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STUDENTERRAPPORT

Determining the effects of NADA acupuncture - The physiologic response to young healthy subjects and the subjective experience in chronic pain patients

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List of abbreviations

ANOVA	Analysis Of Variance
BP	Blood Pressure
BPM	Beats Per Minute
HR	Heart Rate
kPa	Kilopascal
MPQ	McGill Pain Questionnaire
MVL	Musculus Vastus Lateralis
NADA	National Acupuncture Detoxification Association Abstract
NRS	Numerical Rating Scale
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
OTC	Over The Counter
PPT	Pressure Pain Threshold
PRI	Pain Rating Intensity
SD	Standard Deviation
TCM	Traditional Chinese Medicine
TSC	Tværfagligt Smertecenter
QOL	Quality of Life
VAS	Visual Analog Scale
WHO	World´s Health Organization

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Indhold

1. Motivation and Structure Thesis

Besides my work as a student, I am a certified National Acupuncture Detoxification Association (NADA) practitioner offering NADA treatment at my own clinic. Through my work as a NADA practitioner, I have met many different people with various reasons to visit me, However, they do almost all say the same: NADA treatment leads to feeling more relaxed and positive and lead to a better quality of sleep. In September 2018 I went to a NADA conference in Roskilde where I heard about the use of NADA at the Center of Complex Chronic pain in Aalborg. This Center made their own investigation on their patients and found that the patients receiving NADA showed better improvement of their quality of life, and also had a long term effect of NADA acupuncture. This inspired me to explore the NADA method in patients with complex chronic pain.
A literature search in the PubMed database, from September 2019 to and again in January 2020 resulted in less than 30 articles about NADA. Upon review of these articles, it was clear that there was a large gap in the investigation of the mechanisms behind the NADA method in humans, thus, this project was initiated. Briefly, NADA can be compared to acupuncture which also had a slow uptake in the western medicine, as skepticism and criticism arose due to lack of knowledge about the mechanisms underlying acupuncture benefits, despite evidence that patients improve.
This Master Thesis includes a mini-review of NADA, two independent studies, a discussion and perspectives, and supplemental materials (Figure 1.1): Considering that the mechanisms behind NADA acupuncture are unclear, the first study is an experimental study in healthy young adults.

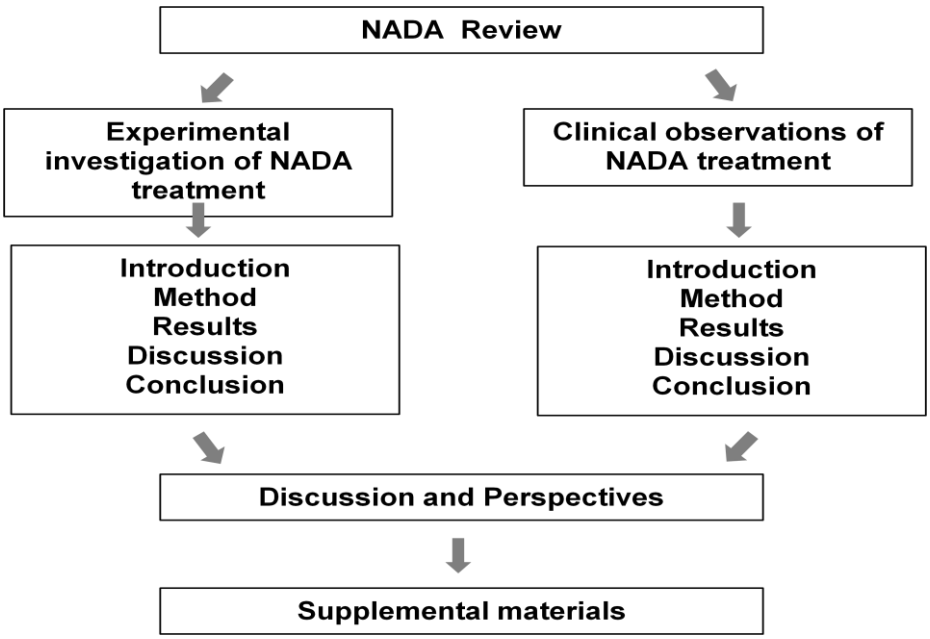

Figure 1.1: A view of the overall structure of this Master Thesis.

Overall Abstract

Background: One of five adults worldwide is estimated to suffer from chronic pain. This is often complicated by co-morbidities including depression, anxiety, sleeping problems, stress etc., which makes it a great challenge to overcome and remain a life with high quality. Moreover, does treatment often include medication, which has shown poor effects and a lot of side effects, thus, there is a need for new treatment options. One suggested method is the National acupuncture detoxification association (NADA), a standardized five-point needles acupuncture method which has been widely used to ease several symptoms including anxiety, sleep, chronic pain, drug addiction, and depression. However, there is a great lack of evidence about the benefits of the NADA method and the mechanisms of action behind.
Method: Two studies are included in this thesis. The first study explored the acute and initiate effect in response to two consecutive 45 minutes sessions divided by 24 hours, of NADA acupuncture in comparison to Rest in healthy young participant. The mechanisms of action was explored by measuring heart rate, blood pressure and Pressure pain threshold (PPT) on three different locations including Tibia Bone, Musculus Deltoid and Musculus Vastus Lateralis (MVL). The benefits of NADA acupuncture was explored by self-reporting of quality of life and subjective experiences of NADA acupuncture. The second study explored the effect of NADA acupuncture as an adjuvant to existing treatment in an 8-week treatment program in patients at the Center for Complex Chronic Pain. The benefits of NADA acupuncture were explored by self-reporting of pain perception, Medication use, quality of life and personality, assessed at both baseline and following the 8-week treatment program.
Results: The first study showed an increase in PPT for MVL in session 2 for the NADA group and a decrease in PPT for the deltoid muscle in session 1, for both NADA and Rest group. Heart rate showed a rapid decrease within the first minute for both groups, from where it stayed decreased. The second study revealed a correlation between sleep quality and the personality trait organized, and a decrease in the personality trait spontaneous. No further differences or changes were shown in neither study one nor two.
Conclusion: This thesis found alterations in both healthy participant and complex chronic pain patients after NADA acupuncture, however, these two studies has faced some challenges. The second study was a one-sided study which only highlighted the effect of NADA acupuncture, due to the fact that there was no control group. The first study may show a gender effect, rather than a NADA effect, due to randomization of the NADA and Rest group led to only women in the NADA group. Finally, an analysis showed that both studies was underpowered. Combined, it is not possible to reveal whether these changes truly relied on the NADA acupuncture or underlying mechanisms.

Samlet Resume

Baggrund: Det er estimeret at én ud af fem voksne på verdensplan lider af kroniske smerter. Over tid kan disse udvikle sig til komplekse kroniske smerter, som bliver komplekse på grund af de komorbide lidelser der kan følge med. Dette kan bl.a. være lidelser såsom depression, angst,

søvnproblemer og stress. Udover at medføre komorbide lidelser, ses det også at komplekse kroniske smerter kan være svære at behandle. Forskellige medikamenter ses ofte som værende, ikke dækkende og med følgeskab af en lang række bivirkninger. Der er derfor brug for mere viden indenfor behandlingen af kroniske smerter. Et eksempel kunne være National aupuncture detoxification association (NADA) metoden, som er en standard akupunktur behandling der er bygget på isætning af fem akupunktur-nåle i fem forskellige zoner i hvert øre. Disse zoner er de samme hver gang og uanset hvad der behandles for. NADA metoden er brugt ved forskellige lidelser bl.a. stofafhængighed, depression, angst, kroniske smerter of søvnproblemer. Der findes dog stadig meget lidt undersøgelse på området, både omkring de virkefulde mekanismer der ligger bag, men også på hvorvidt NADA metoden egentlig har en reel effekt på de fordele både patienter og udøvere oplever.
Metode: Denne afhandling indeholder to undersøgelser. Den første beror på en undersøgelse af den akutte effekt af NADA akupunktur sammenlignet med afslapning i raske unge deltagere. Dette er undersøgt ved to 45 minutters NADA behandling eller afslapning over to dage. For at undersøge de virksomme mekanismer bag NADA akupunktur, blev både blodtryk og hjertefrekvens målt samt Pressure pain threshold (PPT) på tre forskellige lokationer (Tibia knoglen, Musculus Deltoid and Musculus Vastus Lateralis (MVL)). For at undersøge fordelene ved NADA metoden blev forsøgsdeltagerne bedt om at selvrapportere deres livskvalitet og hvordan de subjektivt oplevede sessionerne med NADA eller afslapning. Den anden undersøgelse beror på en undersøgelse af NADA akupunktur som et supplement til den eksisterende behandling, i et 8-ugers behandlingstilbud til personer tilknyttet en Smerteklinik med komplekse kroniske smerter. Fordelene af NADA metoden blev undersøgt både ved behandlingens start og igen ved behandlingens ophør, ved at patienternes selvrapportering af smerteopfattelse, medicinforbrug, livskvalitet og personlighed.
Resultater: Det første studie viste at PPT i MVL var øget i session 2 i NADA gruppen og et fald i PPT i Deltoid musklen i session 1 for både NADA of afslapningsgruppen. Derudover, viste der sig for både NADA og afslapnings gruppen et fald i hjertefrekvensen allerede indenfor det første minut, hvorefter denne forblev nogenlunde stabil. Den anden undersøgelse viste en korrelation imellem søvnkvalitet og personlighedstrækket organiseret, samt et fald i personlighedstrækket spontan. Ingen andre forskelle eller ændringer sås for hverken det første eller andet studie.
Konklusion: Denne afhandling viser at det i NADA gruppen blev fundet en øget PPT vedd den ene af tre placeringer i raske unge forsøgsdeltagere. Derudover sås en ændring i personlighedstrækket spontan samt at ændrede søvnkvaliteten var korrelateret til personlighedstrækket organiseret. Der er dog nogle mangler i denne afhandling, som skal tages i betragtning før det kan bestemmes hvorvidt resultaterne af disse undersøgelser er faktiske resultater. En analyse viser bl.a. at begge studier var underdimensioneret i antallet af forsøgspersoner, derudover var undersøgelsen af NADA behandlingens effekt på kroniske smerte patienter ensidet, idet kontrolgruppen ikke kunne gennemføres grundet manglende mentalt overskud fra forsøgspersonerne. Sidst, var undersøgelsen af NADA akupunkturs effekt på raske unge forsøgsdeltagere randormiseret på en måde således at NADA gruppen kun bestod af kvinder.

2. Overall aim

This Master Thesis investigates NADA in an experimental and clinical setting. The primary goals are to determine (1) the initial and acute physiologic responses to NADA treatment in young healthy adults and (2) assess the effects of an 8-week voluntary NADA treatment program offered by Tværfagligt Smertecenter (TSC) Aalborg University Hospital to patients suffering from complex chronic pain.
The experimental study explored the effects of NADA on pain sensitivity and cardiovascular responses by assessing the pressure pain thresholds, blood pressure and heart rate before and immediately after NADA treatment. In addition, the subjective experience of NADA treatment, Quality Of Life (QOL) and personality were explored by questionnaires. The clinical study explored the QOL, personality and perception of pain at baseline and immediately following the 8 week NADA treatment. The results from the experimental and clinical studies are combined and discussed based on the qualitative subjective self reported quality of life and personality.

3. NADA- Minireview

National Acupuncture Detoxification Association (NADA) is a standardized protocol for auricular acupuncture, executed by insertion of five needles in each ear, where after the person is sitting for 45 minutes in a relaxed position[1]. The treatment is often applied two to three times per week, and continue as long as the receiving person wants it, often weeks to months[2]. NADA is, in many ways, similar to acupuncture, which has been used for thousands of years as a part of traditional Chinese medicine (TCM)[3]. TCM is based on the body to have an energy called Qi (pronounced Chee) that can be regulated by acupuncture through meridians in the body[4,5]. The NADA method is based on micro-acupoints also called somatotopic acupuncture, that can be stimulated through the point-associated organs. Both acupuncture and NADA acupuncture represent energies in the body, which can be stimulated by needles, heat or, pressure. This micro-system of the body can be equated with the homunculus of the brain (Figure 3.1A), and is found on feet, hands, and the external ear among others[4], from where different types of treatment procedures rely. Ear acupuncture, which also is based on this system in order to personalize a treatment, has over the past 50 years been used as a treatment in both migraine, pain management and psychiatric disorders[5]. Another micro-system based treatment option is Reflexology, which is based on the micro-system of the foot[5,6]. In Spanish does the word “nada” mean “nothing”, moreover, is NADA by practitioners also associated with the beginning sound of a word combined with the first step in a temple[7]. These two distinct definitions match what practitioners call “the spirit of NADA", and thus apply, that NADA treatment creates benefits by doing “nothing” and being “still”[7,8].

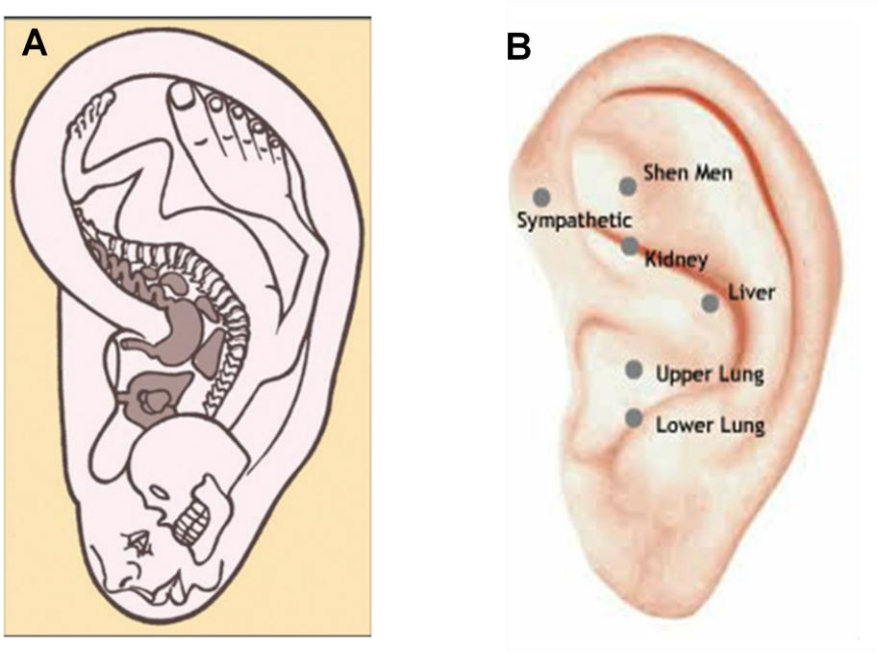

Figure 3.1 A) Homunculus of the micro-system of the ear and B) Schematic view of the five zones included in the National Acupuncture Detoxification Association protocol

History of NADA

The NADA acupuncture was developed as a standardized protocol in the Lincoln hospital, South Bronx, New York, in the 1970´s. The Lincoln hospital was city owned and the population included many lower-income people, why there was a need for alternative treatment to overcome drug related withdrawals[9]. The physician Michael Smith, was looking into acupuncture as a treatment and found inspiration from the Chinese neurosurgeon Wen, who had experienced that a combination of auricular acupuncture, specific acupoints on the body, combined with electrical stimulation had an effect on pain during surgery[10]. A hospital report by Smith and Khan, 1988, illuminates that NADA was explored in different combinations for more than a decade, and had about 200 daily sessions[9], when they found NADA to have great effect on both withdrawal symptoms, craving, relaxation, mental and physical functioning. Moreover, did Smith and Khan, 1988 find NADA to be more efficient when used as an adjunct to other treatments[9]. The organization NADA was founded in 1985 with the purpose of supporting and spreading the idea of using acupuncture as treatment in drug-addicted persons[9]. Today, NADA is provided in around 40 countries with an estimation of 25.000 providers worldwide. In addition, it is the most commonly used acupuncture in the treatment of drug addiction in the USA, UK, and Denmark[8,10].

