reducing the amount of research.

References for Fraud

http://www.its.caltech.edu/~ombuds/html/research fraud.html

http://www.anatomyfacts.com/Research/fraud.pdf

## SIDEBAR END

## SELF RATING SCALES

The following discusses the self rating scales used in this research study. The first scale (Disability Questionnaire) asks the client to check off 24 activities of daily living that are impaired because of back pain. For example the questionnaire asks whether because of back pain the person does the following; use a handrail to get upstairs, get dressed more slowly, can only walk short distances because of back pain. The more items checked by the client the more disabled that person is considered because of their low back pain. The subjects of this research study were given this disability questionnaire before, immediately after, and one month after treatment. A score of 0 would mean a person had no disability and a score of 24 the maximum disability because of their low back pain. As we have discussed since this scale is self reported we couldn't be sure that the measure of disability between the numbers is equal. It is equally impossible to neither know nor establish for sure if a 0 measure means a complete absence of disability from low back pain since not all the of the disability measures may have been included in this study and self evaluation may not be accurate. Technically, it

would then be impossible to obtain a statistic such as a mean (average) or deduce ratio measures such as a score of 10 is twice as disabled as a score of 5 or for that matter establish that a pretreatment score of 10 and a post score of 5 represented a 50% disability treatment improvement. However, in this research study and other are the conclusions reached with studies those this It's instrument, which is widely used and validated. validated in part because it has been associated with objective measures of functional improvement. In this study, as aforementioned, there was no objective functional improvement between pre, post, and follow-up measures.

To score this disability questionnaire, find the difference between scores, divide the larger number into the smaller number (10-5=5/10=.50 or 50%). If a pretreatment score was, 10 and the post treatment score was 5 that represents a 50% improvement. If the pretreatment score was 5 and the post treatment score was 10 that means your client is 50% more disabled after treatment.

The second scale for measuring progress in this study was a self-rated pain scale (Pain Questionnaire). Two scores are derived from patient completion of this questionnaire. The first score (PRI) is the total of the ranked pain attributes of the 20 questions. Each (PRI) attribute in descending order represents increased discomfort rated with the number of the tick mark in the category. For example, number 1 has flickering, quivering, pulsing, throbbing, beating, & pounding. If you selected pounding, your rating would be 6. Once you completed all of the 20 questions, add up the scores and put the total into the PPI box. The second score is the (PPI) which is a scale of pain intensity of 0 to 5 (0=no pain,1=mild, 2=discomforting, 3=distressing, 4=horrible, 5=excruciating). Put the PPI 0-5 score in the PPI box on the form. This questionnaire was also completed before, immediately after, and one month after treatment. These self-rated pain ratings have some of the same problems as the previous disability questionnaire. No equal measure between numbers and no absolute 0. The greater the (PRI) score the more pain a person experiences as the lower score indicates less pain. Pain intensity (PPI) works in the same way with 0 denoting no pain and 5 the maximum pain. These scores are added up for each group and mean score for that group is derived at the various measurement intervals.

The third self-rated measure probably goes under the category of psychological testing. The author sells these tests on the internet and so it impossible to get a copy unless you want to pay \$30. It is therefore impossible to evaluate the test questions without a copy. In general, it takes about 10 minutes to complete and is both a personality inventory and a measure of the current anxiety state. It includes 40 questions 20 to assess the current anxiety state and 20 to assess the personality traits of the individual. Specifically the test was used in this research to determine a person's anxiety before performing low back movements. Presumably, if a particular modality was effective a research subject will be less anxious prior to the movement. This measure was also taken pre, post, and at follow-up. I can find no references for its use with range of motion activities but otherwise this test has been validated as an accurate measure of anxiety prior to imminent surgery, dental treatment, job interviews, or important school tests. Since this is a self-rating test it has the same problems as outlined above.

The fourth measure is the only objective measurement in this research study (Lumbar Range of Motion Test). As aforementioned, this test was completed by 3 physiotherapists who were blind to which group each subject was allocated. 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 (Posterior Superior Iliac Spine) midpoint during flexion and extension activities with the centimeter result recorded for both measurements. Norms have been established. 7 Cm is considered normal. The intervals between the numbers is equal and there is a true 0 point so that numbers can be added together and divided by their number to find a true mean and ratio statements can be accurately made. For example 2 cm improvement in range of motion is exactly 2xs the amount of 1-centimeter improvement. The measurements can be checked by others for accuracy. Since the Physical therapists were blind, to which research subjects were in which groups they could not influence their measurements. In short, we can better trust that these measurements are much less likely influenced by researcher bias. The following may be a little technical. The author of this study did not report statistical differences, post treatment, between any of the groups on the only objective ROM measure (Schober) which was also the only measure evaluated by blinded assessors. There is an inconsistency

when you examine the data tables of the study. These tables show that at follow-up, there are significant P-Values, (probability that the significant difference between groups is due to chance alone). If the p value is lower than .05, for example there is significant difference between two or more groups). When you look at the tables they reveal significant differences between the groups for the ROM (Schober) measure (<u>Outcome Measures</u>) but the author does not reference or explain this result. After questioning the author reports the following; <u>Questions to Author-Question</u> # 5

Lets roll this around in our minds to hammer in the concept. Look at the table again under the heading secondary outcome measures and under follow-up one month. Look at the row heading modified schober test and under the column heading P-Value and you will notice .04. Because this is under .05 it means there was a significant difference between the mean scores of at least one of the treatment/control groups. The number doesn't tell us which one. More complicated statistical tests would have to be completed to find out between which groups there were differences.

What does this mean exactly? What is this P-Value? Please re-read the section on coin flipping. It states "When you see p= or P-Value= that is the probability that your results are due to chance." In the case above the P-Value is .04. This means that there are 4 chances in 100 that the differences between the means of your groups are not significant and due to chance alone. Think about that because it is sometimes hard to get the mind around this concept. Patience, Persistence, Progress. This .04 number tells you what chance you have of being wrong if you concluded your study by saying that there were significant difference between your treatment groups. То most scientists any number below 5 chances in 100 is acceptable. I have no idea why that cut off was decided. If you want to sound really smart to a researcher just ask them what their P-Values were. This is kind of like going to a foreign country and saying the only phrase you know in that language at which point the native speakers tear off into spirited conversation leaving you speechless. The researchers may assume you are a native speaker and give you way more information than you wanted. But at least there was a brief moment of glory.

