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Does Manual Treatment With Craniosacral Therapy Change the Experience of Dry Mouth in People Who Suffers From Dry Mouth After Cancer in Throat Or Mouth - a Pilot Study

NCT05882890

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Scientific background:

The current study aims to assess the efficacy of manual treatment with craniosacral therapy of fascial tissue in throat, neck, cranial and mouth region, on radiation and/or surgery-induced salivary gland hypofunction and xerostomia in patients who have received surgery and/or radiation therapy because of cancer in the throat and mouth regions. In addition, the study will acces whether the treatment also has an effect on other known late sequela in this group of patients

The hypothesis of this project is based on a recent clinical case treated by me: I practice as a physiotherapist and craniosacral therapist in a private clinic. The patient in question was treated with craniosarcal techniques (techniques that, in a broad sense, mobilizes the fascia, including meninges, dura, sleeves around the nerve-tissue etc.). He suffered from xerostomia and hyposaliva after neck surgery and radiation therapy four years prior to my treatment. During the second treatment of fascial release of the scar tissue and of the tissue around atlas, axis and occiput the patient strongly felt that his saliva started flowing. He received an additional 3 treatments, with fascial release techniques in neck, throat meninges and mouth regions, and three months after his last treatment the patient still reported much better production of saliva than before start of treatment. Furthermore, the patient reported significant gains in ease of speaking and eating. This project aim to assess if this was only an isolated event or if craniosacral therapy could be an evidence based method to increase saliva production and decrease xerostomia for patients after surgical and radiation therapy.

This study is inspired by a recent Danish project. In this study, stem cell therapy showed clinically significant improvements on both patient-reported measures and measured the amount of saliva produced. (1) The authors suggest that the results(increased flow of saliva) may be due to a reduction of connective tissue and increased blood flow in the areas affected by radiation therapy. The authors proceed to suggest that hyperbaric oxygen treatment or other treatments attempting to increase blood flow in the radiation-affected areas could be used in combination with stem cell treatment to achieve a synergistic effect.

The hypothesis that treatment that increases the blood flow in fibrous tissue damaged after surgery or radiation has a positive effect on the tissue and its associated physiologic functions is echoed in an article about strength and shoulder mobility after breast cancer surgery(2). In the Danish national guidelines for breast cancer (3), it is also recommended that women that receive radiation therapy for their breasts because of cancer, shall receive instruction in how to treat their radiated tissue manually. The writers of the two last sources hypothesize that manual treatment of fibrous tissue damaged after surgery and radial therapy can prevent tightness in fascia and nerve tissue and preserve a proper function and mobility in shoulder and arm. The writers of the first article claims that the good results after treatment and exercises is partly attributable to the increased blood flow in the area.

A case study with 15 participants that in average 8 years previously has been through surgery or radial treatment because af cancer and who suffered from dysphagia because of fibrous tissue and neuropathy(4), showed that the symptoms dysphagia, airway problems and decreased mobility in the neck would be lowered by manual fascial techniques.The effect of any xerostomia was not monitored, but the study that reveals a new way to treat some of the other sequelae fibrous tissue ind mouth and neck can cause, support my hypothesis that manual treatment of fibrous tissue caused of surgery and/or radial therapy can cause increased tissue mobility, nerve conduction, and function in the fibrous tissue.

In my project I will use the treatment protocol "Avenue of expression" (5)and a few steps from the protocol "Ten steps protocol"(6) which addresses the areas I expect to develop fibrous tissue after radial therapy and/or surgery in neck or head. The techniques used in these protocols is light (5 grams) manual craniosacral techniques, addressing the fascia in the airway system, the neck, the throat, the meninges and nerve sleeves in the cranium, the visceral cranium, and the soft tissue in the mouth. My rationale in this project is that manual treatment of scar tissue and tissue damaged by radiation will increase mobility and blood flow and therefore possibly increase the production of saliva and decrease the sense of xerostomia.