The NADA method

The NADA method has not changed since being developed. It is based on five constitutive zones associated with different systems and organs of the body: Sympathetic, Shen men, kidney, lung and liver visualized in Figure 3.1B. These zones and the function hereof is in both western medicine and TCM associated with different types of functions and benefits. The sympathetic zone is associated with the autonomic nervous system, which also is referred to as “fight or flight” system. This zone reflects relaxation and analgesic effects on the internal organs due to blood vessel dilatations. Shen Men has a sedation effect and both inhibition and excitation of the cerebral cortex[11]. The third zone is the Kidney and that is associated with strengthening of the body, with a close relation to the adrenal glands[11,12]. The kidney is also associated with relief of headache and fatigue both mental and physical. The zone of the lungs can be parted into the upper and lower lung. Both address various respiratory conditions, analgesia and uncontrolled sweating. In addition, targeting of the lower lung, affect the autonomic nervous system through the auricular branch of the 10th cranial nerve (nervus vagus), which facilitates regulation of e.g. the gastrointestinal tract, cardiac tone, blood pressure and breathing[11,13]. In TCM kidney, lung and liver are associated with a psychological meaning as well. Kidney with self-control and coping with fear, Lung with grieving and liver with dissolving aggression[11].

NADA method in the literature

According to scientific literature, NADA is most often studied in populations suffering from drug addiction[14–16]. However, over the past two decades, there has been a growing interest in the NADA method, thus several studies have emerged. Especially, in the field of psychiatric treatment, where NADA acupuncture has been associated with improvement of conditions such as depression, anxiety, sleeping disorders and chronic pain[17–21]. A study by Black et al., 2011 investigated the

effect of three sessions of 45 minutes within two weeks of NADA treatment, compared to sham and relaxation, in people with anxiety provoked by substance abuse. Measurements on both blood pressure, heart rate and the degree of anxiety were performed prior to and post to NADA treatment, Sham or Relaxation. The findings showed a decrease in anxiety, but no differences between the groups. Moreover, no differences for neither blood pressure or heart rate were found[21]. The study by Black et. al, 2011 therefore does not find NADA to be different than either sham acupuncture or relaxation. In the literature, NADA has also shown to improve the measures well being, sleep, anxiety and the ability to contain control, while still feeling relaxed[7,21]. A study by Olsson and Landgren, 2020 explored the NADA method in comparison to meditation as an adjunct to the existing treatment in patients suffering from anorexia nervosa. The findings showed that patients experienced physical improvements in both stomach cramps and intense pain, thus, feeling more relaxed during meals. Furthermore, were the patients appreciated about the NADA acupuncture as pain relieving treatment instead of medication. The patients also reported to experience an improvement of their sleep, and in despite of resting challenges during the day, some patients also experienced to fall asleep during the NADA treatment[20]. Combined, these measures are all included in the definition of Quality Of Life, defined by the World Health Organization (WHO) who has defined QOL within four domains: Physical health, Psychological health, social relationships and environment[22]. Research indicate a correlation between NADA and the subjective feeling of wellbeing, which increases over time in life quality, depression, pain relief, anxiety and withdrawals after drug and/or alcohol addiction[16,20,23]. A qualitative phenomenographic study by Landgren et al., 2019 illuminates the aspect of NADA seen from the healthcare professionals in different types of psychiatric care, by interviewing them about their experience of giving NADA. A physician describes that patients receiving different kind of medicine for long periods without any effect, tries nada and then *"they are just sitting there, completely passed out!"*[17], and another healthcare professional says that, *"NADA acupuncture just feels like an extra tool in the toolbox, which even can be used instead of medication"*[17]. Furthermore, the healthcare professionals describe NADA to have an improving effect on QOL (sleep, anxiety, hyperactivity, depression and irritation), and reliving of symptoms in patients suffering from chronic diseases and finally, did the healthcare professionals experience a reduction in withdrawal symptoms from medication, alcohol and drugs[17]. These studies all reveal that NADA acupuncture is showing to have an subjective effect in humans.

NADA method and the scientific mechanisms of action

In the first description of the NADA method by Smith and Khan, 1988, it was suggested that the mechanisms of action behind NADA acupuncture were the modulation of neurotransmitters, and the regulation of the autonomic nervous system[9]. The scientific mechanisms behind NADA are not clarified thus, it is unknown how or if the NADA method is effective. A study by Kailasam et al., 2016 investigated the effect of the NADA method in a rat model. The rats had four days of repeatedly administration of either saline (control) or morphine followed by six days of abstinences. The two groups of rats were further allocated into two groups a NADA acupuncture and a Sham acupuncture group before receiving NADA or sham acupuncture once a day for six days, followed by a challenge dose of morphine or saline. The results showed that NADA treatment shortened the onset of morphine analgesia and prevented morphine tolerance in rodents[24]. These results suggest that NADA treatment may have an endogenous pain modulation effect. Furthermore, the study by Kailasam et al., 2016 indicates, that NADA treatment could be effective as an adjunct treatment to opioid analgesics in the treatment of chronic pain[24]. Another mechanism behind NADA acupuncture may be activation of the auricular branch of the of the vagus nerve. Vagal nerve stimulation has shown to be able to regulate both heart rate, blood pressure and the

gastrointestinal tract by regulation of the autonomic nervous system[25]. However, The study by Black et al., 2011 investigating NADA treatment, compared to sham and relaxation, in people with anxiety provoked by substance abuse, found no differences for neither blood pressure nor heart rate[21].

NADA Method and further research

When considering research of the NADA protocol, the study setup is to be considered. In the first article investigating the NADA method, Smith and Khan, 1988 indicate that NADA beside drug addiction also is beneficial in combination with other treatments including social reintegration and rehabilitation[9]. Furthermore, a consensus about the NADA method as a method which cannot "stand-alone" are seen among practitioners[9,21,26]. However, there is no evidence to support that it does not exert effects when applied alone or in combination. This challenge can be overcome by investigating the NADA method as an adjunct treatment to the existing treatment. Furthermore, is it a challenge to find a proper control group for assessing the effects of NADA. In general, control groups can be divided into three types: no treatment, sham acupuncture and, non-insertion sham acupuncture. However, studies within acupuncture in general are highly difficult to blind when using a non-treatment control group and independently of which type of control group, double-blinded is not an option in accordance to western medicine procedure[27]. Furthermore, it may be challenging to create a proper study setup with NADA has an adjuvant treatment, also due to the control group, which should be offered the same kind of treatment than the NADA group. In conclusion, this mini-review has highlighted the lack of knowledge about the NADA method. There are huge gaps in the research of NADA, both within the mechanisms of action but also about the validity of the NADA method. Therefore, further studies are needed, both with focus on the mechanisms of action but also in the research of the benefits, with the right study setup.

Acute physiologic effects of the NADA method on young healthy adults

Article 1, Experimental study

Abstract

Background: Chronic pain affects around 1 of 5 adults worldwide, and is usually treated with medication with poor effect and a lot of side effects. National acupuncture detoxification association (NADA) is a standardized five-point needles acupuncture method, which is used to ease several symptoms including anxiety, sleep, chronic pain, drug addiction, and depression.
Method: This was a randomized, controlled experimental study exploring the initiate and acute effect of NADA treatment or Rest, in response to two consecutive 45 minutes sessions divided by 24 hours. Measurements of heart rate, blood pressure and Pressure pain threshold (PPT) (tibia bone, musculus deltoid and musculus vastus lateralis (MVL)) were measured to explore whether endogenous pain modulation is a part of the mechanisms of action behind NADA acupuncture. Furthermore, self-reporting of quality of life and subjective experience of NADA treatment or Rest, were measured to explore the acute effect of NADA treatment or Rest.
Results: An increase in PPT for MVL was shown in session 2 and also a carryover effect from session 1 until session 2 for NADA group. For both NADA and Rest group, a decrease in PPT for deltoid muscle was found in session 1, and it remained decreased until sessions 2. Heart rate showed a rapid decrease within the first minute for both groups, an remained decreased.
Conclusion: in the NADA group was PPT found to increase in one out out three location sites, however, no further differences were seen between groups. Thus, NADA treatment was shown not to provide any new knowledge about neither the mechanisms of action nor the suggested benefits.

4.1. Introduction

In Denmark it is estimated that 825.000 of the population are suffer from chronic pain[28] and globally is it estimated to be one in five adults[29]. Chronic pain is defined as persistent or recurrent pain for more than 3 months[30] and occurs for various reasons e.g. trauma and disease. Further, chronic pain can be divided into simple and complex chronic pain. Simple chronic pain includes conditions which often can be treated with e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) on demand, and complex chronic pain includes conditions which have a multimodal treatment approach e.g. a combination of medication, lifestyle changes, alternative medicine, complementary, psychologic and physiologic therapy[31,32,33]. Moreover, complex chronic pain is correlated to psychosocial challenges[31]. One of the suggested mechanisms behind the multimodal treatment for complex chronic pain is to obtain pain relief through modulation of the pain processing system. Under normal conditions, tissue damage or potential damage initiate a noxious stimuli affecting the peripheral nerve endings, which transmit a signal through the nerve fibers to

the spinal cord. From here it is facilitated by opioid neurotransmitters to either inhibit or accelerate the signal to the thalamus, where it, again, is either inhibited or accelerated by opioid neurotransmitters to the affected area of the cortex and sensed as pain. This process is called endogenous pain modulation[34,35]. In addition, pain conditions e.g. neuropathic pain, are expressed by abnormal sensory processing, which means that the pain perception is either inhibited to a lower content than normal or accelerated to a higher content than normal. If a signal is accelerated it can induce non-painful stimuli e.g. light touch, to be perceived as painful (allodynia) or normal painful stimuli can be perceived as increased pain (hyperalgesia)[35–37]. When the signal is inhibited, a painful stimuli can be perceived as less pain (hypoalgesia). This is the role in endogenous pain modulation in the treatment of chronic pain[36]. Other systems of endogenous modulation are known, e.g. blood pressure (BP) and heart rate (HR), which both are affected by the autonomic nervous system´s modulation through neurotransmitters[25]. In the treatment of chronic pain, the central nervous system´s influence on pain perception is exploited, in the form of opioid targeted drugs, alternative medicine and physical training[35–37].

National Acupuncture Detoxification Association (NADA) is a standardized protocol using a five-point *(sympathetic, shen men, kidney, lung and liver)* needle acupuncture method in combination with relaxation, and may regulate endogenous pain modulating systems as a mechanism of action. NADA was developed in the 1970s in Lincoln hospital, New York. The primary goal of NADA, at the time of development, was to help patients overcome drug addiction[9,11]. An animal study in rats by Kailasam et al., 2016 investigated the effect of the NADA method in rodents, with morphine administered repeatedly, found that NADA treatment prevented morphine tolerance and shortened the onset of morphine analgesia in rodents[24]. However, it is unknown if these effects are the same in humans. Furthermore has a review performed by Couck et al., 2014 revealed that vagal nerve stimulation has an effect on pain modulation[25], thus, leading to an assumption that, the vagal nerve may be involved in the mechanisms of action in NADA acupuncture. The vagal nerve include auricular branches, which can be stimulated by acupuncture through the lung zone in the concheal area[14,7].
Recent studies indicate that NADA may be effective in the treatment of chronic pain, anxiety, depression and sleeping disorders[19,24,38]. A study by Black et al., 2011 explored the effect of the NADA method in comparison to both sham and relaxation in patients suffering from substance induced anxiety. This was explored within two weeks by three 45 minutes sessions of NADA acupuncture, sham or relaxation. Measurements on both BP, HR and the degree of anxiety were performed prior to and post to NADA treatment, Sham or Relaxation. The results showed that NADA acupuncture, sham or relaxation was not able to change either BP or HR, however, a decrease in anxiety post treatment was seen[21]. Even though the study by black et al., 2011 does not reveal a difference between NADA and the controls, it shows that NADA has an effect on anxiety. NADA acupuncture has also shown to improve benefits as well-being, sleep, and energy[7,17,19]. A study by Berman et al, 2004 investigated the subjective experience to NADA acupuncture in drug addicted prison inmates. The participants received NADA acupuncture two times a week for five weeks. The findings showed an experience of improvements in well-being, drug withdrawals symptoms and anxiety. Furthermore, some of the participants experienced a decreased HR and headache, and an increased relaxation and body balance[15]. These experiences is also a part of the definition Quality of Life, which has been defined by World Health organization (WHO)[22]. Combined, these studies leads to the need for further investigation of the NADA method

in humans, combined with an altered study setup in order to clarify, whether endogenous pain modulation is a part of the mechanisms of action. Moreover, to investigate the Whether QOL is beneficial improved by NADA acupuncture.

Another treatment recommended for chronic pain is exercise and physical activity, which, similar to NADA is associated with an improvement of patients QOL and a reduction in pain severity by endogenous pain modulation[32,37,39]. Studies have explored the effect of exercise by measuring Pressure Pain Threshold (PPT), which is a subjective measure used to investigate pain sensitivity. PPT is measured by an increase of a minimum pressure applied to the skin before being transformed to a painful stimuli. Furthermore, continuously increased HR has shown to activate the opioid system of the body, thus, endogenous pain modulation can be activated by the cardiovascular systems and further determined by tracking HR and BP[36,40]. A study by Veagter et al., 2015, investigated pain sensitivity during exercise compared with rest in healthy subjects, and found that exercise increases Pressure Pain Threshold (PPT) measures compared to rest alone[40]. These results indicates that endogenous pain modulation can be determined by using PPT measures in persons suffering from chronic pain.

Due to the very little knowledge about the physiological mechanisms behind NADA treatment this study will focus on understanding NADA effects in healthy participants. The aim of this study is to determine the initial and acute effects of NADA treatment on the cardiovascular system and pain sensitivity in response to two 45 min sessions of NADA treatment, separated by 24 hours, in young healthy adults, as compared to rest as a control. It was hypothesized that NADA will lower BP and HR and increase PPT to a greater extent than rest alone. Additionally, it was hypothesized that NADA would positively affect QOL.