Meanwhile the author of this study may not have included reference to this outcome measure because most research papers have a P-Value of < .001. Look back at the outcome measure table with the outcome measures link above. Notice that most of the P-Values are < .001. This means that there is less than 1 chance in a 1000 that you would be wrong in a conclusion that there were significant differences between your groups. Those are pretty good odds by anyone's standards. The P-Value of .04 (4 chances in a hundred) means that there may be an unacceptably high probability of error for this researcher. It also means that the differences between the groups on this objective measure were not that significant.

If it could be established that the lumbar range of motion of the subjects of this study were within the normal range pre treatment then it may be less likely that the range of motion will change that much since it was in the normal range anyway. In the case of the ROM of the subjects of this research study eyeballing the data it look as if there ROM was a bit low. It is also possible as aforementioned that because there was at least the possibility of researcher bias that the self reported measures did not accurately reflect the person's objective disability since they were encouraged to report improvement when there was none.

#### RESULTS

For the next section, please open and keep open the following three windows which you can refer to during the explanation. (Baseline Measures 1) (Baseline Measures 2) (Outcome Measures) (Outcome Measures Results) There are lots of scores in these tables and so it is kind of confusing. That is why it's best to keep all of the above windows open. I will refer to the windows by their name so that you will know which chart we are commenting on.

Review the concepts of <u>probability</u> so that you can better understand the following. To find the P-Value score look at the outcome measures chart, the P-Value is in the very last column of the chart. In looking at the P-Values you will also notice that they are significant for most of the groups. That is in most cases < .0001 or 1 chance in 1000 that the difference in at least one of the groups in the row is due to chance alone. Certainly all of the measures identified under the column variables (A variable is something that varies-In this case disability and pain lessen with treatment), except for the Schober (ROM) test, have P-Values under the acceptable probability of error limit of .05.

At this point we are "eyeballing" the data in the chart to become more familiar with the scores. We are looking at the data in a general manner. By the way you will impress statisticians if you use the term "eyeballing" because folks "in the know" use that term. The P-Values as aforementioned tell us there are differences between groups but we still don't know which groups are significantly different. Practice looking at charts will help you understand charts in other research papers when you read them. The charts give us the raw data and are sometimes useful in finding information that was not spelled out in the research paper which may include inconsistencies in the research findings.

We can look at the chart for the scores pre treatment which is called baseline data (See Baseline Measures 2). These are the scores which were taken prior to treatment. The column headings are not visible but it follows the groups in the Outcome measures chart. Column 1 (Comprehensive massage,) Column 2 (Soft Tissue massage), Column 3 (Exercise/Postural), and Column 4 (Fake Laser). The measured test is listed in the left hand column RDQ (Roland Disability Questionnaire=0-24), PPI (Present Pain Intensity=0-5), PRI (Pain Rating Index=0-79), State Anxiety Index Score (20-80), Modified Schober Test (No score range listed). The range of scores for each of the measures is listed above in parentheses.

The body of the chart is devoted to the scores which are mean or average scores. As we have previously explained the mean score is a summation of all the scores of the test by each of the clients divided by the number of clients. If you look at the bottom of the chart there is some information in small print. We will refer to that information as we go along. You will notice on the far right hand corner of the chart there is a cross after each of the rows. If you go to the small print explanation beside the cross it states "No significant difference between groups". At baseline, then that means the groups were statistically identical. This suggests that there is no evidence of biased assignment (No Concealed Allocation)

The scores in parentheses is a statistic known as a standard deviation. This is a complex (I won't explain the complicated formula) but important statistic. It's going to take some story telling and your patience to understand the concept. The standard deviation is a measure of how much the average score deviates or varies from the mean. Look at the baseline measures 2 at the first column, first row. 8.3 is the mean baseline disability score which given a total of 24 possible is roughly in the bottom 1/3 of scores. The statistic in parenthesis to the right of this score is 4.2 and is the standard deviation. This means that your average score deviates 4.2 points from the mean score of 8.3 and is not more than 12.5. Each measure of the standard deviation, in this case 4.2, is considered 1 standard deviation from the mean. For example, one standard deviation from the mean would be 12.5 (8.3+4.2) and two standard deviations would be 16.7 ect. If you measure enough of anything, tree trunk size or peoples height and weight something strange happens. You have to have around 100 measurements for this to work although it usually happens somewhat after 30 measurements. This of course is truer if you pick things randomly. Obviously if you purposely went out and pick very large examples and small examples it would throw this phenomena off. Assuming a random selection and enough measurements you would get what is called in the biz a normal distribution. This is another term you can use to impress researchers ask them was your distribution normal? All of the more complicated statistics that compare control groups with treatment groups are based on the assumption that the distribution of scores is normal. If the distribution is not normal then the statistics are not as valid. Also with a normal distribution and the standard deviation you can predict the percentage of scores that fall within a certain range. In our case with these disability scores we can predict that 68% of our scores will be between the scores of 4.1 and 12.5. That is between 1 standard deviation below and above the mean or roughly 34% of the scores below and above the mean score of 8.3. We can do this for each of the 4 groups if we wanted to get a feel for the data.

The numbers right under the chart below are the standard deviation 1 2 ect. The weird symbol beside the number is the symbol for standard deviation. Don't worry about the z

scores for now. The decimal numbers .3413 is the same as 34%.



We don't know in this research study whether or not the distribution was normal. The author says it was when questioned but to be sure we would need to look at more detailed data charts which the author no longer has.

What does a distribution look like when it's not normal and mean? Statisticians call what does it abnormal distributions negatively and positively skewed. The word skew is similar to the word skewer which is long and pointed and is thicker at one end than the other (not symmetrical). A skewed distribution has a thin point on one side. If the thin point is below the mean it is negatively skewed and if the thin point is above the mean it is positively skewed. For your review and comparison all of the distributions along with their estimated percentages of scores are depicted below.