The manual treatment is combined with home exercises that targets posture in upper body and respiration. This for maintaining the effects of the manual treatment. The homeexercises is inspired by pilates and by knowledge about fascia. (7,8) the exercises are available at this link: https://www.rahbekkst.dk/oevelser-til-dig-der-lider-af-vejrtraekningsbesvaer-efter-kraeftbehandling/

Outcome (changes in xerostomi) is measured by a xerostomia questionaire inspired by the one used in "efficacy of the bioextra dry mouth care system in the treatment of radiotherapy induced xerostomia by Dirix P. Etal(9) The questionnaire used in this project was kindly lent by Tejs Ehlers

Klug, research manager at Aarhus University Hospital, and is one they (as far as he knows) use for research on this group of patients there.

This project is a pilot project, which will hopefully lay the foundation for a larger project. I have met with Tejs Ehlers Klug, research manager at Aarhus University Hospital, who found the project relevant and interesting, but who needed to see more (than just one) patient cases with positive results before he would consider collaborating on a larger randomized trial. This project aims, among other things, to investigate on a slightly larger scale whether craniosacral therapy can create these positive results. If the treatment method used in this project proves to be effective, this project will be the first small steps towards:
1. a larger-scale research project, blinded and randomized and where saliva production measurement is included.
2. the development of an evidence-based and effective treatment offer for a patient group that currently lacks effective treatment offers and a treatment offer that may be able to complement stem cell therapy in the long term.

Objectives:

Main:

To examine if craniosacral therapy in chest, throat, neck, cranium and mouth , combined with specific exercises, can decrease xerostomia in people who suffer from this after radiation therapy and/or surgery in neck or mouth because of cancer in mouth or throat, by using a questionaire ”xerostomia after minimun 3 months” and compairing baseline results, with results after end of treatment and results 6 months following the last treatment.

Second

To examine if the intervention has any effect on other well-known late sequelae after treatment of cancer in mouth and neck, by asking if and how participants are expriencng theese symptomps and compairing baseline results, with results after end of treatment and results 6 months following the last treatment.

Third objective

To examine, if there is any sideeffects ore adverse events of the treatment

Design

This project is apilot-study. Its a a one-arm interventionstudy,with before and aftercomparisons. There is no masking(open level)

Measurement method

Main objective: The participants will fill in the Danish questionaire named ” Xerostomia questionnaire after minimum 3 months”.

The questionnaire will be filled in on the treatment day, before starting the treatment, on the 5.(and last time of treatment, before starting the treatment, and as follow up, 6 month after the treatment. The participants will be alone, completing the questionnaire.

Other monitoring

Second objective (other late sequelae)

Participants will be contacted by phone the week before starting the treatment and interviewed about, which latesequelae they are experiencing – thiswill be written down in their journal and will be read aloud so they can confirm. The therapist will ask then about experiencing any changes in the late sequelae mentoned before start of treatment the last time of treatment, and at 6 month following up meeting.

Participants areasked if they experiencing following late sequela: dry mouth, obstipation,lympedema, tinnitus,difficulty swallowing, tense/stiff neck, problems with respiration, stiff jaw,difficulty with speaking, fatigue,difficulty sleeping and pain and mental well-being

.Theese late sequelae are chosed by reading results from a questonaire about late sequelease fulfilled by members of: ”Danish Network for Mouth and Throat Cancer” – a community of people who has been through treatment of cancer in throat and mouth.

Participants are also asked if they have any other late sequelae.

Third objective(side effects)

Participant are at the first reatment session receiving a diary to note if they have any side-effect after treatment. At each session the therapist will ask if the participant hav been experiencing any side effects and theese will be noted in the participant journal and combined together so that the results contain a total overview of experienced side effects

Intervention:

The participants will receive 50 minutes of treatment of craniosacral therapy once a week in 5 weeks. The treatment will follow the protocol "avenue of expression" end step 2c and 2c in "Ten step protocol". Se appendix (1)

Statstical considerations

The participants filled in the danish questionaire ” Xerostomia questionnaire after minimun 3 months”. The questionnaire includes a VAS xerostomia scale 0-10 (10 is worst)
The remaining 14 questions were phrased "how much does [question subject] bother you:" (translated from Danish)

not at all (1) - a little (2) - some (3) a lot (4) very much(5)

The final question(number 15) were:

"How would you feel, if you had to live the rest of your life, with the symptoms you have now?:"

enjoyable(1), very satisfied (2) neither satisfied ore unsatisfied(3), very unsatisfied(4), terrible(5)

the sum of points from the 15 questions gives an overall score.