4.2. Method

4.2.1. Overview and Participants

Eleven healthy participants recruited through Aalborg university participated in this randomized, controlled, pilot study (six in the NADA group). Participants were randomly allocated to receive two consecutive sessions of NADA treatment or rest for 45 minutes, separated by 24 hours. The two sessions had a duration of approximately 1.5 hours including: NADA treatment or Rest, questionnaire, and measuring of: PPT, BP and HR (see Figure 4,1). The questionnaires included questions about the QOL, personality and acute experience of NADA treatment or Rest
All participants received written and oral information about the study prior to the experiment, before giving consent to participating in this study.

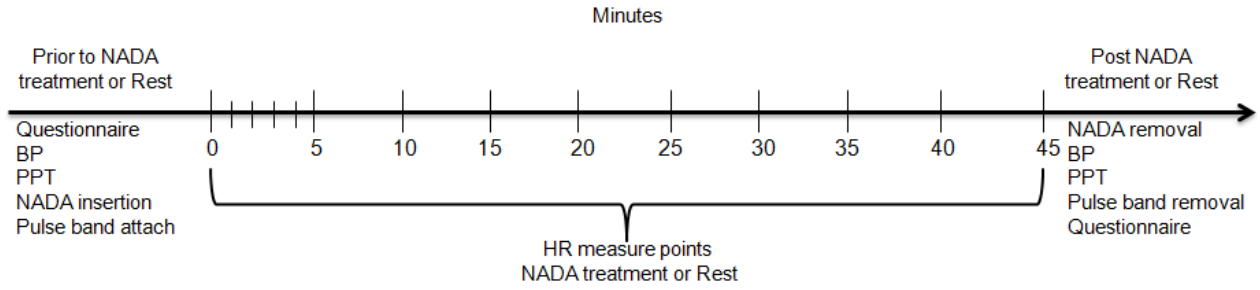

Figure: 4.1: Timeline of each session, for both session 1 and 2. Prior to NADA treatment or Rest, the participants filled out questionnaire, and measurements of BP and PPT were carried out and for the NADA group, needles were inserted before attaching pulse band below the chest muscles. HR was recorded every minute the first five minutes and afterwards every five minutes. Following NADA treatment or rest, Needles were removed in the NADA group. Measurement of PPT followed by BP was performed before fulfilling of the final questionnaire.

4.2.2. NADA Treatment

The protocol for NADA treatment was performed in accordance to the standardized protocol, a 5-point acupuncture method[11]. First, the subjects were shown how to clean both ears with an alcohol swab, to prevent infection. Starting from the cymba concha and following the edge around the inferior crura of antihelix, into the triangular fossa, before continuing into the concha to end the cleaning by swabbing around the edges and the center of concha (Figure 4.A).

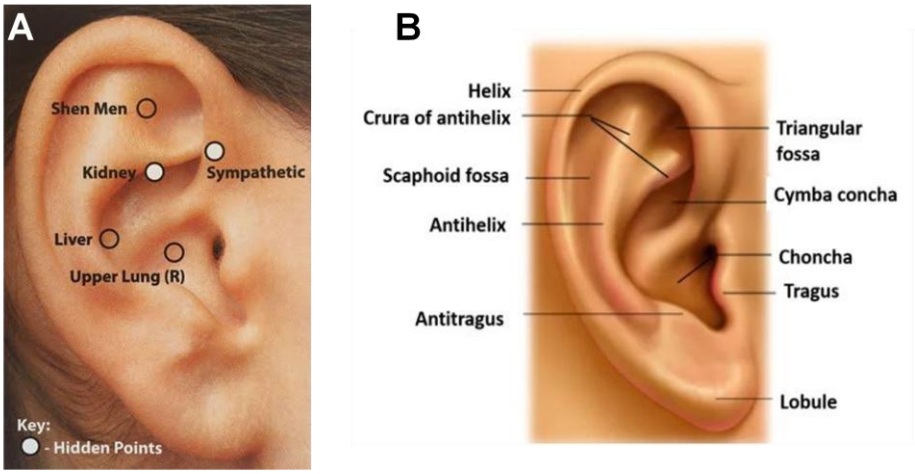

Figure 4.2: A) schematic view over the five zones included in the NADA treatment. Source: https://www.jdavila.us/auricular-acupuncture-nada B) outlining of the different structures of the external ear, which are included in the instruction of the cleaning of the ears before giving NADA treatment Source: https://anatomyga.com/external-auditory-meatus/.

The acupuncture needles (single used, sterile, silicone coated needles, (Sharpline, Denmark) (0.20 mm x 7 mm)) were then placed in the 5 points, in the following order: sympathicus, shen men, kidney, upper lung, and liver (Figure 4.2B)[11]. The subject was then placed in a resting position on a bed with a blanket to maintain a comfortable body temperature. Additionally, the participants were instructed not to talk or read during the Nada treatment or Rest. Needles were removed after 45 minutes and any eventual blood drops were removed with a cotton swab.

4.2.3. Cardiovascular assessments

Blood Pressure (BP)

Measurements of BP were performed prior to and post NADA treatment or rest, with the first measurement performed after fulfilling the first questionnaire, which provided the participant to sit relaxed for 5 minutes in order to get a more reliable BP. The participants were asked to fold their t-shirt on the right arm towards the shoulder, where the BP was measured with an electric monitor (OMRON M6 Comfort,HEM-7000-E (Omron HealthCare, Kyoto-shi, Kyoto, Japan)). BP was measured twice separated by one minute, and the average was determined and used for statistical analyses.

Heart Rate (HR)

The HR was measured using a pulse measure band (Polar F5 SWE (Polar Electro Oy, Finland)). The electrode area on the reverse side of the band was moistened to achieve better connection, before placing it firmly against the skin below the chest muscles. HR was measured throughout the 45 minutes of NADA treatment or rest, and recorded every minute during the first five minutes and every five minutes afterwards.

4.2.4. Pain sensitivity

Pressure Pain Threshold(PPT)

The PPT was manually determined using a handheld electronic pressure algometer (Wagner instrument, Greenwich, USA) with a probe on 1 CM^2. PPT was measured prior to and immediately after NADA treatment or rest. PPT was performed in three assessment sites of the dominant body side: Musculus Deltoidea, Musculus Vastus Lateralis and medial side of Tibia. In each assessment site, three locations separated by 1 cm were marked with a tattoo marker intended for

skin (Tombow ABT, Vietnam) prior to the measure, and remained until session 2, to ensure measurement in the same sites for both session 1 and 2. Application rate of PPT was approximately 50 kPa/s on each location and each site and PPT was then recorded offline. The participants were instructed to say “stop” as soon as the stimuli changed from a non painful to painful.
PPT was measured (without pause) both prior to (pre measure) and immediately after NADA treatment or rest (post measure). An average of the three PPT locations was determined and used to represent the PPT for each assessment site.

4.2.5. Subjective Assessments

Overall, the participants were asked to fill out two questionnaires each session (one prior to and one immediately after NADA treatment or Rest), to explore the QOL, personality and the acute experience of NADA treatment or Rest.

Quality of life (QOL)

The participants of this study were asked to rate 9 different aspects of QOL *(ability to fall asleep, sleep quality, stress, restlessness, mood, energy and power, wellbeing, happiness, and jobsituation)*. Rating was performed prior to each NADA treatment or Rest on a Numerical Rating scale (NRS) between 1-10, with 1 as lowest possible and 10 as highest possible rating of e.g. stress, to investigate the acute subjective changes in QOL e.g. Sleep, mood, restlessness etc. The 9 aspects were based on WHO´s definition of QOL[22] and already known improvements of NADA acupuncture[7,38].

Personality

Participants were asked to self-rate of eight personality *(Extrovert, introvert, spontaneous, organized, curious, unsociable, social and satisfied)* on a NRS between 1-10, with 1 as least possible and 10 as most possible e.g. extrovert. The ratings were assessed to determine homogeneity within the two groups.

Acute experience of NADA treatment or Rest

Immediately after NADA treatment or Rest for both session 1 and 2, the participants were asked how they felt during *(relaxed, comfortable, bored, fell asleep, restless or other)* and after *(relaxed, comfortable, bored, tired, restless or other)* NADA treatment or Rest. Moreover, the participants were asked how they experienced the 45 minutes of NADA treatment or Rest (short, medium or long time). Finally, participants were asked if they had experienced any physical sensation on their external ears during NADA treatment *(warmth, pricking, tickling, pain, or other)*. The above were

investigated in order to detect differences between the NADA and the Rest group and between session 1 and 2.

In Session 2, the participants were asked if they had experienced something unusual in the time between sessions, in order to avoid unexpected experiences to impact the questions about QOL. Additionally, they were asked how they felt between sessions *(same as usual, better than usual, worse than usual or other)* and they were asked to compare the experience of session 2 with session 1 *(better, worse, same, or other)*, in order to determine differences between NADA and the Rest group.

All questionnaires included in this study can be visualized in the supplementary material.

4.2.6. Statistics

The numeric data are presented as the mean and standard error of the mean, unless otherwise stated. Ordinal data are presented as persons in %. P values less than 0.05 were considered significant. Repeated measure Analysis Of Variance (ANOVA) was used to analyze changes over time and between groups for both: BP, HR, PPT measures had the sessions (session 1 and 2) and measures (prior to and post NADA treatment or Rest) as within-subject factor and groups (NADA and Rest) as the between-subject factor. For the QOL sessions (session 1 and 2) was the within-subject factor and groups (NADA and Rest) as the between-subject factor. Repeated measures ANOVA was followed by Bonferroni post hoc test for multiple comparison.
The acute experience of the NADA treatment or Rest was investigated by using Fisher's exact in a 2x2 crosstabs and a multi response crosstabs, to determine differences between groups (NADA and Rest). Independent t-tests were used to analyze homogeneity of the personality traits in the two groups. Bonferroni correction was used to correct for multiple comparisons.
The software SPSS Statistics version 25 (IBM SPSS Inc., Chicago, IL, USA) was used for statistical analysis in this study.

4.3. Result

4.3.1. Participants

This study included eleven participants, (eight women, no dropouts) divided into a NADA group (N=6) and Rest group (N=5) (see table 4.1). No adverse events were reported. Due to Covid-19 lockdown, the recruitment of participants was discontinued prematurely.

4.3.2. Cardiovascular Assessments

Blood Pressure

There was an overall main difference between NADA treatment and Rest in both the systolic BP (P=0.012) and the Diastolic BP (P=0.005). However, no significant changes between pre and post blood pressure measurements were observed for neither session 1 nor session 2 (Figure 4.3.1).

Heart Rate

No significant differences in HR were seen between NADA and Rest, neither for session 1 nor session 2 (Figure 4.3.2). However, a decrease in HR was detected between baseline and 1-minute during NADA treatment or Rest for both groups in session 1 (NADA group (P<0,001), Rest group (P=0,004)) and session 2 (NADA group (P=0,023), Rest group (P=0.049)). No further changes in HR were observed.

Table 4.1: Participant distribution of sex, age and BMI for both groups.

	NADA	**Rest**	**Average**
Male/Female	0/6	3/2	
Age (years ± SD)	25 ± 1.5	26.8 ± 4.1	25.9 ± 2.96
BMI ± SD	24.5 ± 4.8	26.2 ± 5.1	25.33 ± 4.74

Data is represented as Mean ± Standard Deviation (SD)

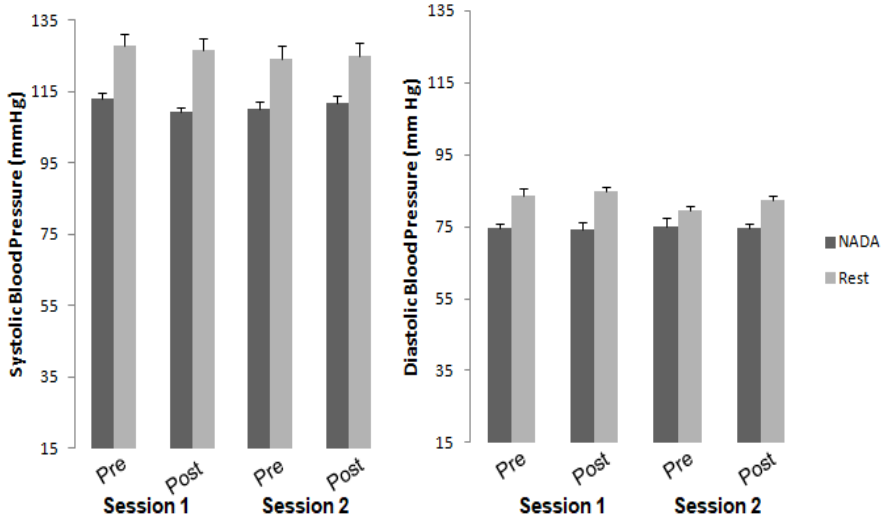

Figure 4.3.1: Average blood pressure measured prior to and immediately after 45 minutes of NADA treatment (N=6) or Rest (N=5) across two daily sessions A) systolic Blood pressure and B) diastolic blood pressure showing no differences between the groups (P>0.05). Blood pressure is presented as the mean mmHg and standard error of the mean.