If the distribution of scores for this study was negatively or positively skewed we might be concerned about the possibility of selection bias as we discussed above (Bias). Given that the number of people in this study and the scores derived from those numbers nears 100 we would expect a normal distribution. The author of this study has been asked regarding the symmetry contacted and of the distribution. The author reports that there were normal distributions. If the screener/assignment person selected people with selection bias it might show up as a skewed distribution. For example if more disabled clients were selected there would be a negatively skewed distribution because more scores would cluster above the mean and fewer scores would be below the mean. Conversely if less disabled clients were selected there would be a positively skewed distribution with less disabled clients clustering below the mean. Given that the groups are statistically identical pretreatment there is no evidence of selection bias and the distribution is probably normal. The groups derived from a normal distribution are also likely to be normal even though they are much smaller than 100 or even 30. In the case of this study even though it may have the appearance of selection bias there is no evidence that the bias actually occurred. This we can tentatively conclude by "eyeballing" the baseline data chart (baseline measures 2). We can't be certain of the conclusion but it is certainly worth preliminary consideration.

What else can we tentatively conclude by just looking in a general way at the numbers in the baseline chart 2? As far as the RDQ disability score it appears as aforementioned that none of the members of any of the groups were that disabled by their low back pain. The standard deviation as aforementioned gives you a general idea of how widely the scores vary from the mean. It looks like for most of the groups it is about 4 points. This again confirms that most of the clients in this study were not that disabled since 68% of the groups were within 4 points of the mean score of 8.3. It would be helpful if we had normative values for all of these measures so that we can compare this sample with other groups of people who have completed the questionnaire. Where possible I have listed those normative values.

As far as looking at the data from the baseline chart 2 for the PPI pain intensity score it also appears most clients experienced low grade pain. This was a O-5 scale rated as follows; O=No Pain, 1=Mild, 2=Discomforting, 3=Distressing, 4=Horrible, 5=Excruciating. Most of the folks in the groups reported pain somewhere between 2-3 which would be between discomforting and distressing. The standard deviation looked to be around 1 either side of the mean which results in 68% of the clients reporting pain between mild and distressing. This group is just not experiencing that much low back pain. That jives with the above mild disability self rating.

The PRI scores at baseline were also in the low range. The PRI measures the quality of pain on a 0-79 scale. The baseline 2 scores of this study ranged from about 10 to 12 and there were no significant differences between the groups. The standard deviation is between 5 and 6 points which gives us a range of between 6 and 16. This still means that there are low end quality of pain ratings.

The State Anxiety Index score has a range of between 20 and 80 which is a pretty large range with higher anxiety measured with higher scores. Again we don't have any normative values so it's hard to know for sure what the scores mean but this is just practice getting familiar looking at the charts. This test takes about 10 minutes and measures current anxiety prior to low back movements. Again the anxiety level pretreatment appears to be in the low end between 30 and 40. The standard deviation is around 10 points on either side so you can say that 68% of the scores are between 25 and 45. This would be low to mid range anxiety scores pretreatment. We would expect if treatment is effective that these scores should go even lower.

The last measure is the modified Schober Test which is in centimeters (cm). More than any of the other tests we need some normative data. Normative statistics tell you that how the average person taking this test does. In this case the average person taking this test is able to achieve a range of 7 cm. Please review how the test was conducted (Schober). The chart lists the average centimeter movement of the spine during flexion and extension. The research study does not tell us if the flexion and extension measurements were totaled and then averaged. I will assume that is what was done. It looks like there was only a centimeter or 2 of range in the standard deviation and that about 5 centimeters of average movement for flexion and extension. That means the range that captures the 68% of the people is between 3 and 7 centimeters movement. There are no significant differences between the groups. It appears that the average range of motion for this group is a bit low.

What about characterizes of clients. Look at baseline chart 1. Let's take a look at the chart to see what kinds of clients were selected for the study. It looks like most of the clients were married, overweight, university educated women equally split between not working/retired and sitting at a desk/movement who are in their 40's who had been suffering with current level of low back pain for about 3 months which was caused by bending lifting/mild strain injury and have had previous episodes of low back pain in the past. There were no significant differences between the groups on sex, age, weight and marital status, while there may have been differences between the groups on education level, Occupational Activity, and cause of problem.

Now how in the world do we know all of this by just quickly looking at the chart? Remember these conclusions are tentative but useful in just getting the big picture. There is always going to be error when you generalize and yet it gives you a feel for the data. Let's examine how it is the above conclusions were reached. Look at the base line 1 chart again. The crosses in the far right hand column of the chart mean that there was no statistical difference between the groups in the indicated row. Rows not marked with the cross have differences between the groups which are significant.

Looking at the first row which is the mean age you can see the range is from 42 to 48 years. In parenthesis we see the standard deviation for each of the groups and it appears to be a rather wide spread. In the first group for example it is 16 years which means 68% of the ages are between 31 years old and 63 years old. Quite a wide spread of ages. The soft tissue group had an even wider spread of age with a standard deviation of 18 years. You can do the math for the rest of the groups as by now you should be able to calculate the spread yourself.

The next row tells us the percentage of women in the groups which range from 41% to 56%. All of the groups are dominated by women except the exercise group which has a majority of men. There are no significant statistical differences between the groups. When there are no parenthesis it means no standard deviation is available.

Looking quickly at the % of clients at the various educational levels it appears the highest percentages are at the university level. I'm assuming university level means graduate work and college undergraduate (It is not clarified in the study). The next most frequent is high school and then college. This is an educated group. Probably because many were recruited thru university E-Mail and it appears that this might have been a town with a local college. There were differences between the groups on education level.

A body mass of between 25 and 30 is considered overweight and in the next row (mean mass body index) you can see that most of these women would be considered overweight by that standard. There are no significant differences between these groups.

The next several rows separate out the various daily activities (no work, student, desk, physical labor ect). There are significant differences between all of these groups. Some of the groups stand out. There seem to be greater percentages of folks who are at their desk either with or without movement and folks who are retired or not working. There does seem to be wide variation between the groups activities but not enough to make much of a difference in self reports of disability/pain or objective ROM as we have observed above.

The next row tells us how long the clients have had their low back pain and there are no significant differences between the groups. It looks like most of these clients have had their low back pain for about three months. There is also a wide range given the standard deviation which ranges between 8 to 11 weeks. That means clients could have had their low back pain anywhere from two weeks to 5 months. This is a broad estimate by the way but gives you a sense of the wide difference between subject's reports.

Between 50% and 68% of the clients reported a previous episode of low back pain and there were no significant differences between the groups.

The next several rows are devoted to describing the cause of the low back pain and significant differences exist between the groups. It looks like at least for some of the groups bending and lift and mild strain are the most frequent causes.