The remaining 14 questions were phrased "how much does [question subject] bother you:" (translated from Danish)

not at all (1) - a little (2) - some (3) a lot (4) very much(5)

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the sum of points from the 15 questions gives an overall score.

This will give two scores:

the was-scale-score between 0-10 (10 is worst)

and the score for the remaining questions between 15 – 75 (75 is best)

The questionaire will be filled in on the treatmentday, before starting the treatment, on the 5.(and last time of treatment, before starting the treatment, and as a followingup, 6 month after the treatment. The participants will be alone, completing the questionnaire.

The result will be the participants' average score from the 3 times the questionnaire is completed. Averages will be calculated omitting missing values. Unfortunately, I have not been able to find information about, how large a change in the score there is clinically relevant.

Since there is no control group, I have decided that the participants must have completed the treatment at least two years before the start of the trial to ensure that any positive effects on xerostomia and the other side effects are not simply a result of natural healing. This choice was made on the basis of a systematic review of 1366 patients(10), where it is argued that it is probably

at least after 2 years after end of cancer-treatment that a relatively static state with regard to dry mouth occurs.

Because the intervention group is so small, and heterogene, when it comes to age, time since treatment, gender and cancer treatment methods results should be generalised to future patient populations with great caution.

During the calculation I have received supervision, from a colleague that has a lot of experience with statistics during research.

Participants:

Inclusion critaria

- More than 18 years, able to consent to participate.
- Have finished radiation treatment and/or surgery for oro-pharyngeal head or necḱ cancer at least two years before enrolling the project
- They shall score at least 4 on an xerostomia numeric scale where 0 is no xerostomia.

Exclusion cristeria

- Persons who by surgery have got both their submandibular saliva glands removed.

And severel contraindications:– se below:

- New case of cancer within a year
- Known to have an intercranial aneurysm or 2 close family members (parents, siblings, children) known to have aneurysm or bleeding under the brain.
- Perforation of the dura within a month
- Diagnosed bulge in the medulla oblongata
- History of traumatic neck or head injury that required hospitalization
- Planning to become pregnant, or pregnant before the twelfth week at the start of the project
- Signs of active disease - must be investigated by paticipants own doctor first Sorted out in

this project:

- radiation damage to the cervical vertebrae
- If I during my journal procedure of my participant finds any signs of active disease, I will send them to their doctor and do not start my treatment before the doctors approval.

Risks, Side effects, disadvantages (long and short term)

Serious sideeffects of craniosacraltherapy is very seldom. When I was going to apply to ”The central Denmark region Commitees on health research ethics” for permission to carry out the project, they demanded a study of cases of serious side effects after craniosacral therapy, wich made me makesome extra exclusion critiria to this study. There is a single case where a person who was pregnant and had fallen had a spontaneous abortion after treatment. There are also a few cases where people who have been exposed to serious head or neck trauma have had side effects that required medical attention. Therefore, pregnancy and serious head/neck trauma are contraindicated in this project. In addition, there are a number of precautionary contraindications that are taken into account to avoid serious side effects. Read more under exclusion criteria.
Participants are instructed to contact their doctor if they experience anything concerning during the trial.
Any serious side effects will result in immediate cessation of the trial, and will ofcause be reported.

Commonly occurring/ not serious sideeffects

It is common for all types of patients to experience temporary fatigue, dizziness, flu symptoms, aches and pains, and increased digestive activity. It is also common to experience temporary emotional fluctuations. Since I have not treated many people with late effects of cancer, I do not know if they will have any other common late effects than the general population. Therefore it is a object in this study to list any side-effects any this study.

Hygiene:

Since the participants belong to a group of people who are particularly vulnerable to infections and since the experiment was conducted during Covid times, face masks will be used during treatment and gloves are used when treating the mouth.

The table is disinfected between each treatment.