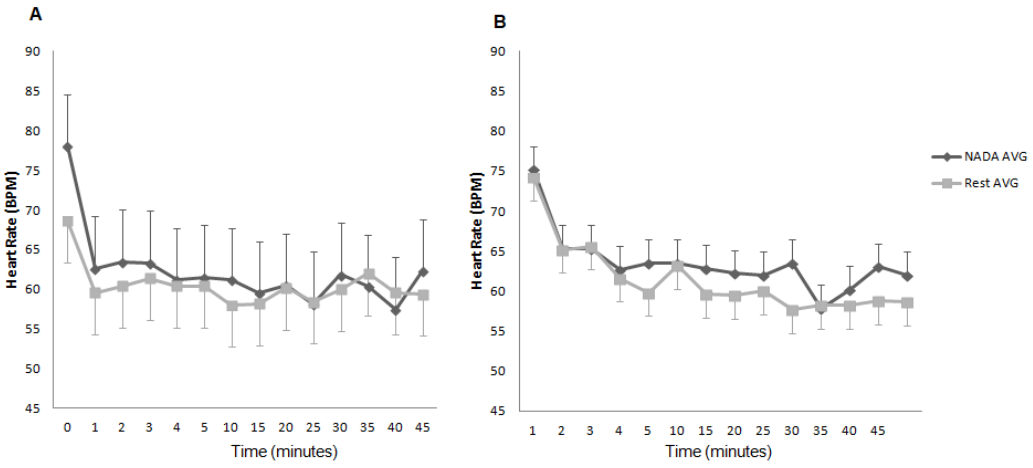

Figure 4.3.2: Average heart rate in response to two consecutive 45 minutes of NADA treatment or Rest across two daily sessions A) session 1 and B) session 2 showing no differences between the groups. A rapid decrease within the first minute in both sessions for both NADA group and Rest group (P<0.05). Heart Rate represented as the mean beats per minute (BPM) and Standard Error of the Mean

4.3.3. Pain sensitivity

Pressure Pain Threshold

The NADA-group, which consisted of women only, showed lower PPT than the Rest group in two of three test sites ($P<0.05$) in session 1, pre-measure. However, PPT was differentially altered in the NADA and Rest groups across muscle groups and sessions. The deltoid muscle, decreased in session 1 for both NADA and Rest group (Figure 4.3.3B, NADA-group $P=0.045$, Rest group P=0,022), and remained decreased until session 2, pre measure (NADA group $P=0.010$, Rest group $P=0.013$). An increase for the MVL muscle (Figure 4.3.3C, NADA group $P=0.046$) was seen in session 2. Additionally for MVL, a decrease was seen from session 1, pre-measure to session 2, pre-measure (Figure 4.3.3C, NADA group ($P=0.005$)

4.3.4. Subjective Assessments

Quality of life (QOL)

The QOL rating was generally high in this present study, as may be expected from healthy participants recruited at a university institution (Figure 4.3.4). However, a decrease from session 1 to session 2 was seen in Stress ($P=0.040$) for the Rest group and a difference between groups occurred in session 2 for Wellbeing ($P=0.004$). No further differences were seen in the QOL ($P>0.05$)

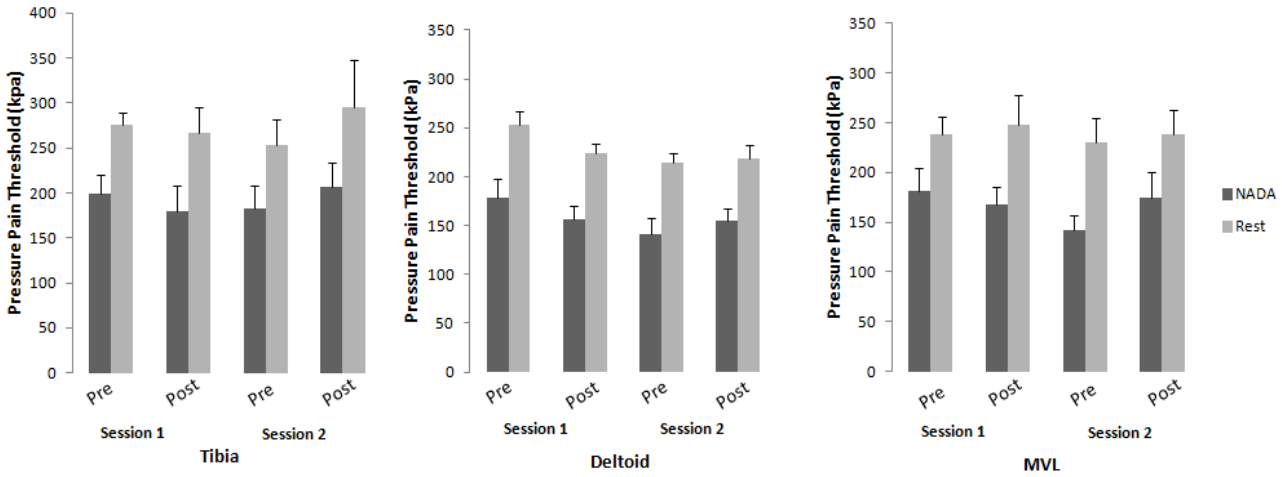

Figure 4.3.3: Average Pressure Pain Thresholds of A) Tibia bone, B) Deltoid muscle and C) MVL (Musculus Vastus Lateralis) measured prior to and immediately after 45 minutes NADA treatment (N=6) or Rest (N=5) across two daily sessions showing a increase between pre and post measure for MVL in session 2 (P<0.05), a decrease between pre measure, session 1 and pre measure, session 2 in MVL for the NADA group (P<0.05), a decrease between pre and post measure, session 1 in deltoid for both NADA and Rest group (P<0.05) and decrease between pre measure, session 1 and pre measure, session 2 in deltoid for both NADA and Rest group (P<0.05). Nor further differences were found, neither between NADA and Rest or between measures (P>0.05). Data are shown as mean kPa and standard error of the mean.

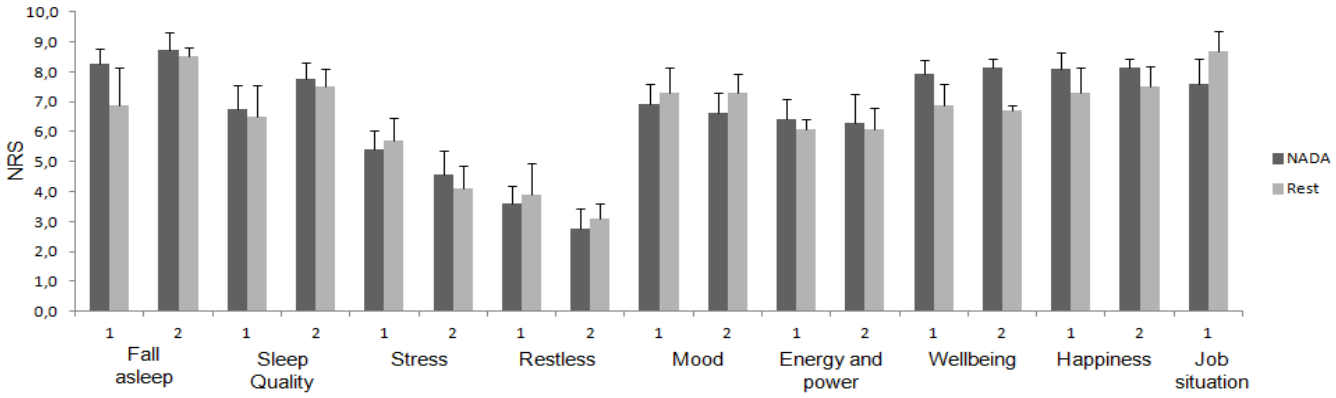

Figure 4.3.4: Average quality of Life characteristics in response to two consecutive 45 minutes of NADA treatment (N=6) or Rest (N=5) across two daily sessions (1 and 2), showing no differences between groups. Quality of life is presented as mean value from a Numeric Rating Scale (NRS) from 1-10 (1=lowest possible, 10=highest possible rating) and standard error of the mean.

Personality

Analysis of the self-reported personality traits in the NADA and Rest group found P>0.05 in all eight parameters. Thus, it was assumed that the two groups were homogeneous.

Acute experience of NADA treatment or Rest

There were no differences between how the participants felt during or after NADA treatment or Rest. Furthermore, no differences were seen in their rating of the duration time for either session 1 or 2 (P>0.05), assessed by post NADA treatment or Rest questionnaire. For the physical sensation, there was a difference between NADA and Rest group (Fisher's exact; Session 1 P=0.002, Session 2 P=0.015) (Figure 4.3.5). The Rest group had no physical sensation on their ears compared to the NADA group who both experienced warmth, pricking and pain in their ears during NADA treatment. Finally, no participant reported to have experienced anything unexpected between the two sessions, and 17 % of the NADA group reported the time between sessions to be better than usual. The remaining participants reported the time between sessions to be "same as usual" (Figure 4.3.6). A comparison of session 1 and 2 showed that there was no difference between NADA and Rest (fisher's exact, P=0.80).

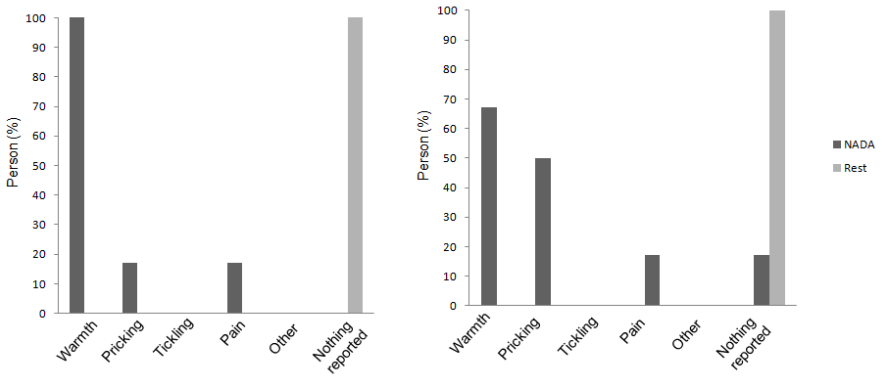

Figure 4.3.5: Percentage persons experiencing a physical sensation during to two consecutive 45 minutes of NADA treatment (N=6) or Rest (N=5) across two daily sessions A) session 1 and B) session 2 showing a difference between groups (P<0.05)

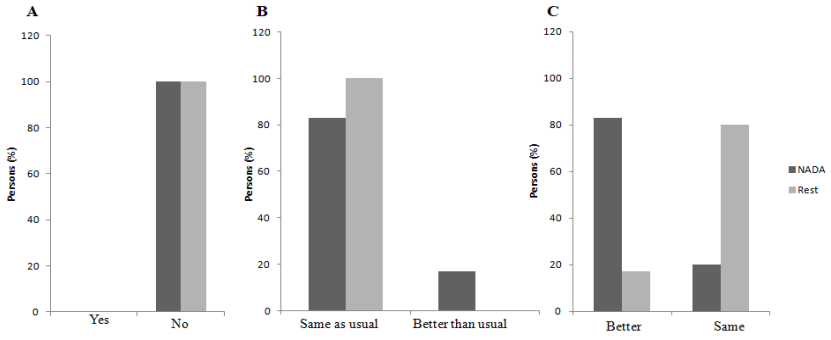

Figure 4.3.5: Percentage persons in response to two consecutive 45 minutes NADA treatment (N=6) or Rest (N=5) showing similar responses to A) if they have experienced something unexpected between session 1 and 2 and how they B) would describe their time between session 1 and 2 and, C) a comparison between groups in how they experienced sessions 2 compared with session 1, showed a tendency towards NADA groups to have a better experience than the Rest group, but no differences were found (P>0.05).

4.4. Discussion

This study showed an increase in MVL for session 2 and a decrease between pre measure, session 1 and pre measure, session 2 for the NADA group. For both NADA and Rest group a decrease in session 1 was seen for the Deltoid Muscle, and it remained decreased until session 2. Moreover, the NADA group reported a statistically higher incidence of physical sensation on their ears during NADA treatment. No further differences were seen between the pre and post measure in PPT and BP for session 1 and 2. Furthermore, no differences were found between NADA and Rest group for PPT, BP, HR or QOL. A limitation of this study was that the random allocation resulted in the Nada group to consist of women only.

This was the first study to investigate the mechanisms of action behind NADA acupuncture. Resting HR can be measured with a normal range between 50-90 beats per minute, with a decrease at nighttime compared to daytime[41], which can be reflected in this present study. Although no differences between NADA and the Rest group were found for the HR measures, a rapid decrease within the first minute was found in both groups (NADA and Rest) and sessions (1 and 2). This could lead to an assumption that laying on a bed in a resting position, with or without NADA, might induce the sensation of nighttime. Another explanation is that HR was increased to a higher a level than normal resting HR due to the PPT measures prior to NADA treatment or Rest. Pain has shown to increase sympathetic nervous system, and thereby the HR[42]. This result is also consistent with the results found in the article by Black et al., 2016 who measured HR prior to a post three sessions of either NADA treatment, sham or Relaxation, and found HR to decrease in each session. However, no further differences were seen, neither between groups or between the three sessions. Therefore, NADA does not appear to acutely alter resting HR, However, the study in drug addicted prison inmates experienced a decreased HR after five weeks NADA treatment program[15]. This may indicate that non-normal HR can be decreased, however, the study by Berman et al, 2004 did not measure the HR, thus, it is unknown whether this finding was only a subjective experience.

A main difference between NADA and Rest groups were seen for all BP and PPT measures (prior to and post NADA treatment or Rest, for both session 1 and 2) towards the Rest group having a higher BP and PPT than the NADA group. A study by Wiinberg et al., 1995 investigated 24-hour BP in “Normal Danish subjects”[43], and found that BP increases with age and that men generally have a higher blood pressure than women. Another study by Petrini et al., 2015 investigated PPT in both young and elderly healthy people, and found young women to have lower PPT measures than young men, however, no differences were seen for the elderly.[44]. Thus, the differences in PPT observed in this present study may be wholly or partially due to gender differences rather than NADA treatment alone, as the NADA group was 100% women and the Rest group 40% women. Although in this study, an inspection of a gender effect is not possible since there are only a few men in the study cohort.

Even though, NADA has been used for the past 50 years, it is still not certain how or which parameters that affect the QOL, though one thing is certain, the patients and practitioners of NADA do agree that NADA acupuncture improve QOL in both sleep, wellbeing, relaxation, energy and anxiety[2,17,20]. However, this present study was not able to confirm those benefits.

There has been an increased interest in the NADA protocol over the past decades, thus leading to investigation of the method and its benefits. This has included different types of study designs in order to make the best fit for evidence based medicine in the pharmaceutical industry[27]. This present study has focused on Rest as a control, which also can be categorized as non-treatment. Other studies have used both non-treatment, non-insertional sham or insertional sham. A review by Chen et al., 2016 investigated the outcome of the three mentioned controls (in general acupuncture in the treatment of pain) and found: 84 % non-treatment controls, 53 % non-insertional sham, and 38 % insertional sham of the reviewed studies had positive outcome[45]. These results can lead to the assumption that a possible nocebo effect exists. In this present study a non-treatment group was used, however, no differences were found, so in this case it is difficult to either confirm or reject the presence of a possible nocebo effect.

No differences were found in the acute effect of the QOL, whether this is due to the fact that the participants in this study is healthy young participant, with a general high score of QOL is unknown. In comparison to other studies investigating the NADA method, all were investigating a patient groups enrolled in a treatment program over a longer period [15,17,19]. This may indicate, NADA acupuncture has a better effect over time.

4.4.1 Limitations of the study:

This study was a first of a kind pilot study, exploring the effect of two sessions of NADA treatment divided over two days. Due to the fact that no differences were seen, a power calculation was made, to determine if the study was sufficiently powered. A power calculation was therefore made with $\alpha=0.05$, $\beta=0.80$ and the effect was calculated to be Effect=0.19. This showed that this study should have included 58 persons in order to see any effect of the NADA treatment compared to Rest.

The PPT were measured three times on each spotsite in a row without a break, if the participant were sore after the first measure, they had no time to recover before the next pressure was applied. Therefore, it is suggested that a short break of 1 minute between measures should be applied to limit any possible soreness.

The participants received information prior to the study, which explained that they on experimental day would receive either NADA or Rest, however, for future analysis it would be suggested to instead recruit participants on the behalf that they are going to receive Rest with or without NADA. This is suggested in order to reduce any possible nocebo effect. A study by Black et al., 2016 allocated the participants into three groups before giving information of the study thus, the participants were only given information about their group and were unaware about the fact that there were one actual treatment group and two control groups[21].

The participants in this present study received NADA acupuncture individual why it can be considered whether it is a true study of the NADA protocol, due to that NADA has constructed the protocol on the basis that it is given in groups[46].

4.5 Conclusion

This study found NADA treatment to increase PPT between the pre and post measure in session 2 and between pre measure, session 1 and pre measure, session 2 for MVL. Furthermore, PPT for both NADA treatment and Rest decreased pre and post measure in session 1 from where it remained until session 2. A rapid decrease was seen for HR within the first minute. However, no difference between the NADA and Rest group were revealed. No further differences were found for either PPT, QOL, HR or BP neither between NADA and Rest nor session 1 and 2. In conclusion, this study was not able to determine NADA acupuncture as more efficient than Rest in the initial or acute response to two 45 minutes sessions in healthy young adults recruited from a university institution. Thus it still remains unclear which mechanisms may underlie the benefits of the NADA method.