Hopefully you can see why "eyeballing" the data is useful. You can find out a lot before you even read the research paper. When you know what the numbers mean it makes you a much smarter consumer of research. You are less likely to be fooled by research and more likely to demand that researchers give you the real deal.

What about outcomes in this study post treatment and follow-up? Does eyeballing give us some general information about how the groups did after treatment? Look at (Outcome Measures) chart if you have it open or click and open the link for a separate window. The set up for these numbers is a bit different. The standard deviation now has a separate column and the numbers in parenthesis represent a new statistic called a confidence interval. A confidence interval is simply a range of values with a lower and an upper limit. With a certain degree of confidence (usually 95% or 99%), you can state that the two limits contain the parameter. In this case the parameter is the mean or average measure of the group. The significance of confidence intervals is to predict how close the mean of your sample is to the mean of the larger population of all the people who have low back pain and who have been study. screened in the manner of this research In statistics a population means all the members of a specified group. Sometimes the population is one that could actually be measured, given plenty of time and money. Sometimes, however, such measurements are logically impossible. Inferential (conclusions about a population from a sample) statistics are used when it is not possible or practical to measure an entire population.

Of course it would be beyond the budget and scope of this study or most studies to screen millions of people to obtain the total population of people who fit into the criterion of this study. Statisticians use the term population to mean the larger group of people while knowing it is rare to actually know exactly what the total population for any study would be. A sample, of course, is some part of the whole thing; in statistics the "whole thing" is a population. The population is always the thing of interest; a sample is used only to estimate what the population is like. Interferential statistics will help us make inferences (generalizations (with calculated degrees of certainty) about the larger population) by just looking at the sample. One obvious problem is to get samples that are representative of the population. The confidence interval tells you that if you took 1000 samples for example where your means of all those samples would likely be. That is your mean would be between the upper and lower numbers.

The probability is stated as a percentage of how confident you will be that this is true. Usually stated as 95%. There is a 5% chance that you will be wrong. This is different from the previous probability statistics, aforementioned where the emphasis was first on the probability of error (< .0001=less than 1 in a 1000 chance of error). The confidence interval could be seen as a measure of how much "wiggle room" you have with your statistics and it follows within what range the populations mean is likely to be.

For example, if you look at the outcome measures chart you will notice the RDQ score, post treatment, under the comprehensive massage group. The RDQ score is 2.36 with a confidence interval of 1.2-3.5 which means if we went back another community and did the out to same study groups/treatments the mean of this group would end up somewhere between 1.2-and 3.5. This is several measures better than our starting off score of 8.3 (See baseline 2) which is outside of both the upper and lower margins of the aforementioned confidence interval. This suggests that even if you took many other samples even the upper end mean of 3.5 would at least from an eyeballing viewpoint be significantly better than the pretreatment score of 8.3. Confidence intervals can also be used to roughly estimate whether there are significant differences between groups by determining whether or not overlap exists between the confidence intervals of the groups (see below).

To recap, if you look at the pre treatment score baseline 2 and then at the post treatment and or follow up score you can see if the means appear significantly different. Apply the confidence intervals with upper and or lower end to see if those differences still seem significant. The standard deviation of this group is 2.8 which further informs the eyeball analysis. This gives a range of from 0-5.16 where 68% of the scores would be placed. The higher end of this range would be less impressive and of course outside of even the wiggle room provided by the confidence intervals.

The other number which is new to this chart is N=25, for example, which tells you the number of people in the groups who actually completed the study. The range appears to be from around 21 to 26 but in most cases around 25 which means most people who began the study completed it since 25 people were assigned to each group from the start.

There are a lot of numbers on this chart and so it can seem a bit confusing. Remember we are only interested in looking at the chart in a general way to pick out the most significant numbers. The research paper for this project did not report differences between beginning and ending scores since its focus was on comparing the differences between the groups, eg comprehensive soft tissue ect.

## Matriculation and Drop Out

Number of people in each group; Pre Treatment=Comprehensive 26 Soft 27 Exercise 24 Sham 27 Total=104 Post treatment= Comprehensive 25 Soft 25 Exercise 22 Sham 26 Total=98 Follow-up= Comprehensive 24 Soft 22 Exercise 21 Sham 24 Total began=104 Total Completed=91 Total drop out= 13 See matriculation chart for further details.

107 were selected for the study who met eligibility requirements. 3 dropped out before randomization. 104 people were randomly assigned to one of four treatment groups. 2 people dropped out before receiving any treatment, one in comprehensive and one in exercise. 4 people started treatment but did not complete it, 2 in soft, 1 in exercise, and 1 in sham. 7 people dropped out of the study before follow-up measurements could be taken comprehensive 1, soft 3, exercise 1, sham 2. 91 completed the study in four groups.

The next section is a bit technical. If you want to cut to the chase and just read the summary scroll down or click (<u>Summary</u>). It would be good to open and keep open for reference. (Outcome Measures Results)

**POST TREATMENT** References; If you don't already have all of the references open see the following (References)

The summary of scores listed are from both from the baseline measures 2 and outcome charts. Each of the groups is labeled and then has several numbers which follow. Confidence intervals and standard deviations are listed in parenthesis. The numbers always follow the same order which is; Pre treatment score(standard deviation)-Post treatment score (Confidence Interval) (standard deviation). Also included in the summary section is the scale for the measure and any normative (normal values for other people the particular test). What follows these taking descriptions is the eyeball analysis of the numbers taking from the referenced charts. It is probably best to keep the charts open with the above link. This way you can see how these numbers are displayed in chart form and get used to eyeballing chart data and deriving meaning.

Summary of Scores for RDO (Roland Disability Questionnaire) (Scale=0-24) Comprehensive 8.3(4.2)-2.36(1.2-Soft 8.6(4.4)-3.44(2.3-4.6)(2.8) (2.8)Exercise 7.2(5.2)-6.82(4.3-9.3)(5.6) 7.2(4.2)-6.85(5.4-Sham 8.2) (3.5) A score of 14 or more is considered a poor outcome. All of our clients in this study had scores below 14. The scores are reported in the following order and this instruction shall apply to future summaries.

