Evaluating the effectiveness of CranioSacral Therapy

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Location: International Academy of Massage

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Abstract

Aims: To determine if CranioSacral therapy has an effect on pain perception.

Reason: The reason for this study is to establish a baseline validity for CranioSacral therapy in order to allow health care practitioners and the public to make informed decisions in regards to treatment.

Method: This study will be conducted using both subject feedback and subject monitoring of their intake of pain relievers as well as pain scale. To help ensure the validity of results all sessions will be taped and later reviewed to ensure that the practitioner has in no way revealed in which group a subject is in. The subjects selected will be questioned on their knowledge of CranioSacral therapy, only those who have no prior knowledge of it's specifics will be selected to participate. This study will focus on subjects suffering from Fibromyalgia, who present with no other major health issues. To help ensure the validity of results, this will be a blind study, the subjects will of course, not be informed whether they are in the control group or the group receiving CranioSacral therapy. After each session, the subjects will be asked to fill out a questionnaire detailing in their own words what effect they believe the therapy to be having and any change in the amount or type of pain they are in. This information, along with pain scale and drug monitoring will ultimately be compiled to help determine if the subject group receiving the CranioSacral therapy is seeing any more benefit from the treatment then those in the control group.
**Introduction**

CranioSacral Therapy is an oft sought after alternative therapy, and often used in conjunction with massage therapy (often by the same practitioner). Unlike massage therapy however, CranioSacral Therapy has had very little scientific research put behind its belt, and most of the research that has been done is either old, poorly done, or both. CranioSacral therapy is often sought after as an alternative therapy by patient suffering from chronic, long standing pathologies like Fibromyalgia, Migraines, Chronic Fatigue Syndrome, etc. Often this therapy is sought after a fruitless effort to cure or manage conditions by modern western medical systems – therefore it would be very beneficial to clear the matter as to whether or not CranioSacral Therapy is effective, which pathologies it is effective for – if any, and then pass this information on to the public and the medical community to aid in making informed health care decisions and improve quality of life.

**Literature Review**

Abstract #1:

“Influence of CranioSacral Therapy on Anxiety, Depression and Quality of Life in Patients with
Fibromyalgia

This study was chosen for its focus on Fibromyalgia patients. This study aims to study what the effect of CranioSacral therapy is on anxiety, depression, and “quality of life” in patients with Fibromyalgia. This study seems to not want to accept its results, as evidenced by the last lines of the abstract where they state “.. at the 1-year follow-up, the groups only differed in the Pittsburgh sleep quality index.” And then immediately stating “.. CranioSacral therapy contributes to improving anxiety and quality of life levels in these patients.” Which contradicts their previous statement of results.

Abstract #2:

“CranioSacral therapy for migraine: protocol development for an exploratory controlled clinical trial”

This study was chosen for its research on general effectiveness of CranioSacral therapy, as well as the fact that many patients with Fibromyalgia suffer from headaches and migraines. This study aims to research the safety and efficacy of CranioSacral therapy for preventing migraines. The choice of using low strength static magnet (LSSM) for their control group seems dubious however.

Abstract #3

“Intraexaminer and interexaminer reliability for palpation of the cranial rhythmic impulse at the head and sacrum”

This study aims to evaluate the effectiveness and reliability of practitioners to judge the cranial rhythmic impulse (CRI), an important part of the claimed effectiveness of CranioSacral therapy. The subject base seems small and the idea of a control group not clearly identified. The remaining
criteria seem sound.

Abstract #4

“A systematic review and critical appraisal of the scientific evidence on CranioSacral therapy”

This study aims to evaluate multiple previous research studies about CranioSacral therapy’s effectiveness, in order to provide scientific and factual data to the Worker’s Compensation Board (WCB) so they can make informed decisions about whether to support and provide compensation for this alternative therapy. This study was chosen because of its research into the general efficacy of CranioSacral therapy, which also applies to the effectiveness of CranioSacral therapy in regards to the treatment of Fibromyalgia. This research intends to review previous research in a thorough manner in previous history right up until almost the publication date of this study, giving it as much material to work with as possible.

Methods

- Design
  - Study will involve people who know nothing of CranioSacral therapy
  - Study will be single-blind
  - Study group will receive CranioSacral therapy from a professional
  - Control group will receive a placebo treatment which mimics the general touch involved in CranioSacral therapy, but no actual treatment, by a professional
  - Videos of the treatments and written experiences by the subjects will aid as a control to ensure the therapist was not giving away that they were the placebo / treatment group
  - Subjects will be treated at the same time of day, in the same setting
- Subjects will be asked to monitor their use of prescription or over the counter pain relievers
- Location will be the International Academy of Massage

  • Population
  - Age > 13 years
  - Suffering from Fibromyalgia
  - No other major complicating pathologies
  - Study will be advertised on the school notice board and the local pennysaver newspaper

  • Instrumentation
  - Sessions will be videotaped with a generic videocamera
  - Subjects will be asked to write out their experiences in a brief 1 or 2 paragraphs in their own style after each session
  - Data will be processed on an early 2008 MacBook using Microsoft Word and Microsoft Excel

  • Procedures
  - One subject will come in for a treatment at a given time in the day
  - The next day another subject will come and receive a placebo treatment at the same time of day
  - Immediately after the session the subjects will record their experiences
  - Immediately after the subject has left the researchers will review the video

**Data Collection & Analysis**

The data will be processed and analyzed on an Apple MacBook Early 2008
The processing will attempt to analyze the reduction in painful symptoms between groups – the mean average of reduced pain symptoms.