4.6 Future perspectives

For future studies it is suggested to include more participants, due to the fact that this study was underpowered and thereby is it uncertain whether it is a false or true result. Furthermore, it would be interesting to expand the NADA treatment with more sessions, in order to explore whether the effect on MVL and deltoid muscle seen in this study can be expanded to cover the other PPT spots over time. Another suggestion, is to use the Lower-Lung-point instead of the Upper-Lung-point. This is due to the advantage of the auricular branch of the vagal nerve, which are believed to be directly attached through the Lower-Lung-Point[47]. Furthermore, vagal nerve stimulation has been proven to have an analgesic effect and influence on both HR and BP[25]. Thus, this could be interesting to investigate whether this is the fact that makes the difference in the NADA method.

The influence of NADA on patients suffering from complex chronic or recurrent pain

Article 2, Clinical study

Abstract

Background: Complex chronic pain is a condition which affects the patients in more ways than just the perception of pain. Co-morbidities including depression, anxiety, sleeping problems, stress, lowered social activity etc. often occur, and makes it a great challenge to overcome and remain a life with high quality. One suggested method which is used to ease both chronic pain, stress, sleeping problems and anxiety, is the National acupuncture detoxification association (NADA), a standardized five-point needles acupuncture method. Tværfagligt smertecenter (TSC), Aalborg university Hospital has through the past years offered NADA acupuncture to patients suffering from chronic pain

Method: Patients at TSC were recruited (N=9) on a voluntary basis to receive NADA acupuncture as an adjunct treatment to the existing program or/and participate in this study. rating of pain perception, quality of life and personality were done at baseline and following an 8-week treatment program. to explore any changes and to determine a possible correlation between personality and quality of life. Furthermore, Questions about the use of medication were asked to determine any possible changes.

Result: A correlation between sleep quality and the personality trait organized, and a decrease in the personality trait spontaneous were shown. No further differences revealed between baseline and post treatment questionnaire for either pain perception, quality of life nor personality. Finally, no further correlation between quality of life and personality were seen
Conclusion: This study was not able to confirm an 8-week NADA treatment program in persons suffering from complex chronic pain is sufficient to improve life quality and lower pain perception.

5.1 Introduction

Pain is an unpleasant, emotional, subjective, sensation arising from the body in order to prevent injury or damage to the tissue and the organs[34]. Under normal conditions, tissue damage initiate a noxious stimuli affecting the peripheral nerve endings, which transmit a signal through the nerve fibers to the spinal cord, from where it is transmitted to the thalamus, and further to the affected area of the cortex, where it is sensed as a noxious stimuli[34,35]. In addition, the travel of the noxious stimuli is facilitated by endogenous modulators e.g. neurotransmitters as opioids which either inhibit or accelerate the stimulation[25]. Pain can also occur as a condition e.g. neuropathic pain, which is expressed by abnormal sensory processing and can be either persistent or recurring[35]. Abnormal perception of pain can be due to abnormal facilitation of neurotransmitters leading into highly sensitive conditions where a stimuli which normally do not provoke pain is perceived as

painful (allodynia), and stimuli which normally provoke pain, are increased leading to the an increased perception of the stimuli (Hyperalgesia)[35]. Over time it can lead to the development of chronic pain, defined by the World Health Organization (WHO) as *"persistent or recurrent pain for more than 3 months"* [30]. In Denmark it is estimated that 825.000 of the population are suffering from some kind of chronic pain[28] and worldwide is it 1 out of 5 adults[29]. Chronic pain can be divided into two subgroups; Simple chronic pain and complex chronic pain. Simple chronic pain, includes conditions which often can be treated with e.g. Non-Steroid Anti-Inflammatory Drugs (NSAIDs) on demand, and complex chronic pain, which often requires a multidisciplinary treatment including medication, lifestyle changes, alternative medicine, complementary, psychological and physiologic therapy[31,32,33].

Multidisciplinary treatment takes into account that chronic pain often is complicated by decreased quality of life (QOL) including sleeping problems, social retainable and affected mood combined with insufficient coping strategies[22,31]. Treatment with medication is often opioid targeted medication like morphine, methadone, tramadol etc, which results in several side effects including pain, medical tolerance, addiction, sedation and nausea among others[34,46,48]. The mechanism of action behind these drugs are to inhibit the neurotransmitter in the neurons thus, inhibit the pain signal and thereby prevent perception of pain[35]. To overcome the challenges in treating chronic pain, many patients look into the alternative medicine as an adjunct to existing treatment[49]. One option is the National Acupuncture Detoxification Association (NADA), which is a standardized protocol using a five-point *(sympathetic, shen men, kidney, lung and liver)* needle acupuncture method combined with relaxation[11].

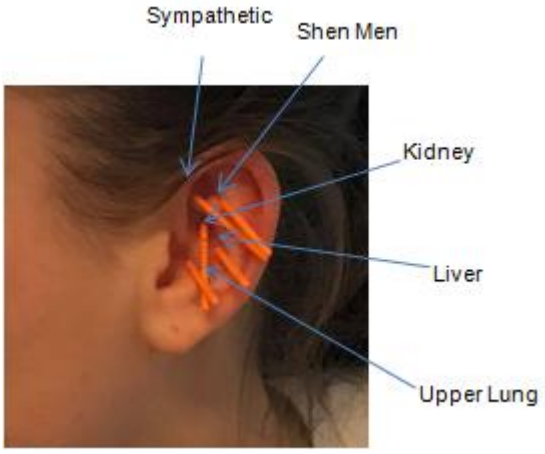

Figure 5.1: Person receiving NADA acupuncture in accordance to the standardized 5-point needle acupuncture method.

NADA was developed in the 1970s in Lincoln hospital, New York and the primary goal at the time of development, was to help patients overcome drug addiction[9,11]. An animal study in rats by Kailasam et al., 2016, showed that NADA treatment was effective in preventing morphine tolerance and that it could alleviate morphine-induced locomotor sensitivity in rats. Moreover, it was suggested to improve side-effects caused by morphine and other opioid medications[24]. The literature about the effect of NADA acupuncture in chronic pain is sparse, thus, it is unclear whether the results found in the article by Kailasam et al., 2016 also applies to humans.

Studies over the past two decades have primarily focused on the effect of NADA acupuncture in drug addiction. NADA has since been extended to the treatment of other conditions including depression, anxiety, sleeping problems and anorexia[18–21]. Several studies also refer to NADA acupuncture as effective in chronic pain relief[19,38,46], nevertheless, is the literature n NADA acupuncture in Chronic pain very sparse. An article by Kurath-Koller describes that an adolescence suffering from phantom pain receives NADA acupuncture two times a week over a period (unknown). The article reveal that the adolescence is improving in both pain perception, well-being and energy[19]. Furthermore, has a survey study of practitioners offering NADA acupuncture obtained by Stuyt et al., 2018 found that one practitioner, by using questionnaires after NADA acupuncture, discovered that 80 % of persons suffering from chronic pain reported pain relief and improvements in self esteem and wellbeing[38]. These studies leads to further investigation of NADA acupunctures effect on chronic pain patients, due to the fact that chronic pain patient often experience a lowered QOL. Beside the above studies, NADA acupuncture has shown to improve QOL by improving well being, sleep, anxiety and the ability to contain control, while still feeling relaxed[7,21]. Combined, this leads to the suggestion that NADA acupuncture should be considered when looking into chronic pain, due to the co-morbidities including increased risk of depression, lowered QOL and development of addiction or tolerance to medicine[24,46]. Another consideration when looking into QOL is personality. Research has shown that personality can be compared to different conditions. Personality is a mixture of genetics and experiences through life, with the childhood and adolescence as the most open period for modulation. Recent research indicates that personality change in correlation to both cognitive treatment, life experience and across life courses[50,51].

Due to the very sparse knowledge about how NADA acupuncture affects patients suffering from chronic pain, this study will focus on understanding the subjective experiences hereof. The aim of this study is to determine the effect of NADA acupuncture on QOL, personality and pain perception in response to an 8-week NADA treatment program, including two treatments per week, in patients suffering from complex chronic pain attending a Center of Complex Chronic Pain clinic. It was hypothesized that NADA will improve QOL and decrease pain perception after the 8-week treatment program as compared to a control. Additionally, it was hypothesized that changes in personality would be correlated to changes in QOL.

5.2 Method

5.2.1 overview and patients

This study was designed as an observational, controlled, prospective cohort, pilot study, where the patients were included based on their wishes to receive NADA treatment and/or participate in the study. However, the control group was not formed due to the fact that the patients did not have mental profits to participate in the study. Additionally, three of nine patients did not fully complete the NADA treatments in the 8-week treatment program (last three treatments) due to Covid-19 lockdown.

Nine patients suffering from complex chronic pain agreed to participate and were recruited through Tværfagligt smertecenter Aalborg university Hospital (TSC). All patients were naive to the NADA method and were new patients attending the TCS. In accordance to standard treatment at TSC, patients were offered standard treatment (treat as needed) plus two 45 min group-sessions of NADA treatment, twice a week for eight weeks. Prior to and following the 8-week program the patients were asked about their QOL, personality, perception of pain and use of medication (Figure 5.2) to determine the subjective effect of NADA as a complementary treatment. All patients received oral information about the study at their first visit at TSC, before providing their written consent to participate.

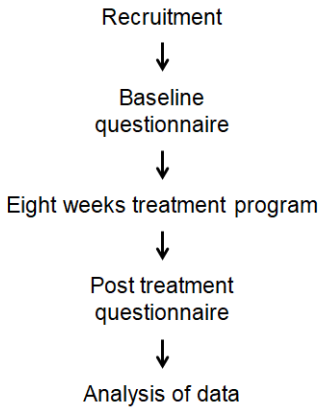

Figure 5.2: Timeline and structure of the observational study.

5.2.2 NADA Treatment

NADA treatment was performed as a group session in accordance with the NADA protocol´s five-point acupuncture method[11]. Both ears were cleaned with an alcohol swabs to prevent infections, followed by insertion of acupuncture needles (single used, sterile, silicone coated needles (0.20 mm x 7 mm)) in the five points: sympathetic, shen men, kidney, upper lung, liver[11]. The patients were then placed in a seated relaxed position with a group of patients receiving NADA. Additionally, the patients were instructed not to talk during the Nada treatment. Needles were removed after 45 minutes and any eventual blood drops were removed with a cotton swab.

5.2.3 Subjective assessments

The Patients were asked to fill out two comparable questionnaires, one at Baseline (Baseline questionnaire) and one after eight weeks treatment program (post-treatment questionnaire). The questions included multiple choice and Numeric rating scale (NRS), and included questions about self reported pain perception, QOL and personality, to investigate if NADA treatment in patients suffering from complex chronic pain has any subjective effect on life quality, pain and personality.

Baseline and Post-treatment questionnaire

At baseline, the patients were asked if they had any experience with NADA *(Yes/No)*, why they agreed in receiving NADA *(Confidence that it works, I know one who had benefit from NADA, curious, no adequate pain relief is known, other)* and if they have got a diagnosis *(yes/no)* and which diagnosis if yes. In addition, they were asked about the total duration of their chronic pain *(five years interval)* and if they received permanent treatment with medication *(Morphine, Over the Counter(OTC), other)*, if yes, they were asked about the treatment period *(< six month, >six month).* Finally, questions were asked about medication type *(morphine, OTC or other)*, frequency of medication on demand *(never, daily, weekly, monthly)* and, whether the treatment was adequately pain relieving.
The post-treatment questionnaire included questions about the patients experience of NADA treatment; if they liked NADA *(yes/no/do not know)*, if they wanted to continue if possible *(yes/no/do not know)*, and if they have experienced a change in their pain within the eight weeks NADA treatment *(less pain, more pain, or unchanged)*.
The patients were asked if they after the eight week NADA treatment program received permanent treatment *(Morphine, OTC, other)* and if dose had changed *(escalation, withdrawal or unchanged)* the past eight weeks. Finally, questions were asked about type *(morphine, OTC or other)* and frequency of medication on demand *(never, daily, weekly, monthly)* and, if the treatment is adequately pain relieving.

Pain perception

Pain was assessed using a short form of the Danish version of McGill pain questionnaire (MPQ)[52] at baseline and upon conclusion of the 8-week treatment. The MPQ included: 1) Rating of their current pain, worst pain and least pain on VAS between 1-10, with 1 as least possible and 10 as most possible pain. 2) Pain Rating Intensity Score (PRI) using ranking in four different dimensions *(sensory, affective, evaluate, miscellaneous)*, represented by twenty subgroups each consisting of 1-3 words. The patients were instructed to choose the words describing their pain, but maximum one word from each subgroup. The words in the subgroups were ranked from 0-1 (0-100 %) eg. 1/3=0.33 (33 %), and a sum score was calculated for each dimension and the total score. 3) A drawing of the human body in two dimensions, where the patients were told to draw the areas affected by pain. Moreover, the patients were asked to describe the temporal nature of their pain from eight various statements *(short, immediate, passing, rhythmic, periodic, sporadic, continuous, constant).*

Quality of Life (QOL)

The Patients were asked to rate eight different characteristics of QOL *(sleep, sleep quality, stress, restlessness, mood, energy and power, Social activity, physical activity (daily chores))*. Rating was performed at both baseline and after the 8-week NADA treatment program on a NRS between 1-10, with 1 as the lowest possible and 10 as the highest possible e.g. stress level, to determine any possible changes in QOL. The eight characteristics were based on WHO´s definition of QOL[22] and already known improvements of NADA treatment[7,11].

Personality

Personality was explored by self-rating of eight personality traits *(Extrovert, introvert, spontaneous, organized, curious, unsociable, social and satisfied)* on a NRS between 1-10, with 1 as least possible and 10 as most possible e.g. organized, to determine any possible changes in response to the 8-week NADA treatment program and correlation with QOL.

All questionnaires included in this study are attached in the supplementary material.

5.2.4 Statistics

All numeric data were analyzed for normality using Shapiro-Wilks test. Numeric data are presented as mean with standard error of the mean and ordinal data are presented as number of patients. $P<0.05$ were considered significant. Changes over time for QOL, personality and pain perception were assessed using paired t-test (normal distributed data) and Wilcoxon signed-rank test (non-normal distributed data). In addition, a Bonferroni correction was used to correct for multiple comparisons.
Multiple response questions of pain perception were analyzed using multiple responses crosstabs, Chi-Squared. Medication use, pain relief and subjective measures were analyzed using Wilcoxon signed-rank test.
The software SPSS Statistics version 25 (IBM SPSS Inc., Chicago, IL, USA) was used for statistical analysis in this study.