If you look at the RDQ score in the comprehensive and soft tissue massage groups it dropped from 8s to 2s and 3s. There isn't much of a difference between the comprehensive and soft tissue groups on these same RDQ scores. Remember the confidence intervals (CI), they overlap between these scores as a measure of the small statistical difference between the scores. For example; Comprehensive (1.2-3.5) Soft-tissue (2.3 - 4.6). With greater statistical significance between groups there would be less overlap. Instead of doing a complicated statistical test, long equations and all you can eyeball the CI to determine whether or not significant difference exists. When the same comparison is made between the Comprehensive massage group and the exercise and or sham laser group there is no of the confidence intervals. For overlap example; Comprehensive (1.2-3.5) Exercise (4.3-9.3) Sham laser (5.4-Significant differences do exist between 8.2). the comprehensive and exercise sham laser groups but there may be no differences between the soft tissue group and the exercise group. For example; Soft-tissue (2.3-4.6) which overlaps slightly with the exercise group (4.3-9.3) but not

with the Sham laser (5.4-8.2). It turns out according to the research study that by running more complicated were significant statistical tests (F-Test) there differences between the soft tissue group and the exercise/sham laser groups on this self-reported disability measure. That teaches us that when the overlap is slight there still may be some statistical difference. The "eyeballing" technique of using confidence intervals allows you to draw tentative conclusions.

The RDQ scores of the exercise pre and post treatment went from 7.2 to 6.82. The RDQ for the sham laser went from 7.2 to 6.85. The RDQ scores of the exercise and sham laser groups were virtually unchanged from their baseline scores. Since there is significant confidence interval overlap between the groups, Exercise (4.3-9.3) Sham laser (5.4-8.2), it likely that there is no statistical difference post treatment between these groups on the RDQ disability measure.

Summary of Scores for PPI (Pain intensity)(Scale=0-5)(Scale=0=No Pain, 1=Mild, 2=Discomforting, 3=Distressing, 4=Horrible, 5=Excruciating) Comprehensive 2.4(.8)-.44(.6)(.17-.71) Soft 2.2(.8)-1.04(.76-1.3)(.7) Exercise 2.2(.7)-1.64(1.3-2)(.8) Sham 2(.7)-1.65(1.3-2)(.8)

The self rated pain PPI score was also better post treatment from pretreatment in all of the groups. The difference in some was greater than others where the difference was slight.

The drop in the pain intensity score was most dramatic in the comprehensive massage group where the scores were about 5 times lower post treatment. Soft tissue improved less but still was about twice reduced from pre treatment scores. There is no overlap of CI's between soft and comprehensive but they appear close. This probably means that there is a significant difference between the groups. If we peek at the outcome measures results chart there were in fact statistically significant differences between the comprehensive and soft groups and the comprehensive did significantly better post treatment on pain intensity. Both comprehensive and soft had about the same variation of scores as evidenced by their standard deviations of 1/2 to 1 point along the pain scale where 68% of the scores would reside.

Exercise and placebo groups didn't do so well post treatment from their baseline score on PPI. They both saw around a 25% reduction in pain symptoms from baseline and their confidence intervals not only overlapped but were the same. These two groups were essentially identical. People in these two groups saw very little reduction in their pain symptoms post treatment. Their standard deviations were exactly the same. The CI upper range of soft was the lower range of the exercise group which might suggest no significant difference and if we look at the outcome measures results chart the measure of differences between the soft and exercise group were not reported in the study. It is then unclear whether no significant differences between these groups exist.

Summary of Scores for PRI Pain Quality) (Scale=0-79) Comprehensive 12.3(5)-2.92(1.5-4.3)(3.4) Soft 10.6(5.8)-5.24(2.9-7.6)(5.7) Exercise 10.2(6.4)-7.91(5.2-10.6)(6.1) Sham 11.1(5.5)-8.31(6.1-10.5)(5.4)

The comprehensive saw a 5 fold decrease in PRI scores from pre to post treatment whereas the soft saw only a 50% decrease in PRI scores. The CI between these two groups overlaps significantly which suggests no statistical differences between the groups and the outcome measures results chart does not report significant differences. The variation of scores narrowed between the pre and post comprehensive but stayed about the same for the soft.

Both the exercise and sham groups saw about the same 20% reduction in PRI symptoms and their CI nearly overlapped suggesting no statistical difference between them. The research paper did not report whether the differences between these two groups was significant (see the outcome measures results chart).

The standard deviation for all of the groups was about the same pre treatment to post treatment except in the case of the comprehensive where we saw a reduction in the standard deviation post treatment.

Summary of Scores for State Anxiety (Prior to low back movement)(Scale=20-80) Comprehensive 31.8(9.8)-23.96(22.4-25.5)(3.8) Soft 37.3(10.3)-28.96(25.5-32.4)(8.4) Exercise 32.6(7.5)-30.91(27.9-34)(6.9) Sham 34.1(8.4)-32.54(29.4-35.7)(7.8) The state 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.

There were no significant statistical differences between the pretreatment anxiety scores among the various groups. The anxiety scores of this study appear to be within the normal range of scores. The standard deviations of comprehensive and soft pretreatment seem similar and within the normative values whereas the exercise and sham groups seem a little low when compared to the standard deviation of the normative data.

As with every measure so far the comprehensive and soft groups did significantly better than the exercise sham groups, which you can conclude by using just your eyeballs. The reduction from pre to post was much greater in the comprehensive and soft groups. Doing a little math will give you the additional information that Comprehensive saw a 23% reduction, soft 22%, exercise 5%, and sham 5% reduction in anxiety scores from pre to post treatment.

Between groups the comprehensive CI upper end was the same as the lower end CI for the soft but statistically according to the outcome measures results chart there are no differences between these groups post treatment. Similarly, but more dramatically the confidence intervals (CI) of the exercise and sham overlap almost completely and there are no reported statistical differences between these groups post treatment.

Summary of Scores for Schober Comprehensive 5.6(1.3)-6.36(5.8-6.9)(1.2) Soft 5.2(1.8)-5.87(5.2-6.5)(1.5) Exercise 5.3(1.1)-5.86(5.3-6.4)(1.3) Sham 5.5(1.2)-5.98(5.5-6.5)(1.2) The ROM (Schober) measure can be assessed with normative data (Schober test has a norm of about 7 cm (SD 1.2)).