Gdpr

As this experiment takes place in Denmark, which is a member of the EU, there are a number of rules according to GDPR that must be observed. These are ensured in cooperation with ”The central Denmark region Commitees on health research ethics”

Economy:

sponsor/collaborators:

No sponsors - this study is self-financed

collaborators:

Danish Cancer Society (has made treatment rooms available
DLHM - Danish Society for Mouth and Throat Cancer (recruitment of participants)
Danish Network for Mouth and Throat Cancer (recruitment of participants)

Recruitiment of participants

I have contacted various relevant hospital departments and asked if they wnated to collaborate on recruiting participants, but they have not been interested.

Participants have received information about the possibility of participating in the project through presentations held in collaboration with:
DLHM - Danish Society for Mouth and Throat Cancer
and
Danish Network for Mouth and Throat Cancer

Informed concent

The participants have signed informed consent, which is based on templates developed by ”The central Denmark region Commitees on health research ethics”. The information has been given both orally - via oral presentations - and in writing and contains everything the research ethics committee requires. They have also signed informed written consent, where they give permission for the

publication of the results.I have been in contact wih employees from ”The central Denmark region Commitees on health on health research ethics”, to make sure that this procedure has been done properly

Insurance

In the application procedure to the ”The central Denmark region Commitees on health research ethics”, I had to ensure that the participants in the project are covered by my medical insurance. The participants are covered by my medical insurance

Publication of results:

The results will be published on clinicaltrials.gov. I will work to have the study published in a peer-reviewed journal – also in my professional journal (Danish physiotherapists) and on Upledger International's website (the institute that trains craniosacral therapists), where they have a subpage with links to various research. If the trial has positive results, I will communicate the results orally at relevant conferences/professional days or in patient associations.I will also make the results availible n my own webside.

Scientific ethics section

This treatment is aimed at a patient group that currently only has suboptimal and symptom-relieving treatment options for a disorder that can be very bothersome and for some have a negative impact on eating, speaking, social contact and other basic human needs. For some, these problems are temporary, for others they are chronic. Research is currently being conducted into stem cell treatment, and fortunately this has yielded promising results in terms of both patient safety and saliva production, but it will probably be some time before this treatment is a standardized offer for this patient group. In addition, stem cell treatment is currently not well-established in terms of long-term effects and is costly. And – it has also not been shown to have much effect on xerostomia except for the parameter thirst. My treatment is risk-free – and with only mild and temporary side effects in the days following the treatment. If my hypothesis holds (based on a single patient case and transfer of knowledge on manual treatment of radiation-damaged tissue elsewhere on the body), this trial could be the first step towards an evidence-based, inexpensive and effective treatment option that not only relieves symptoms, but instead treats the root of the problem – namely the damaged tissue.

Approval from ”The central Denmark region Commitees on health research ethics” (see appendix 2)

References:

(1)Gronhoj C, Jensen DH, Vester-Glowinski P, Jensen SB, Bardow A, Oliveri RS, Fog LM, Specht L, Thomsen C, Darkner S, Jensen M, Muller V, Kiss K, Agander T, Andersen E, Fischer-Nielsen A, von Buchwald C. Safety and Efficacy of Mesenchymal Stem Cells for Radiation-Induced Xerostomia: A Randomized, Placebo-Controlled Phase 1/2 Trial (MESRIX). Int J Radiat Oncol Biol Phys. 2018 Jul 1;101(3):581-592. doi: 10.1016/j.ijrobp.2018.02.034. Epub 2018 Mar 6. PubMed ID: 29678523

(2)Lauridsen MC, Torsleff KR, Husted H, Erichsen C. Physiotherapy treatment of late symptoms following surgical treatment of breast cancer. Breast. 2000 Feb;9(1):45-51. doi: 10.1054/brst.1999.0087. PubMed ID: 14731584

(3)URL: https://www.fysio.dk/globalassets/documents/fafo/kliniske-retningslinjer/onkologi/nkr_brystkraef...
Description: National Clinical Guideline for Consequences After Surgery for Breast Cancer

(4)URL: https://dysphagiacafe.com/2018/04/22/the-role-of-myofascial-release-and-manual-therapy-in-dyspha...
Description: The Role of Myofascial and Manual Therapy in Dysphagia Treatment

(5)Type: Study Protocol: You can find the protocol in this study guide: SomatoEmotional Release 1, Study guide s. 29, J. E. Upledger, 2017 edition, Upledger Institute International

(6)Type: Study Protocol. You can find the protocol in this study guide: Craniosacral Therapy 2 study guide, J.E. Upledger, s. 25, 2014 edition, Upledger institute International

(7)Paoletti S, ”The fascia: anatomy, dysfunction and treatment”, 2006, Eastland Pr.

