
# Research design assignment HEL320A

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# Efficacy of neuroscience education (NE) in patients undergoing spinal surgery

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## Abstract English

**Background:** One in four patients with radiculopathy experience persistent pain and disability after lumbar surgery. Postoperative rehabilitation for lumbar radiculopathy has shown little effect on reducing pain and disability. Previous research provides evidence for Neuroscience Education (NE) as a way to decrease pain, disability and fear avoidance before surgery.

**Methods:** A multiple Single Subject Experimental Design (SSED) with six participant was completed at Martina Hansen Hospital in Norway during spring of 2014 to investigate if NE in addition to standard pre-operative hospital routines would result in superior outcomes with regards to pain, disability, fear avoidance, attitudes regarding pain and psychological status before spinal surgery. Patients on waiting list for lumbar surgery were allocated to either receive standard hospital preoperative regime or NE. Roland Morris Disability Questionnaire (RMDQ), Numeric Pain Rating Scale (NPRS), Fear Avoidance Belief Questionnaire (FABQ), Hopkins Symptom Checklist (CSCL-25) and Survey Of Pain Attitudes (SOPA) were assessed three times during baseline, one time during intervention and one time 14 days after the last NE intervention session. No postoperative outcome measures were detected.

**Result:** NE intervention group showed an increase in SOPA and one participant showed clinical detectable reduction in RMDQ (3points), NPRS (2points) and FABQ PA/W scores (13 to 6 and 6 to 0). No significant change occurred in the rest of the NE group. Normal variation of symptoms occurred in the control group.

**Conclusion**: Reconceptualising of pain occurred in one of three participants in the NE group who showed an improvement in all outcome scores. Increase in SOPA does not seem to significantly change pain ratings, disability score or fear of movement. Results implicates NE alone, is not efficient of changing pain behaviour. This SSED is hypothesis generating for future research in NE and patient characteristic.

**Keywords**: SSED, Pain, Neuroscience Education, Low back pain, LBP, Spinal Surgery,

## Abstrakt Norsk

**Bakgrunn:** En av fire pasienter med radikulerende smerter opplever smerter og tap av funksjon etter ryggoperasjon. Postoperativ rehabilitering har vist liten effekt i å redusere smerte og øke funksjon hos disse pasientene. Tidligere forskning gir evidens for at preoperativ ”Neuroscience Education” (NE) er en god måte å redusere smerte, frykt for bevegelse øke funksjon før operasjoner.

**Metode:** En ”Multiple Single Subject Experimental Design” (SSED) ble gjennomført på seks pasienter ved Martina Hansen Sykehus våren 2014 for å se om preoperative smerteundervisning i form av NE tillegg til sykehusets standard preoperative protokoll kunne resultere i redusert smerte, bedret funksjon, redusert frykt for bevegelse, endrede holdninger til smerte- og psykosomatisk tilstand før rygg operasjon. Pasienter på venteliste ble allokert i to grupper NE eller standard sykehus protokoll. Tre baseline målinger ble utført for å detektere funksjon (Roland Morris Disability Quastionnaire), opplevd smerte (Numeric Pain Rating Scale), frykt for bevegelser (Fear Avoidance Belief Questionnaire), u spesifikke psykosomatiske lidelser (HSCL-25) og smerteforståelse (Survey Of Pain Attitudes- SOPA). Utfallsmål ble også innhentet en gang under intervensjonen og en gang 14 dager etter NE.

**Resultater**: To menn og fire kvinner fulførte alle utfallsmålinger. NE gruppen viste bedring i SOPA score, én av tre opplevde bedring i alle utfallsmål. Klinisk relevante endringer ble funnet i smerte (NPRS 2poeng) og funksjon (RMDQ 3poeng). Frykt for fysisk aktivitet og jobb (FABQ PA/W) ble redusert fra 13 til 6 og 10 til 0 hos denne pasienten. Ingen klinisk endring ble funnet hos resterende deltakere i NE gruppa. Kontrollgruppen viste normal variasjon av symptomer.

**Konklusjon**: NE kan føre til økt kunnskap og re konseptualisering omkring smerte og funksjon. Bedring i SOPA resulterer nødvendigvis ikke i bedret funksjon, redusert frykt for bevegelse eller smerte. Dette var en hypotesedannende SSED, og fremtiden burde vi se nærmere på hvilke pasient karakteristika som er avgjørende for effekt av NE.

**Nøkkelord**: SSED, Smerte, Neuroscience Education, smerteundervisning, LPB, ryggoperasjon.

# 1.0 Introduction

## 1.1 Background

In todays practice as physical therapists, evidence based knowledge is considered to be the benchmark of what treatment decisions are based upon (Drageset and Ellingsen, 2009). Low Back Pain (LBP) is one of Norway`s most expensive health costs with an estimation of 15 Billion NOK annually for the Norwegian government (Lærum, 2002
). A lifetime prevalence of up to 70% indicates that LBP is a major health problem in the society (Werner et al. (2010). Most acute LBP resolves within a few weeks, but as much as 15% of the acute back patients goes on to become long standing (>3months), and more than 70% will have one or more recurrences within a year (Werner et al., 2010). In the majority of cases (85%), a specific diagnose or pathological reason for the patients complaints of back pain cannot be found (Waddel, 2004). Nevertheless the implementation of surgery as a treatment for non-specific low back pain has increased the last decades (Cowan et al., 2006).