These scores will increase from pre to post because they represent the increase in ROM that treatment will hopefully provide. This is the one objective measure of the study conducted by blinded physical therapists. All of the scores seem a couple of cm short of the normal mean value of 7 cm. Since the normative value we do have is just a mean value and doesn't include a normal range of scores or scores rated for disability we can't be certain of our eyeball analysis.

ROM improvements were comprehensive 12%, soft 11%, exercise 10%, and sham 8%. These objective ROM improvements are rather modest. The CI ranges of all the groups overlap significantly suggesting no statistical differences between these groups. No statistical differences were reported in the study. The outcome measures chart reports P-Values of .051 which is greater than .05 and therefore suggesting no statistical differences between the groups.

The improvements in ROM measures were not impressive between pre and post treatment or between the groups.

**FOLLOW-UP** References; If you don't already have all of the references open see the following (References)

The author herself lacked confidence in the follow-up measurements because of the low numbers of people in each group and loss of subjects due to drop out especially in the soft tissue group. Look at questions to author in references above question # 5.

Summary of Scores for RDQ (Roland Disability Questionnaire) (Scale=0-24) Comprehensive 8.3(4.2)-1.54(.69-2.4)(2) Soft 8.6(4.4)-2.86(1.5-4.2)(3.1) Exercise 7.2(5.2)-5.71(3.5-7.9)(4.8) Sham 7.2(4.2)-6.50(4.7-8.3)(4.2) A score of 14 or more is considered a poor outcome.

The improvements in RDQ from pretreatment scores were as follows; comprehensive 82%, soft 67%, exercise 21%, sham 10%.

Eyeballing confidence intervals reveals significant overlap between comprehensive and soft suggesting no significant differences between these groups despite the 15% better percentage comprehensive improvement in disability ratings. Recall that this is a ordinal scale treated like a ratio scale and so these percentages may not represent a true reports that measure. The research there were no statistical differences between the comprehensive and soft groups. The research papers abstract summary incorrectly cites significant differences between comprehensive and soft "The comprehensive massage therapy group had improved function...compared with the other 3 groups." As aforementioned above the body of the research paper state

there are no statistical differences between these groups as inspection of the overlapping confidence interval further reveals.

The soft and exercise group have some overlap in their CI scores suggesting no statistical difference (NSD) between these groups. The comprehensive and exercise have no overlap between their CI scores and the research study reports significant statistical differences between these groups. There is a simple explanation for how the comprehensive and soft can be matched and the soft and the exercise matched but not the comprehensive and exercise. The comprehensive was on the lower end of RDQ scores as was its range, the soft was of the more middling range and the exercise was in the higher range of scores. The lower end scores (comprehensive) and the higher end scores (exercise) were sufficiently separated to create a statistically significant difference between the groups.

The CI of the exercise and sham overlap, suggesting NSD but the sham and soft CIs are sufficiently separated to infer statistically significant differences between these groups. The research study confirms statistically significant differences between the soft and sham groups. (see Outcome Measures Results Chart). The comprehensive and sham have significant differences between both CI range and statistically as reported in the research study.

Summary of Scores for PPI (Pain intensity)(Scale=0-5)(Scale=0=No Pain, 1=Mild, 2=Discomforting, 3=Distressing, 4=Horrible, 5=Excruciating) Comprehensive 2.4(.8)-.42(.17-.66)(.6) Soft 2.2(.8)-1.18(.52-1.8)(1.5) Exercise 2.2(.7)-1.33(.97-1.7)(.8) Sham 2(.7)-1.75(1.5-2)(.6)

The improvements in PPI from pretreatment scores were as follows; comprehensive 83%, soft 46%, exercise 40%, sham 13%. Those reporting no pain at follow-up are as follows; comprehensive 63%, soft 27%, exercise 14%, and sham 0%.

No matter which group you were in by follow-up your pain intensity level was between mild to near distressing. The comprehensive group achieved the most pain relief .42 and the sham group the least 1.75. Comprehensive achieved 2.81 times more pain intensity relief than the soft tissue group but there is some CI overlap and there was no statistical difference between the two groups according to the study. Soft was only 11% better in its pain intensity improvements than exercise and there was considerable overlap of the CI and no statistical differences were found between the groups in the study. No CI overlap existed between comprehensive and exercise and according to the study there were significant statistical differences between these groups. There was some CI overlap between soft and sham and between exercise and sham but the study did not report whether these differences were significant. Just from eyeballing it looks like there may be no statistical differences between the pain improvement of the soft/exercise and sham.

Comprehensive did achieve statistically significant differences in its scores over exercise and sham and its CI range doesn't overlap with either exercise or sham.

Summary of Scores for PRI (Pain Quality) (Scale=0-79) Comprehensive 12.3(5)-2.29(.5-4)(4.2) Soft 10.6(5.8)-4.55(2-7.1)(5.7) Exercise 10.2(6.4)-5.19(3.3-7.1)(4.3) Sham 11.1(5.5)-7.71(5.2-10.3)(6)

The improvements in PRI from pretreatment scores to followup scores were as follows; comprehensive 81%, soft 57%, exercise 49%, sham 31%.

Comprehensive CI overlaps the CI of soft and exercise but not with the CI of sham suggesting no statistical differences between comprehensive and soft/exercise but statistical difference between comprehensive and sham. The research study reports no statistical difference between comprehensive and soft but does report statistical difference between comprehensive and sham. The author did not report whether there was statistical difference between comprehensive and exercise.

Soft CI had significant overlap with exercise and sham and so there were probably no statistical differences between these groups although the author only reported no statistical difference between soft and exercise.

Summary of Scores for State Anxiety (Prior to low back movement)(Scale=20-80) Comprehensive 31.8(9.8)-23.79(22.2-25.4)(3.8) Soft 37.3(10.3)-30.73(26.4-35.1)(9.8) Exercise 32.6(7.5)-28.81(25.6-32)(7.1) Sham 34.1(8.4)-32.63(29.5-35.7)(7.4) The state 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.

The improvements in SA from pretreatment scores to followup scores were as follows; comprehensive 25%, soft 18%, exercise 12%, sham 4%.

The CI for comprehensive did not overlap with the CI from soft but the upper and lower limits were close. The study reports no statistical difference between comprehensive and soft on this measure. Soft, exercise, and sham all overlap significantly (CI) on this measure but the study does not confirm that there were no differences between these groups.