5.3. Results

5.3.1 Overview and participants

Patients were recruited for this study between December, 2019 and March 12, 2020 (the date for the Danish lock down due to Covid-19). nine patients suffering from complex chronic pain were

enrolled in this study, seven patients completed the program, and due to Covid-19, three patients were incomplete in the 8-week NADA treatment program and two patients had to drop out. No adverse events were reported.

5.3.2 Subjective Measurement

Baseline assessments

All patients included in this study were naïve to the NADA method, and had a diagnosis prior to the referral at the TSC, diagnosis included: Fibromyalgia, chronic pain, hypermobile, osteoarthritis, endometriosis, joint lip rupture (hip) and chronic tenosynovitis. Patients reported pain duration between <5 years and 15 years and similar usage of medication (Morfin P=0,059, Other medication P=0.368) as shown in Table 5.3.1.

Post treatment assessments

Six out of seven patients reported to have liked the NADA treatment, and five out of seven would, if possible, like to continue. In addition, no changes were found in the reported use of medication (Morphine P=0,368, Other medication P=0.129), and five out of seven reported their pain to be unchanged (Table 5.3.1) No differences between baseline and post treatment questionnaire for adequate pain relief was revealed (P=0.096). One patient reported to have an increased pain due to Covid-19 lockdown of all treatment options, both physical and mental therapy.

Pain perception

No differences were found between baseline and post-treatment questionnaire, for neither current, worst, or least pain (Figure 5.3.1), as well as PRI (Figure 5.3.2) or the temporal nature of their pain (Figure 5.3.3) (all P>0.05). Finally, no differences between Baseline and Post-treatment questionnaire revealed any differences in the percentage of the body affected by pain.

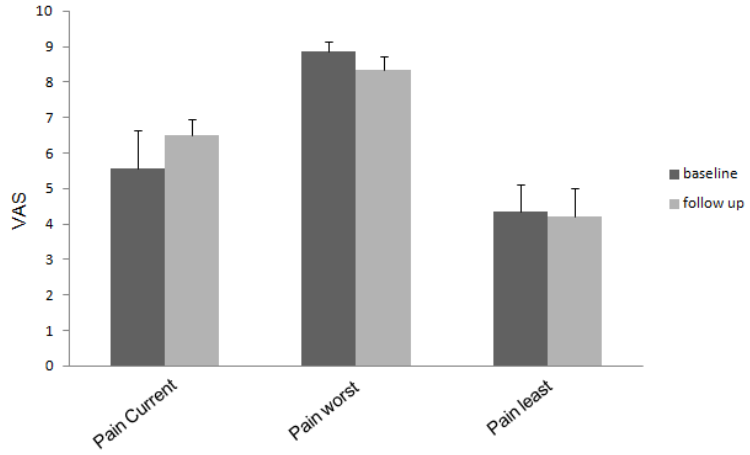

Figure 5.3.1: Average rating of the current, worst and least pain in response to an 8-week NADA treatment program showing no differences (P>0.05). The pain rating was rated on a Visual analog scale (VAS) by the patients in the NADA group (N=7), at both baseline and post treatment questionnaire. Ratings are shown as mean and Standard error of the mean.

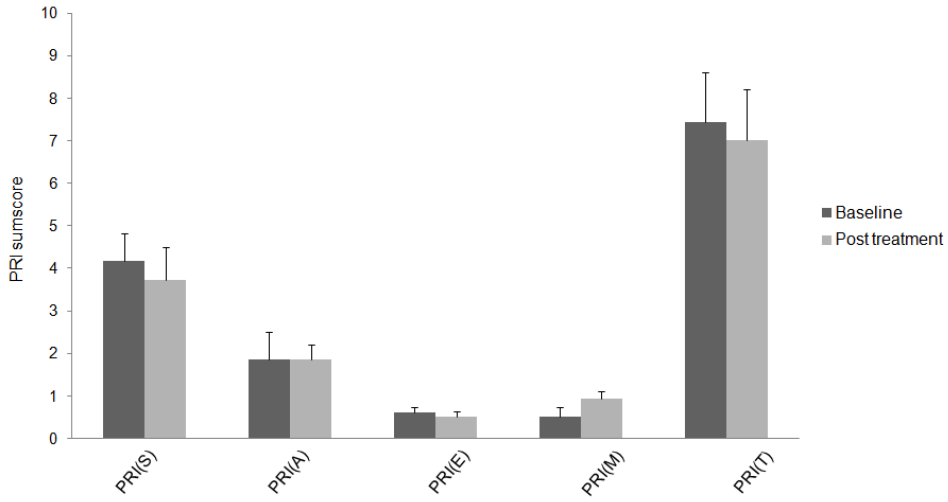

Figure 5.3.2: Average Pain Rating Intensity (PRI) in response to an 8-week NADA treatment program showing no differences (P>0.05) in the four dimensions Sensitivity (S), Affected (A), E (Evaluate), M(Miscellaneous) and the overall score (T). PRI included 20 subgroups including 1-3 questions each ranked from 0-1. PRI are presented as mean and standard error of the mean.

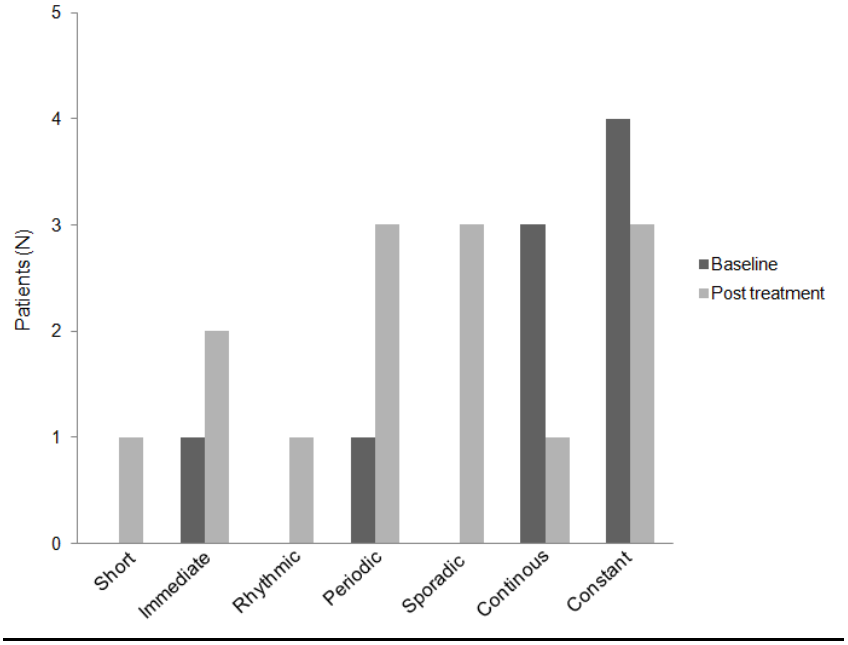

Figure 5.3.3: Patients (N) describing the temporal nature of their pain, in response to a 8-week NADA treatment program showing no differences (P>0.05) between baseline and post treatment questionnaire.

Quality of Life

In overall, no differences were found for any of the characteristics in the QOL (Figure 5.3.4) as assessed through the baseline and post treatment questionnaires.

Personality

According to the personality questionnaire, patients reported being less spontaneous following the 8-week NADA treatment period (P=0.014). However, no other changes were revealed in their personality (Figure 5.3.5). The difference between baseline and post treatment personality trait organized and the difference between baseline and post treatment QOL characteristic sleep quality was correlated (r= -0.897, P=0.006). No further correlations were found for the difference between baseline and post treatment personality traits and QOL characteristics.

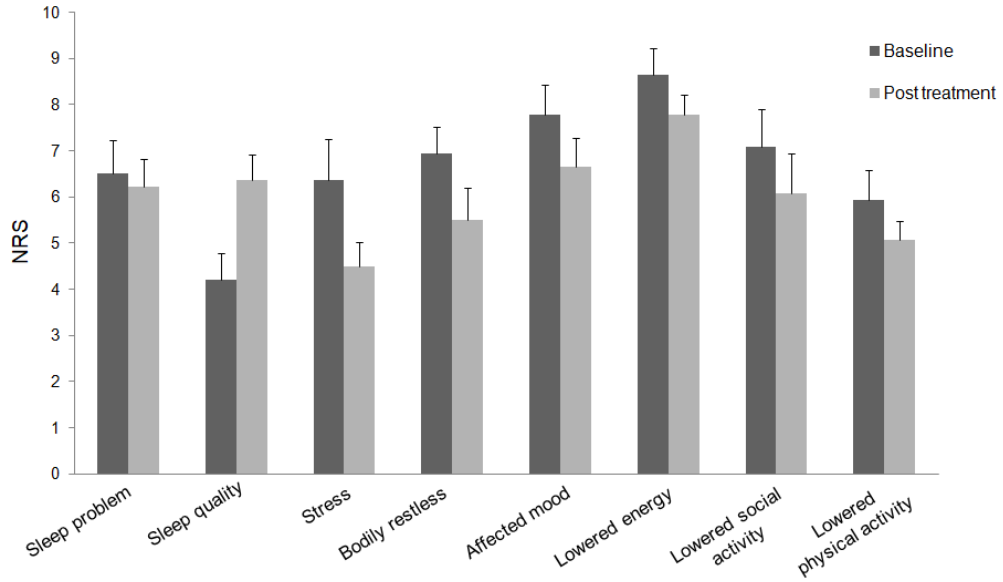

Figure 5.3.4: Average quality of life in response to a 8-week NADA treatment program showing no differences (P>0.05) between baseline and post treatment questionnaire. Quality of life was rated on a Numerical rating scale (NRS) by the patients in the NADA group (N=7). Data are shown as mean and Standard error of the mean.

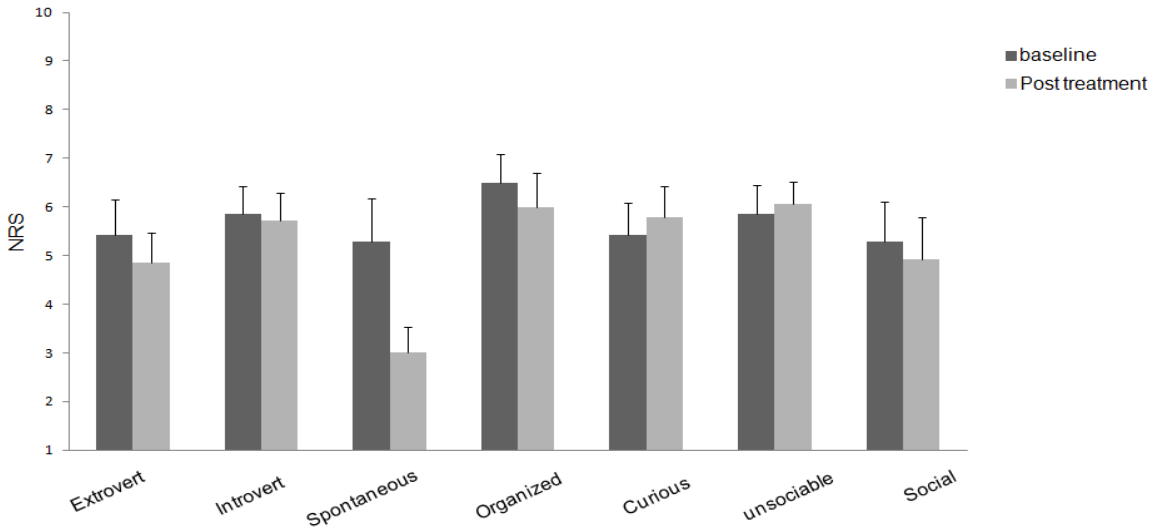

Figure 5.3.5: Personality rated on a NRS (Numerical rating scale) by the patients in the NADA group (N=9/7), at both baseline (number 1) and follow up measurement (number 2). Data are shown as mean and Standard error of the mean.

Table 5.1 Characteristics of the patients showing the total duration of their pain condition as assessed by the baseline questionnaire. Further, does it show the medication use and if the patients experience adequate pain relief as assessed by both baseline and post treatment questionnaire. Finally, it was assessed by post treatment questionnaire if the patients liked the NADA treatment program, if they would like to continue and if they have experienced any change in their pain in response to the 8-week NADA treatment program. Data are presented as the total number of patients.

characteristics	Patients (N) Baseline	Patients (N) Post treatment
Pain duration		
• < 5 years	2	-
• 5-10 years	2	-
• 10-15 years	3	-
Permanent treatment Morphine		
• no	6	6
• yes >6 month	1	-
• yes, down regulation	-	1
Permanent treatment other medication		
• no	4	3
• yes <6 month	1	-
• yes >6 month	2	-
• yes, up regulation	-	3
• unchanged	-	1
Medication on demand		
• daily	-	1
• weekly	3	4
• monthly	4	2
Medication as required – medication type		
• Morphine	-	1
• OTC	4	3
• Morphine + OTC	1	-
• Other	2[a]	3[b]
Adequate pain relief		
• No	7	4
• Yes	-	3
Liked NADA		
• Yes	-	6
• Do not know	-	1
Would like to continue NADA		
• Yes	-	5
• No	-	1
• do not know	-	1
Pain change		
• Yes, less pain	-	1
• Yes, more pain*	-	1
• No, unchanges	-	5

OTC ; Over the counter

*This patient experienced an increase in pain due to the Covid-19 lockdown of all treatment and training programs.

a: Panodil 665, Codeine

b:Panodil 665, Pinemol 500mg, Amitriptylin,

5.4. Discussion

This study could not show changes between baseline and post treatment questionnaire in pain perception for neither current, worst or least pain, PRI nor the temporal nature of pain. Moreover, no changes were found for either QOL measures or the medication use. A change between baseline and post treatment questionnaire was found for the personality trait spontaneous and a correlation between the change of the personality trait organized and the change of the QOL characteristic sleep quality, was found. No further changes for the personality traits or correlations between the change of personality trait and the change of QOL were found. A limitation in this study was that it was one-sided, due to the missing control group.

It was not possible to determine any changes in the pain perception. However, one patient reported to be down regulated in the permanent treatment and three of seven reported adequate pain relief post-treatment in comparison to none at baseline. Furthermore it was seen that three out of seven patients were up regulated in their permanent treatment and one patient started to receive morphine as medication on demand. This indicate that the patients included in this study, were not having improvement of their usage of medication. Nevertheless, six out of seven patients reported that they liked NADA acupuncture, and five out of seven that they would like to continue. These findings suggest that the patients must have positively experienced something from the NADA treatment program. A survey study of practitioners offering NADA acupuncture obtained by Stuyt et al., 2018 found that one practitioner, by using questionnaires after NADA acupuncture, discovered that 80 % of persons suffering from chronic pain reported pain relief and improvements in self esteem and wellbeing[38]. The above study by Stuyt et al., 2018, and the fact that six out of seven patients in this current study liked NADA and five out of seven wanted to continue, leads to the assumption that the patients were gaining other benefits than pain relief. A tendency in this current study towards the patients feeling less stress and notion of a better quality of sleep was seen in this study, which in other studies has proven as a factor influencing the severity of pain perception[31,32].