Study Rationale & Purpose

There has been very little research done in regards to CranioSacral therapy at all, and most of the research that has been done has used flawed methods and poor understanding of scientific theory.

This research needs to be done to scientifically validate the efficacy of CranioSacral therapy, to either disprove it’s worth and therefore prevent people from wasting their time and money on something useless, or to prove it’s worth and encourage doctors to refer to a proven helpful therapy as well as to encourage health care to cover the costs of cet proven health care.

Questions

Does CranioSacral therapy have any effect on the body aside from what normal touch would?

Does CranioSacral have any effect on pain?

Does CranioSacral therapy improve fibromyalgia pain symptoms?
Limitations

This study will not seek to define exactly what effects CranioSacral therapy has, nor its extent, simply if there is an effect in terms of pain perception.

Since CranioSacral therapy seems to be a popular choice for patients suffering from fibromyalgia, the subject base is drawn from people with this pathology, and thus may limit its usefulness in a more broad application.

People not included in the subject include the very old, very young, or anyone with a co-morbidity other than fibromyalgia that may complicate or skew the results of the study.

Budget

The following budget would cover the cost of 20 subjects being treated over a ten week period, with two weeks for data compilation and study writeup.

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Care of Human Subjects

There are no risks beyond the acts of daily living.

Conclusion

Main Question: Does CranioSacral Therapy have an effect on pain perception?

This research will benefit many people, either letting them know if CranioSacral Therapy is a worthwhile therapy or if they should instead pursue another avenue.

References

Website reference


“Influence of CranioSacral Therapy on Anxiety, Depression and Quality of Life in Patients with Fibromyalgia”


“CranioSacral therapy for migraine: protocol development for an exploratory controlled clinical trial”

“Intraexaminer and interexaminer reliability for palpation of the cranial rhythmic impulse at the head and sacrum”

Journal article reference

4- “A systematic review and critical appraisal of the scientific evidence on CranioSacral therapy”

British Columbia Office of Health Technology Assessment

Joint Health Technology Assessment Series

From the University of British Columbia

May 1999
Appendices A: Questionnaire

Evaluating the effectiveness of CranioSacral Therapy

Patient Monitoring Questionnaire

Name:_______________________________ Date:_______________

After each session, you will be asked to fill out this questionnaire detailing in your own words what effect you believe the therapy is having and any change in the amount or type of pain you are feeling. Please add any comments, concerns or suggestions you may have below.

____________________________________________________________________________
____________________________________________________________________________
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____________________________________________________________________________
On a Pain Scale of 0 to 10, where 0 is no pain and 10 is extreme pain, please select the number that best describes how you felt:

Before the treatment: 0

After the Treatment: 0

For Office use only:
Patient Number: ____________
Practitioner: ________________
Treatment number: ____________
Group: ______________________
Appendices B: Consent Form

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study title: Evaluating the effectiveness of CranioSacral Therapy
Study sponsor: International Academy of Massage
Principal Investigator: Kristen McWilliam

Main Study
You are being asked to participate in a research study to establish a baseline validity for CranioSacral therapy in order to allow health care practitioners and the public to make informed decisions in regards to treatment.

In order to decide whether you want to be part of this study, you should understand enough
about the activities and responsibilities involved, and any risks and benefits of participation, so that you can make an informed choice. This is known as “informed consent.” Please take your time to make your decision.

How many people will take part in the study, and who is being recruited?
Twenty subject suffering from fibromyalgia will participate in this ten week study, to take place at The International Academy of Massage.

Who is eligible to participate?
Participants who enroll will be required to have a doctors diagnosis of fibromyalgia, have no other major medical issues and be required to commit to a ten week course of treatments.

Patients must:
a) Have a doctors diagnosis of fibromyalgia
b) Be otherwise physically sound
c) Be able to read, write, and speak English
d) Agree to participate in data collection, treatments and to have treatments videotaped.
e) Complete a brief screening interview by phone with the Investigator.

What is involved in being in the study?
1. You will be interviewed by phone to determine if you are eligible to participate in the study.
2. If accepted into the study you will complete a brief survey about your health and well-being. You will be asked to complete this same survey after each treatment.
How long will I be in the study?
This study is to be ten weeks in duration.

What are the risks of the study?
There are considered to be no risks beyond the acts of daily living.

Compensation:
There will be no direct renumeration, however treatments for those in the study are at no cost.

Voluntary Participation/Withdrawal:
Your participation in this study is voluntary. You may choose not to take part or may leave the study at any time.

Who will see the personal information provided?
1. The information on your application form will be seen only by the Investigator and the study staff.
2. Your responses on the questionnaires will be entered into a computer program by a research assistant, and will be analyzed by the Investigator.
3. No information about your identity will be included in any publications about the project.
4. No information about your participation or your responses to surveys will be released to anyone outside the study.

What about confidentiality?
You will be asked to respect confidentiality of personal information or feelings other participants may disclose during the project. Your records will be kept safely in the offices of the International Academy of Massage. Efforts will be made to keep your personal information
confidential. We cannot guarantee absolute confidentiality, as your personal information may be disclosed if required by law.

What are the costs?
There is no cost to you for participating in this study.

Who do you call if you have questions or problems?
For questions about the study contact Kristen McWilliam at the International Academy of Massage at 613-820-4046