Summary of Scores for Schober Comprehensive 5.6(1.3)-6.47(6-7)(3.8) Soft 5.2(1.8)-5.93(5.3-6.6)(1.4) Exercise 5.3(1.1)-5.39(4.8-6)(1.4) Sham 5.5(1.2)-5.50(4.8-6.1)(1.5) The ROM (Schober) measure can be assessed with normative data (Schober test has a norm of about 7 cm (SD 1.2)).

The improvements in ROM from pretreatment scores to followup scores were as follows; comprehensive 14%, soft 12%, exercise 2%, sham 0%.

There was slight overlap between the CI of comprehensive and soft suggesting no statistical difference between these groups but just. There was more overlap between CI's of soft, exercise, and sham indicating no difference between these groups. P-Values for at follow-up for these groups indicated significant differences between one or more of these groups (.04) but no statistical information on the ROM values was provided in the study. This was due to the authors own decision not to include this information. See questions to author at the beginning of this paper and look at question # 5. See aforementioned comments on this development at the beginning of follow-up results section (Follow-up Results Intro).

# Letters (Summarized Comments) to the Editor

#### Lloyd Oppel Emergency physician Vancouver, BC

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.

## Chris Sedergreen, M.D. Family physician Coquitlam, BC

Improper screening which should have included physician examination (self-reported 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.

## Analysis

Both physicians pointed out some of the flaws of this research but missed the essential elements of deception and possible fraud not only by this researcher but also involving the larger community of university personnel, Journal Editors ect.

## SUMMARY/RECAP

165 people responded to E-Mail/Flyer/advert over an 8 month period and 107 were selected and about 91 people completed the study which took about 10 months to write and was published in one of Canada's leading medical journals in June of 2000 being the first randomized (selected using arbitrary number assignments to hide the individuals identity) controlled trial (one group received no treatment) of the effectiveness of massage therapy for sub acute low-back pain (not serious or severe).

Clients were married, overweight, university educated women equally split between not working/retired and sitting at a desk/movement who are in their 40's who had been suffering with current level of low back pain for about 3 months which was caused by bending lifting/mild strain injury and have had previous episodes of low back pain in the past. There were no significant differences between the groups on sex, age, weight and marital status, while there may have been differences between the groups on education level, Occupational Activity, and cause of problem.

Clients were randomly assigned to one of four groups in rough numbers of 25 in each group with various modality combinations. Group # 1=Comprehensive (soft tissue manipulation and exercise/postural), Group # 2=Soft (soft tissue manipulation only), Group # 3=Exercise/Postural only Group # 4=Sham Laser only.

Broadly, the modalities (Independent Variables) were; 1.) Soft-tissue manipulation- Included Friction Massage (Used for Fibrous Tissue), Trigger Point Therapy (Muscle Spasm), Neuromuscular Therapy (unspecified) to subject identified areas. Subjects were simply asked what areas of the low back hurt them and the soft tissue modalities were applied to that area according to the aforementioned criterion eq. Friction to fibrous tissue ect. Soft tissue manipulation sessions lasted between 30-35 minutes for 6 sessions. 2.) 15-20 Exercise/Postural- 6 sessions for minutes of stretching exercises for the trunk, hips and thighs, including flexion and modified extension for 30 seconds within pain free range with postural education (postural education and proper body mechanics instruction). Home exercises included these same stretches twice one time per day, strengthening or mobility exercises such as walking, swimming or aerobics and to build overall fitness progressively, and biomechanical mindedness during daily activities (lifting, sitting, ect). 3.) Sham Laser (sham low-level laser (infrared) therapy) - This was a real laser machine which was made to look like it was functioning but was not. Patients were in side lying with adequate supports to facilitate relaxation. The Laser was held over the area of patient complaint (within the lumbar area) by the treatment provider for 20 minutes for 6 sessions over about one month.

The <u>dependent variables</u> included 4 ordinal (greater or lesser value only-no equal intervals) scale measures (Self Rating scales) and 1 objective measurement (interval scale=greater or lesser-equal intervals). The ordinal scale measures are; 1.) Roland Disability Questionnaire (RDQ) 2.) McGill Pain Questionnaire (PPI) (Present Pain Intensity) 3.) McGill Pain Questionnaire PRI (Pain Rating Index) (Quality)) 4.) State Anxiety Index (SA) (State-Trait Anxiety Inventory Form Y (STAI)) The one interval scale objective measurement was the Modified Schober test (lumbar range of motion).

All of these measures were taken pretreatment, post treatment and at one month after treatment ended.

The RDQ measured self rated disability on a 24 point scale with greater numbers representing increased disability and lesser numbers decreased disability. Subjects were asked to check off the functional limitations imposed by their back pain. A score of 14 or more is considered a poor outcome.

The PPI scale measures pain intensity on a 0 to 5 scale with increasing numbers representing greater pain intensity and lesser decreased pain intensity.

The PRI scale measures the quality of pain on a 0-79 with increasing numbers representing more painful qualities and lesser numbers lesser pain qualities.

The state anxiety (SA) assesses the level induced by stressful experimental procedures and by unavoidable reallife stressors such as imminent surgery, dental treatment, job interviews, or important school tests. 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.

Modified Schober test (lumbar range of motion) 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. The Schober test has a norm of about 7 cm (SD 1.2).

The subjects of this study, pre treatment, were reporting mild disability (RDQ) from their low back pain, a pain level somewhere between discomforting and distressing (2-3)(Scale=0-5)(PPI), a relatively mild quality of pain (10-12)(Scale=0-79)(PRI), and a relatively low level of anxiety prior to low back movements (31-37)(Scale=20-80)(SA).

It seems clients did much better in the comprehensive massage group and soft tissue group from their baseline scores and also better than the exercise and sham laser groups when compared. The comprehensive massage group had significantly better scores than the soft tissue group on intensity of pain (PPI) post treatment. Comprehensive did better than exercise and sham on RDQ, PPI, PRI and better than sham on SA. Soft was better than exercise on RDQ and better than sham on RDQ and PPI.