This current study found the personality trait spontaneous to decrease between baseline to post treatment measure. The general knowledge is that personality is something that stabilizes through childhood from where it will stay stable[50]. Nevertheless, the systematic review by Roberts et al., 2017, has highlighted that personality traits do not only change, but it changes in relation to life experience e.g. traumatic interventions and psychological treatment[51]. The personality traits in this current study, was based on self-reported rating on different adjectives describing personality traits, and not a specific personality test. One personality test which can be used is The Big Five, which is focusing on the five biggest personality dimensions including extraversion, agreeableness, conscientiousness, neuroticism and openness. Every dimension includes eight personality adjectives which each are rated from statements as most likely to least likely[53]. This study do not represent all dimensions of The Big Five model which lead to the assumption that this current study not adequately represent all dimensions of the five biggest personality dimension. Nevertheless, this current study, showed a correlation between organized (personality) and sleep quality (QOL). In accordance with The Big Five model, organized is one of the adjectives in the dimension conscientiousness. A study by Krasner et al., 2009 investigated whether mindfulness meditation could lead to better wellbeing in healthcare physicians by exploring changes in the

personality. The Big Five model was used to explore the possible changes. Kramer et al., 2009 showed an improvement after 8-week mindfulness meditation for both agreeableness, neuroticism and openness. Moreover, improvements in all five dimensions were seen after 12 month of mindfulness meditation program and at a 3-month follow up measures showed an improvement of extraversion, agreeableness, conscientiousness and neuroticism[53]. In combination, the study by Krasner et al. 2009, shows that modulation of personality is possible, which is consistent with the statistical findings in this current study. However, due to the fact that this study was based on self-reporting of personality, and not on a schematic personality test, it is likely to assume that the correlation between organized and sleep quality is a coincidence. Another explanation could be, that the patients actually feel less organized when they experience a greater quality of sleep. Sleep deprivation has been shown to affect people on their mood, cognitive function and chronic pain patients to experience an increased pain perception[54]. This indicate, that chronic pain patients who experience an increased sleep quality also experience an improvement of mood, pain perception and the cognitive function, leading to an improvement of mental health, which in the end may be the cause of patients feeling less organized during high sleep quality. However, more research in this field is needed to determine whether improvement of sleep quality can affect single parts of the personality during an 8-week NADA treatment program.

5.4.1 Limitations of this study

Due to the absence of mental capacity and interest from the patients who declined to receive NADA acupuncture, this study was a one-sided study, and only one aspect was elucidated. Therefore, it was not possible to determine whether the results of this study is actually due to an effect of NADA acupuncture, thus, future studies are suggested to contain a control group, in order to see if the effect is a true effect of NADA acupuncture, or if it is an effect of the regular treatment program on TSC. In order to see if the results in this study was a true result, a power calculation was made for both changes in current, worst and least pain with $\alpha=0.05$, $\beta=0.80$ and the effect size calculated to be Effect=0.41. This showed that this study should have included 49 persons in order to see any changes in the current, worst least pain. The sample size was also calculated for the PRI to with $\alpha=0.05$, $\beta=0.80$ and the effect was calculated to be Effect=0.18. This revealed that 245 patients should be included to see any effect. This showed, that this current study was underpowered, thus, future studies with the same constellation are suggested to contain respectively 49 and 245 patients for pain perception (current, worst, least) and PRI measures in order to determine if NADA acupuncture has an effect in complex chronic pain patients. However, a future study containing a control group, which has the same significance level, power and effect size and the same study setup, should only contain 14 and 64 patients for respectively pain perception (current, worst, least) and PRI measures in order to determine if NADA acupuncture has an effect in complex chronic pain patients.
The patients were asked to report their perception of pain at both baseline and post treatment, however this only gave a long term picture of the NADA acupuncture, and did not consider any acute responses. Therefore it is suggested that the patients should rate their pain on e.g. Visual Analog scale before and after NADA acupuncture, in order to investigate the acute effects. Finally, three out of seven patients were incomplete in the treatment program due to the challenges of

Covid-19 lockdown, which is reflected in the results and one participant reported to experienced an overall increase of pain due to the lockdown of all treatments both physical and mental.

5.5 Conclusion

This study found a correlation between sleep quality and the personality trait organized, furthermore a decrease was seen in the personality trait spontaneous. However, this study was unsuccessful in determining any differences between baseline and post treatment questionnaire for either pain perception (current, worst, least), the PRI measure or within the temporal nature of pain. Furthermore, no differences between baseline and post treatment questionnaire were shown for any of the characteristics of the QOL. Finally no further correlation between QOL and personality were seen or further differences in personality traits were seen. In conclusion, this study was not able to clarify a true effect of an 8-week NADA treatment program in persons suffering from complex chronic pain.

5.6 Future perspectives

This study did not take into account patients age, diagnosis, sex, or combining treatments, thus, it is uncertain whether the findings and tendencies seen is a course of NADA acupuncture or other combined treatments. Furthermore was this study unsuccessful in recruiting a control group, leading to a one-sided study. For future studies, it is suggested to also consider combined treatment types and duration and also to include a control group.

6. Discussion

6.1 Summary of the two studies

In overall, only a few differences were seen in the two studies, thus, it was concluded in both studies that no overall effect was seen. In addition, both studies appeared underpowered, which led to the conclusion that it is unclear whether the findings of the two studies are true or false. Nevertheless, there are some comparisons seen between the two studies. The studies will for the following section be referred to as study 1 (experimental study including healthy persons) and study 2 (clinical study including chronic pain patients).

6.2 Comparison of studies of the thesis

This thesis did not reveal any conclusive results, thus, comparison of results are truly difficult. In study 2 five out of seven wanted to continue if possible, as in comparison to study 1, where five out of six said that the NADA treatment was better in session 2 compared with session 1. This may indicate that NADA acupuncture develop over time. Furthermore, has other studies seen that NADA had an effect on different characteristics of QOL, however, all studies included a treatment program over a longer period[15,17,19].

One of the differences seen in study 2, was the change in personality (spontaneous) and the correlation between organized and sleep quality. The review by Roberts et al. 2017 describes that personality can change in comparison to life changes e.g. trauma, therapy or education[51]. However, No changes for personality beside spontaneous were seen, and a comparison of personality between study 1 and study 2 revealed no differences either, thus, the self-reported personality indicate that there is no difference in personality between healthy young participants and chronic pain patients in this thesis. Furthermore, does study 2 of this thesis only provide a snapshot of the personality without consideration about the personality before diagnosis with chronic pain. For future studies, it is suggested to use a personality test, in order to get a more valid perspective of personality traits and thereby detect any possible changes. Furthermore, is it suggested that future analysis including personality traits should look into the different types of traits, to further investigate how it can be correlated to wellbeing.

6.3 Scientific mechanisms of action in NADA acupuncture

Already in 1988 did, Smith and Khan,1988, discuss the scientific mechanism of action behind the NADA acupuncture and suggested, even though the mechanisms behind acupuncture were unknown, that the mechanisms somehow involves modulation of the autonomic nervous system and neurotransmitters [9]. This theory has been shown in an animal rat model by Kailasam et al., 2016[24]. However, it is still unclear whether this is the mechanisms of action in humans. Another direction in the research of the scientific mechanisms of action behind NADA acupuncture, is to look into other explanations e.g. the role of the vagus nerve which is also the 10th cranial nerve. The review by Couck, 2017 reveals an overview of the vagal nerve in accordance to pain modulation, and describe that stimulation of the vagal nerve leads to endogenous pain modulation through both central and sympathetic nervous system, inflammatory opponents, and the opioid system. Furthermore, the vagal nerve can be targeted in different sites in order to utilize the pain modulating properties, including the auricular branch of the vagal nerve[25]. In comparison to NADA, the auricular branch of the vagal nerve is placed in the lower lung zone[47], thus, the vagus nerve may be involved in the mechanisms of actions behind NADA acupuncture. One way of measuring the modulatin of the vagal nerve is to measure the cardiac vagal tone, which is determined based on baroreceptor responses[55]. In order to determine if the vagus nerve do play a role, future studies on NADA acupuncture is suggested to include measurement of cardiac vagal tone to determine any changes. In addition, it is suggested to measure pressure pain threshold, due to that study 1 in this current thesis were able to detect a difference in the Musculus Vastus Lateralis in session 2.

6.4 NADA method and evidence

When looking into the literature, NADA is found to have benefits in both sleep, mood, anxiety, drug addiction among others[18–21]. However, when looking into trials, NADA appears to have no different than e.g. the control groups. This finding is of highly interest, due to the fact that the NADA method is one of the most used in accordance to treatment of drug addiction[56]. Nevertheless, in the end, it should be considered whether it is important to prove that NADA acupuncture works better than other treatment, due to the fact that, all healthcare professionals just would like to help patients improving and overcoming life challenges. A healthcare professional described in an article by Landgren et al., 2019 that patients receiving different kind of medicine for longer periods without any effect, tries nada and then *"they are just sitting there, completely passed out!"*[17]. Another healthcare professional explains that NADA acupuncture makes it possible to gather all thought and become completely calm. Furthermore did the healthcare professionals experience that patients after NADA acted more calm, even though they just before NADA had been very excited and wounded up[17]. The article by Landgren et al., 2019 elucidated NADA acupuncture from a healthcare professionals point of view, which can provide knowledge about other factorial benefits in order to look into administration of NADA acupuncture e.g. benefits by using NADA in comparison to other treatments. Landgren et al., 2019 describe that beside behavioral benefits, the healthcare professional also experience that NADA acupuncture provides release of resources due

to that NADA is a non-verbal and provided as group sessions. This improves the experience of connection between the patients, and furthermore the patient to receive personalized treatment[17].

6.5 future perspectives

In conclusion, this master thesis was unable to reveal new knowledge pertaining to the mechanisms of action behind NADA acupuncture. However, this study also showed to be underpowered, thus, it cannot be concluded whether these findings are true findings. Further studies in the NADA method is suggested to include more participants in accordance to the power calculation made for both study 1 and study 2, in order to determine the true effect. Further, it is suggested to measure Cardiac vagal tone, in order to include regulation of the vagal tone, which can provide knowledge about the changed response in vagal nerve activity. A control group should also be considered in further studies at TSC in order to determine if the effect is due to NADA acupuncture or the existing treatment program in the Center of Complex Chronic Pain. Finally, conduction of personality traits is suggested to be done by personality tests instead of self-reporting on the traits, in order to have a more objective measure.

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Supplemental Material

The following pages includes the supplemental materials from the two studies in this Mater thesis including the informed consent statement, questionnaires from the experimental study and questionnaires for the clinical study.

Informeret samtykke til deltagelse i et sundhedsvidenskabeligt pilot studie

Projektets titel: *The acute physiologic effects of the NADA method on young healthy adults*

Erklæring fra forsøgspersonen:
Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at miste mine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til, at deltage i projektet og har fået en kopi af dette samtykke-ark samt en kopi af den skriftlige information om projektet til eget brug.

Forsøgspersonens navn:

Dato: _____. Underskrift: _____.

Ønsker du at blive informeret om projektets resultat samt eventuelle konsekvenser for dig?:

Ja ___ (sæt kryds) Nej _____ (sæt kryds)

Erklæring fra den, der afgiver information:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet information: _____.

Dato: _____. Underskrift: _____.

Questionnaire Prior to NADA treatment or Rest - Experimental Study.

This questionnaire is 1 of 4 questionnaires, and should be answered before the beginning of the experiment.

1. **Answer the questions below from a scale from 1 to 10. (1 = not at all and 10 = Most possible**

Currently, to what extent do you feel like a person who is:

Extrovert	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Introvert	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Spontaneous	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Organized	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Curious	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Retaining/Unsociable	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Social	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Satisfied	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

2. Answer the questions below from a scale from 1 to 10. (1 = *Worst possible* and 10 = *Best possible*

Currently; to what extent would you characterize your:

Ability to fall asleep	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Quality of sleep	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Stress level	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Bodily restlessness	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Mood	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Energy and power	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Wellbeing	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Happiness	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Jobsituation	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

Questionnaire Post NADA treatment or Rest - Experimental study

This questionnaire is 2 of 4 questionnaires, and should be answered after the trial at day 1.

1. Answer the following questions by marking the statement(s) with the best fit.

How did you feel during the session?

O Relaxed	**O** Comfortable	**O** Bored	**O** I fell asleep	**O** Restless	**O** Other

If you have answered “Other” you can elaborate it here:

_____

How did the session feel in time?

O Long time	**O** Short time	**O** Medium time	**O** I do not know	**O** **Other**

If you have answered “Other” you can elaborate it here:

_____

How do you feel now?

O Relaxed	**O** Comfortable	**O** Bored	**O** Tired	**O** Restless	**O** Other

If you have answered “Other” you can elaborate it here:

2. Answer the following questions by marking the statement with the best fit.

Did you physically something on your ears during the session? - E.g. Warmth, pricking, tickling etc.

O Yes	**O** No	**O** Don´t know

If “Yes”, what did you feel?

O Warmth	**O** Pricking	**O** Tickling	**O** Pain	**O** Other

If you have answered “Other” you can elaborate it here:

_____

If “Yes”, which area(s) did you feel it? Mark on the sketch below

Questionnaire Prior to NADA treatment or Rest – Experimental study

This questionnaire is 3 of 4 questionnaires, and should be answered before the trial at day 2.

1. **Answer the questions below from a scale from 1 to 10. (1 = *Worst possible* and 10 = *Best possible***

The last 24 hours; to what extent would you characterize your:

Ability to fall asleep	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Quality of sleep	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Stress level	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Bodily restlessness	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Mood	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Energy and power	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Wellbeing	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Happiness	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

2. Answer the following questions by marking the/those statement(s) with the best fit.

How would you describe your last 24 hours?

O Same as usual	**O** Better than usual	**O** Worse than usual	**O** Other

If you have answered “Other” you can elaborate it here:

_____

Have you experienced something unexpected the last 24 hours, which has affected your answers?

O Yes	**O** No

Questionnaire Post NADA treatment or Rest – Experimental study

This questionnaire is 4 of 4 questionnaires, and should be answered after the trial at day 2.

1. Answer the following questions by marking the statement(s) with the best fit.

How did you feel during the session?

O Relaxed	**O** Comfortable	**O** Bored	**O** I fell asleep	**O** Restless	**O** Other

If you have answered “Other” you can elaborate it here:

_____

How did the session feel in time?

O Long time	**O** Short time	**O** Medium time	**O** I do not know	**O** Other

If you have answered “Other” you can elaborate it here:

_____

How do you feel now?

O Relaxed	**O** Comfortable	**O** Bored	**O** Tired	**O** Restless	**O** Other

If you have answered “Other” you can elaborate it here:

_____

How would you describe this session compared with last session?

O Better	**O** Worse	**O** The same	**O** Other

If you have answered “Other” you can elaborate it here:

_____

2. Answer the following questions by marking the statement with the best fit.

Did you physically something on your ears during the session? - E.g. Warmth, pricking, tickling etc.