(8)(Lesondak D. ”Fascia – What it is and why it matters”, 2017, Handspring Publishing

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Dec;15(12):1429-36. doi: 10.1007/s00520-006-0210-y. Epub 2007 Jan 18. PubMed ID: 17235501

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Appendix section

Appendix 1

Treatment protocol Xerostomi

- anamnesis and introduction to the treatment. Here I made an oral agreement with the participant that they can ask me to stop the treatment at any time. I will also ask for consent to start the treatment in another bodily area than mentioned in the protocol, if I find that it is necessary.

Physical examination:

I will examine the cranial rhythm of heels, ankles, thighs, the pelvis, the ribbs, the shoulders, in the three global cranial hand positions, and the temporal hand position with a technique intended for listening for this rhythm.

I will do an arching to find energy cysts
All findings are documented in the journal.

Treatment

In every session I will start with a stillpoint at the feet.
I'll go through the protocol as far as I can during the time available, and continue in the next session.

Diaphragm with diaphragm handgrib

- diaphragm -

- Thoracic inlet
  with diaphragm handgrib

- Infrahyoid musles
  with diaphragm handgrib

- os hyoideum and retrohyoid tissue
  with diaphragm handgrib

- c1 og c2 (1 gram technique)

- treatment of the cranium in 5 steps:

- 1: melt in the suborcipital tissue

- 2: platform technique

- 3: 5 grams traction of occiput in the direction of the cranium starting from atlas

- 4 : decompression technique of the occipital condyles
-
- 5: 5 grams dural traction

Cranial treatment

- frontal lift

- parietal lift

- sphenoidal compression-decompression

- temporal unilateral og bilateral ear-pull technique
- os mandibularis compression – decompression
- os nasalis technique
- os zygomaticus og processus pterygoideus – decompression techniques
- soft-tissue-technique upper and lower lip
- os maxillaris technique
- os vomer technique
- os palatinum technique
- roof of the mouth technique
- fascial glide of suprahyoid tissue
- tongue technique
- treatment of teeths and gums
- technique for re-stabilisation :
- Os maxillaris technique– in flexion and extension
- os mandibularis technique – compression and decompression
- os sphenoidalis technique – compression and decompression
- os temporale (earpull technique)
- cranial base technique

- CV4-technique

After each session I will retest the cranial rhythms . Test results and treatment is documented in the journal.

Finish the treatment with conversation, questions etc, and with information about expected side effects of the treatment.
Ask the participant to write down if there is any side effects on the treatment in the coming days.
Instructions in home exercises is given. Exercises targeting upper posture and breathing exercises. The exercises is given when the therapist has reached some anatomical milestones in the treatment protocol. For example, an exercise with diaphragmatic breathing is given after manual treatment of diaphragma.Home exercises can be found here: https://www.rahbekkst.dk/oevelser-til-dig-der-lider-af-vejrtraekningsbesvaer-efter-kraeftbehandling/

Appendix 2

Regionshuset
Viborg
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Dato 30-08-2024
Sagsbehandler Anne-Marie Eybye
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Sagsnr. 1-10-72-53-20

Dear Cathrine

The Central Denmark Region Committees on Health Research Ethics assessed your study "Efficacy of Manual Treatment of Tissue in the Diaphragm, Neck, Throat, Cranial and Mouth Region for Radiation-Induced Xerostomia and Hypo- or Subnormal Salivation - a case study" at a meeting April 16, 2020.

According to the Consolidation Act on Research Ethics Review of Health Research Projects, Consolidation Act number 1083 of 15 September 2017 section 14 (1) only health research studies has to be notified to the Committees. The Committees did not consider your study to be a health research study (section 2 (1)).

Therefore your study may be conducted without an approval from the Committees.

Kind regards

Anne-Marie Eybye
Secretary

The Central Denmark Region Committees on Health Research Ethics