The author herself lacked confidence in the follow-up measurements because of the low numbers of people in each group and loss of subjects due to drop out especially in the soft tissue group. Look at questions to author in references above question # 5. At follow-up both the massage groups comprehensive and soft tissue saw significant lessening of the disability they experienced from their low back pain but their was no significant difference between these two groups, that is, whether receiving comprehensive massage or soft tissue clients post treatment. improved about the same Both the comprehensive and soft tissue groups did better than the exercise sham laser groups and they did about the same as each other. Both exercise and sham laser groups did not improve much from pre treatment scores. Comprehensive did better than exercise and sham on RDQ, PPI and better than There were no statistical difference sham on PRI SA. between soft and exercise at follow-up. Soft was better than sham on RDQ.

In the abstract summary the author implied that at 1 month follow-up comprehensive was statistically superior than the other three groups on disability (RDQ), Pain Intensity (PPI), and Pain Quality (PRI) when in fact comprehensive and soft were statistically indistinct (no statistical differences) on all these measures. Comprehensive was also than exercise on PRI. Comprehensive no better was statistically superior to exercise and sham on RDQ and PPI. Comprehensive was also superior to sham on PRI. In addition the author used questionable percentage statistics to report no pain ratings at follow-up on the PPI intensity scale knowing that these statistics may be inaccurate due to high drop out rates in the soft group. The author also reported in same summary report that patients with subacute low back pain benefited from massage therapy (same as provided to the Comprehensive massage group) from experienced massage therapists who were CMT registered when CMT registration, education and or experience were not measured variables in this research project.

The author utilized several deceptive practices which suggest conscious intent to mislead the reader into accepting false conclusions. In particular, she implied statistical significance when there was none especially between the comprehensive and soft groups by using deceptive and targeted statistical reporting. This included placing misleading information in the abstract summary where hurried readers could be easily mislead. The author also used percentage of no pain reporting as a follow-up scientifically unproven statistic knowing that this measure was probably invalid due to high drop out rates and small sample sizes. The author blatantly plugged the research institution which funded the research by suggesting the study showed that experienced massage therapists registered by this institution (CMT) benefited subacute low back pain. This interpretation by the researcher is an untruth because this research project did not determine whether experience, education, or institutional registration status benefited subacute low back pain. The combined accumulation of several deceptive practices does not suggest that these were random clerical errors or oversights but rather reveals a pattern of conscious intent to deceive on the part of the author of this study. Further it seems likely that those who reviewed this study must have known or should have known that these unethical research practices were evident and these same reviewers should have forced revision of the study. None of the reviewers of this study which may have included University Personnel (University of Toronto), Peer Reviewers (CMAJ), and editors of Canada's leading medical journal (CMAJ) forced revision. Further the College of Massage Therapists, the source of funding with its pledge to honesty should also have caused revision of this study. As far as can be determined none of these unethical practices were challenged or changed. This seems to at least in the case of this study imply a system of checks and balances which is broken and or hijacked by business interests over science. Both physicians (Oppel, Sedergreen) who correctly pointed out, in their letters to the editors, some of the research and design flaws, failed to note the patterns of deception and possible research fraud.

Although the aforementioned pattern of deception which implies conscious intent but are these fraudulent practices, that is do they harm anyone. By the incomplete and summarized definition of fraud offered by just one university source (Caltech) this research study is not

fraudulent. That is there is no evidence of "faking data, plagiarism (coping others work), or misappropriation (stealing) of ideas". It would probably be considered fraudulent though by most university sources if you include misleading the reader to false conclusions which may be equally harmful to the public and science in general. By the legal definition of fraud this study is probably fraudulent. That is, "....false suggestions or suppression of the truth", for the purpose of fooling or cheating people to the advantage of the perpetrator. In this case the researcher wants us to become registered massage therapists by the College of massage therapists (funding source) and go to schools that teach some form of comprehensive massage therapy (combine soft tissue and exercise) and wants clients to pay for more expensive therapy. The harm here is financial, in that, prospective students may pay money for education they don't need and clients may spend more money and time than needed on unnecessary therapy. Science is harmed since massage research may not be trusted unless more expensive research and design measures are employed thus reducing the amount of research because it is more costly to do with limited research funds.

All things considered does this study contribute to the scientific understanding of the effect of soft tissue massage alone, exercise alone and in combination with each other on subacute low back pain? Although combining soft tissue manipulation with therapeutic exercise does seem to provide some greater pain relief that benefit disappears at follow-up where there are no differences between the combo of soft/exercise and soft alone. By all of the other measures there are no statistical differences between comprehensive and soft at follow-up.

By eyeballing the data it does appear that comprehensive is better than soft, exercise and sham, these statistics are suspect given the clear patterns of the author's conscious deception and apparent fraudulent practices as well as the high drop out rate in the soft group at follow-up. We are left with muddled and contradictory conclusions as a result of misleading research practices. Future studies should avoid catering to business interests over sound ethical research. It does both harm to the public interest and to the profession of massage therapy. Any short term gains to the careers of individual researchers or institutions are lost to the long term mistrust by the greater scientific community and by the public.
## NOTES ON READABLITY OF THIS ANALYSIS

## Flesch Reading Ease 54.4

Rates text on a 100-point scale; the higher the score, the easier it is to understand the document. For most standard documents, aim for a score of approximately 60 to 70. The formula for the Flesch Reading Ease score is:  $206.835 - (1.015 \times ASL) - (84.6 \times ASW)$  where: ASL = average sentence length (the number of words divided by the number of sentences) ASW = average number of syllables per word (the number of syllables divided by the number of words)

## Flesch-Kincaid Grade Level 10.3

Rates text on a U.S. grade-school level. For example, a score of 8.0 means that an eighth grader can understand the document. For most standard documents, aim for a score of approximately 7.0 to 8.0. The formula for the Flesch-Kincaid Grade Level score is:  $(.39 \times ASL) + (11.8 \times ASW) - 15.59$  where: ASL = average sentence length (the number of words divided by the number of sentences) ASW = average number of syllables per word (the number of syllables divided by the number of words)

## Passive Voice= 21%

Passive voice=Subject Receives Actions. Active Voice=Subject performs action. Juanita was delighted by Michelle. Michelle Delighted Juanita. Eric was given more work. The Boss gave Eric more work. The garbage needs to be taken out. You need to take out the garbage

7196/300=23.99 **57** 

Notes massage-free full text

Endnote X.0.2 Demo Build 2283

EndNote X for Students\* (Win)

RefViz ProCite Reference Manager Photocopy of current and valid student I.D. must accompany student orders.

Aaron Mattes-Active Isolated Stretching

Multiple sclerosis