O Yes	**O** No	**O** Don´t know

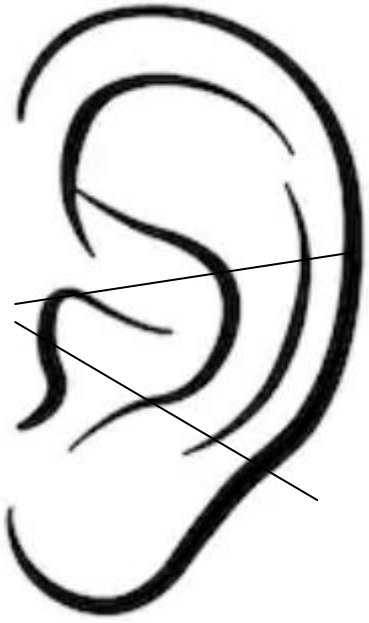
If “Yes”, what did you feel?

O Warmth	**O** Pricking	**O** Tickling	**O** Pain	**O** Other

If you have answered “Other” you can elaborate it here:

_____

If “Yes”, which area(s) did you feel it? Mark on the sketch below



Spørgeskema Baseline – Clinical study

Følgende spørgeskema skal besvares ved undersøgelsens start. Undersøgelsen varer 8 uger, og afslutter med spørgeskema nr.2.

1. Sæt kryds i nedenstående

_____ Jeg er indforstået med at mine besvarelser bruges til dataanalyse i forbindelse med afgangsspeciale på Aalborg Universitet. Spørgeskemaerne vil være anonymiseret.

2. Besvar nedenstående spørgsmål

	O	**O**
Har du fået en diagnose?	JA	NEJ
Hvis ja, hvilken?		
	O	**O**
Har du tidligere fået NADA?	JA	NEJ

3. Besvar nedenstående spørgsmål ved at afkrydse det/de udsagn der passer bedst på dig.

Hvad har fået dig til at sige "Ja tak" til NADA?

O	**O**	**O**	**O**	**O**
Jeg har tillid til at det virker	Jeg eller en jeg kender har tidligere fået NADA med god effekt	Jeg er nysgerrig og prøver gerne noget nyt	Jeg har endnu ikke fundet noget der dækker mine smerter	Andet

Hvis du har svaret "Andet" ved foregående spørgsmål kan dette uddybes her:

_____

Hvor længe har du haft kroniske smerter?

O Under 5 år	**O** 5-10 år	**O** 10-15 år	**O** 15-20 år	**O** Andet

Hvis du har svaret "Andet" ved foregående spørgsmål kan dette uddybes her:

_____

Hvordan oplever du varigheden så af dine smerter?

O Kortvarig	**O** Øjeblikkelig	**O** Forbigående	**O** Rytmisk	**O** Periodevis	**O** Sporadisk	**O** Uafbrudte	**O** Konstant

4. Besvar nedenstående spørgsmål ud fra en skala fra 0-10, hvor 0 = ingenting og 10 = værst tænkeligt

Hvordan oplever du:

Smerter lige nu	0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Smerter når de er værst	0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Smerter når de er mindst	0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

5. Nedenstående er en række ord, der beskriver forskellige former for smerte. De er inddelt i grupper fra 1-20, lav en cirkel om det/de ord der bedst beskriver din **nuværende** smerte. Du må vælge så mange ord du vil, **men kun ét ord** fra hver af grupperne.

1	Vibrerende Pulserende Dunkende	5	Gnavende Knusende	9	Værkende Kraftig	13	Frygtelig Forfærdelig	17	Gennemtrængende
2	Lynende Jagende	6	Vridende	10	Spændt Kradsende	14	Opslidende Grusom	18	Følelsesløs Knugende
3	Stikkende Borende	7	Brændende Svidende	11	Trættende	15	Ødelæggende	19	Isnende
4	Skærende	8	Snurrende Kløende	12	Kvalmende	16	Irriterende Intens Uudholdelig	20	Væmmelig Torterende

6. Besvar nedenstående ved at afkrydse det der passer på dig

Er du i fast smertestillende behandling med et morfin præparat?	**O** JA, mindre end 6 måneder	**O** JA, Mere end 6 måneder	**O** NEJ
Er du i fast smertestillende behandling med anden smertestillende medicin?	**O** JA, mindre end 6 måneder	**O** JA, Mere end 6 måneder	**O** NEJ
Hvor ofte supplerer du din smertebehandling med smertestillende medicin efter behov?	Aldrig —-månedligt —- ugentligt —- dagligt		
Hvilken type medicin bruger du til supplerende smertestillende medicin?	**O** Morfin præparater	**O** Håndkøbsmedicin	**O** Andet
Hvis du har svaret "Andet" ved foregående spørgsmål kan dette uddybes her:			
Føler du din smertestillende behandling er tilstrækkelig	**O** JA		**O** NEJ

7. **Besvar nedenstående spørgsmål ud fra en skala fra 1 til 10, hvor 1 = mindst muligt og 10 = mest muligt**

På nuværende tidspunkt: I hvilket omfang føler du dig som en person der er:

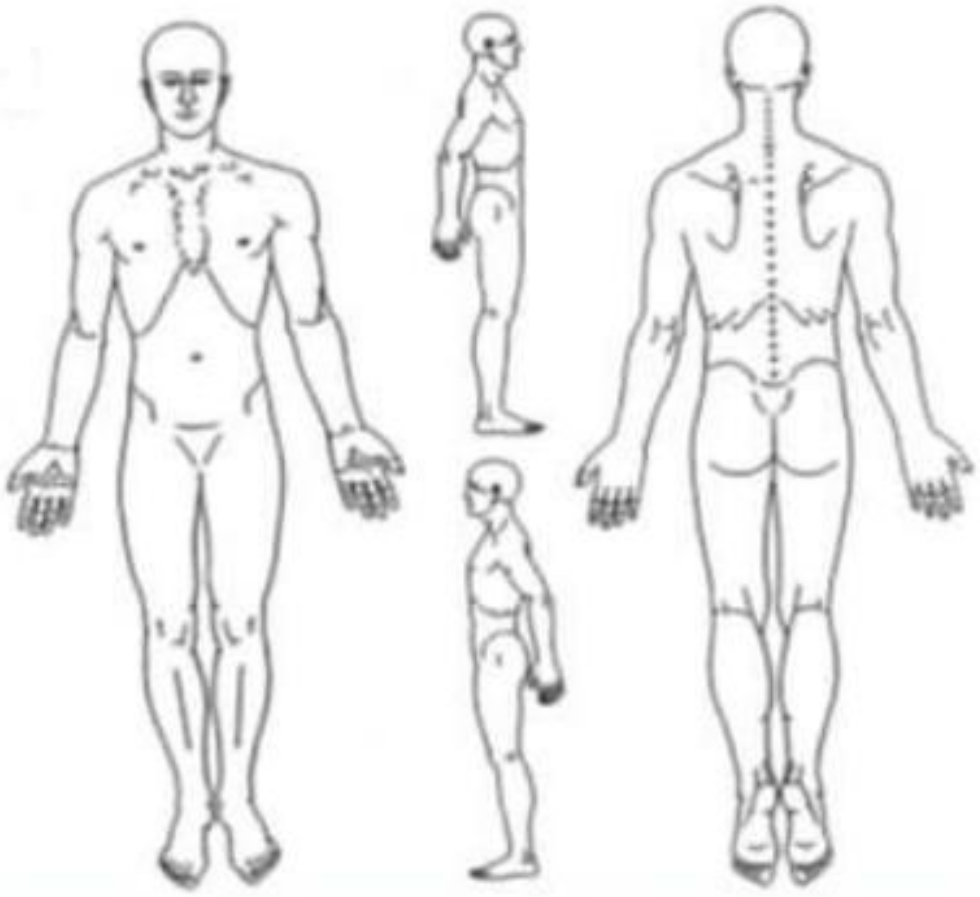
Udadvendt	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Indadvendt	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Spontan	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Organiseret	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Nysgerrig	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Tilbageholdende	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Social	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

8. **Besvar nedenstående spørgsmål ud fra en skala fra 1 til 10, hvor 1 = mindst muligt og 10 = mest muligt**

På nuværende tidspunkt: I hvilket omfang oplever du

Søvnproblemer	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Din søvnkvalitet	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Stress	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Kropslig uro	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Påvirket humør	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Nedsat energi og kræfter	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Nedsat social aktivitet	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Nedsat fysisk aktivitet (daglige gøremål)	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

9. Marker og skraver på figuren hvor dine smerter er:



Mange tak for din deltagelse!

Spørgeskema Post-treatment – Clinical study

Følgende spørgeskema skal besvares ved afslutningen af de 8 uger med NADA.

1. Sæt kryds i nedenstående

_____ Jeg er indforstået med at mine besvarelser bruges til dataanalyse i forbindelse med afgangsspeciale på Aalborg Universitet. Spørgeskemaerne vil være anonymiseret.

2. Besvar nedenstående spørgsmål

Har du været glad for at få NADA?	**O** JA	**O** NEJ	**O** Hverken eller
Hvis muligt, ville du så fortsætte med at få NADA?	**O** JA	**O** NEJ	**O** MÅSKE

3. Besvar nedenstående spørgsmål ved at afkrydse det/de udsagn der passer bedst på dig

Hvordan har du oplevet varigheden af dine smerter de seneste 8 uger?

O Kortvarig	**O** Øjeblikkelig	**O** Forbigående	**O** Rytmisk	**O** Periodevis	**O** Sporadisk	**O** Uafbrudte	**O** Konstant

Har dine smerter ændret sig de seneste 8 uger?	**O** JA, færre smerter end før	**O** JA, flere smerter end før	**O** NEJ, mine smerter er uændret

4. Besvar nedenstående spørgsmål ud fra en skala fra 0-10, hvor 0 = ingenting og 10 = værst tænkeligt

Hvordan oplever du:

Smerter lige nu	0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Smerter når de er værst	0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Smerter når de er mindst	0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

5. Nedenstående er en række ord, der beskriver forskellige former for smerte. De er inddelt i grupper fra 1-20, lav en cirkel om det/de ord der bedst beskriver din **nuværende** smerte. Du må vælge så mange ord du vil, **men kun ét ord** fra hver af grupperne.

1	Vibrerende Pulserende Dunkende	5	Gnavende Knusende	9	Værkende Kraftig	13	Frygtelig Forfærdelig	17	Gennemtrængende
2	Lynende Jagende	6	Vridende	10	Spændt Kradsende	14	Opslidende Grusom	18	Følelsesløs Knugende
3	Stikkende Borende	7	Brændende Svidende	11	Trættende	15	Ødelæggende	19	Isnende
4	Skærende	8	Snurrende Kløende	12	Kvalmende	16	Irriterende Intens Uudholdelig	20	Væmmelig Torterende

6. Besvar nedenstående ved at afkrydse det der passer på dig

Er du i fast smertestillende behandling med et morfin præparat?	**O** JA, med nedtrapning	**O** JA, med optrapning	**O** NEJ
Er du i fast smertestillende behandling med anden smertestillende medicin?	**O** JA, med nedtrapning	**O** JA, med optrapning	**O** NEJ
Hvor ofte har du suppleret din smertebehandling med smertestillende medicin efter behov?	Slet ikke—-månedligt —- ugentligt —- dagligt		
Hvilken type medicin bruger du til supplerende smertestillende medicin?	**O** Morfin præparater	**O** Håndkøbsmedicin	**O** Andet
Hvis du har svaret "Andet" ved foregående spørgsmål kan dette uddybes her:			
Føler du din smertestillende behandling er tilstrækkelig	**O** JA		**O** NEJ

7. **Besvar nedenstående spørgsmål ud fra en skala fra 1 til 10, hvor 1 = mindst muligt og 10 = mest muligt**

På nuværende tidspunkt: I hvilket omfang føler du dig som en person der er:

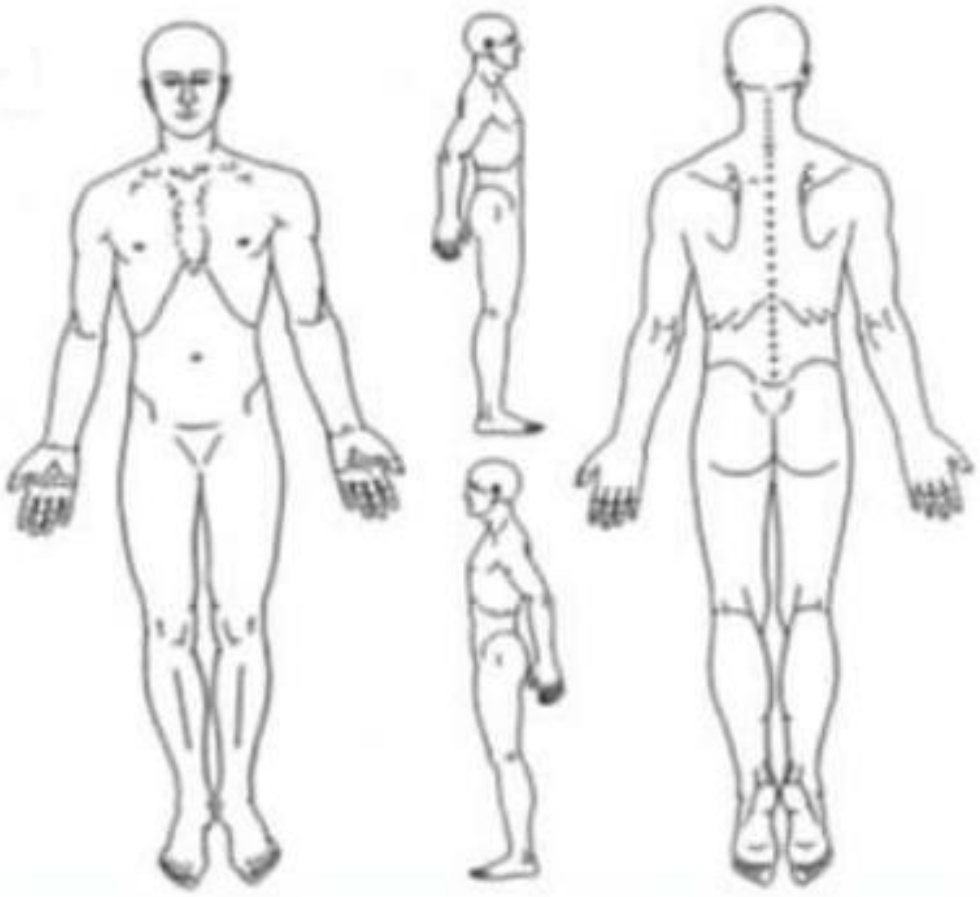
Udadvendt	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Indadvendt	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Spontan	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Organiseret	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Nysgerrig	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Tilbageholdende	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Social	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

8. **Besvar nedenstående spørgsmål ud fra en skala fra 1 til 10, hvor 1 = mindst muligt og 10 = mest muligt**

På nuværende tidspunkt: I hvilket omfang oplever du

Søvnproblemer	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Din søvnkvalitet	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Stress	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Kropslig uro	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Påvirket humør	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Nedsat energi og kræfter	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Nedsat social aktivitet	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Nedsat fysisk aktivitet (daglige gøremål)	1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

9. Marker og skraver på figuren hvor dine smerter er:



Mange tak for din deltagelse!