The amount of back surgeries related to specific back pain conditions utilising lumbar fusion and discectomy has also exploded the last 20years. Short-term results have showed no superior effect of surgery versus cognitive intervention and exercise rehabilitation (Brox et al., 2010; Hellum et al., 2011; Kleinstueck et al., 2011; Froholdt et al., 2013; Mannion et al., 2013). Studies also show insufficient consensus about assessment methods for better patient selection for fusion surgery (Perneros et al., 2014).

A recent 9-year follow up study showed no significant different between lumbar fusion versus cognitive intervention regarding outcome measures like fear avoidance beliefs, return to work and Oswestry Disability Index (Froholdt et al., 2013). The cognitive intervention focused on identification and modification of patients thoughts and behaviours regarding pain and disability. The findings in Froholdts study reflects the importance of understanding long term pain as a much more complex multifactorial phenomenon rather than relying on the patho anatomical structures alone.

There is low evidence on the effect of rehabilitation addressing pain reduction and increased function after lumbar surgery. Research indicates that the long-term success rate concerning back or leg pain, restrictions in daily activities or time off work capacity vary from 60-90% (Ostelo et al., 2003; den Boer et al., 2006; Louw, 2013; Louw et al., 2013b). Louw et al also points out what he considers to be flaws in current preoperative education intervention. These flaws are related to the current one-dimensional biomechanical understanding in the preoperative education being performed by surgeons. Literature has shown that focusing on anatomical and patho-anatomy during preoperative information may increase fear in patients and thus potentially have the capacity to increase pain. These explanatory model has also showed limited efficacy in reducing pain and disability in patients undergoing surgery (Louw, 2013)

As a physical therapist I daily intervene with patients struggling with long-standing pain disorders, showing clinical signs of long-term sensitization and additional problems (i.e. lack of sleep, fear avoidance and deconditioning). In the tradition of manual therapy we are specialized in diagnosing musculoskeletal disorders and most often providing "hands on" treatment with regards to manipulation and mobilization. However, recent literature indicates that we can offer much more in the world of understanding pain and explaining this phenomenon to patients in the rehabilitation of their pain condition (Nijs et al., 2011; Nijs et al., 2013). Recent studies shows that patients urge for more education and information regarding pain in advance of surgery, and it has been suggested that physical therapist is well suited to this task (Louw A, 2009; Louw A, 2012).

## 1.2 Pain

*Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"(IASP, 12.05.2012).*

*"Pain is a personal, subjective experience influenced by cultural learning, the meaning of the situation, attention and other psychological variables. Pain process do not begin with the stimulation of receptors" (Melzack and Katz, chapter 1,page 1,2013).* (Appendix 1 for further definitions of pain)

Acute pain sensation is crucial for human and animal survivor. An acute perception of pain is normally described as a result of activated nociceptors in the peripheral tissue either by damaged tissue or by threat to tissue damage (Butler et al., 2003; Brodal, 2005). Free nerve endings (nociceptors) are high threshold receptors triggered by chemical, mechanical and temperature stimuli. These receptors will not fire until the stimuli reaches noxious level. Firing of a nociceptor will produce a cascade of signals from the peripheral tissue along the nerve into the dorsal ganglia and then into the dorsal horn of the spinal cord. In the dorsal horn, the signal that is transported through the 1.order neuron (from the peripheral tissue) will connect via interneurons to the ascending 2.order neuron, which travels up towards the hypothalamus and thalamus within the spinal cord. Thalamus acts like a coordinator that register, localize and describe the stimuli in order to distinguish whether it is important to act upon or not. Within the thalamus, 2.order neuron will connect via new interneurons to 3.order neuron that will pass the signal on to the neuromatrix of the brain/cortex (*for neuromatrix illustration see appendix 2*) (Butler et al., 2003). The thalamus and cortex are connected to the hypothalamus and autonomic nervous system. Activation of the nociceptive system will therefore lead to immediately reactions in the autonomic and motor parts of the nervous system, a protective response aiming to limit or avoid further injury. Mobilizations of stress hormones (cortisol), altered energy metabolism, liver catabolism, increasing pulse and increasing blood pressure are results of neurologic reactions to acute pain. These reactions work in synergy as a defence system so that the organism can react upon the perceived external threat (Butler et al., 2003; Brodal, 2005).

Maladaptive mechanisms may occur resulting in persistent pain even though the initial injury has healed (McGreevy, 2011). The connection between acute and long lasting pain is generally said to occur when perception of pain persist beyond the expected timeframe for resolution and recovery of tissue injury. Maladaptive mechanism may evolve from bio psychosocial factors such as depression, anxiety, emotional status, physical activity status, occupational status or lack of social support from friends and family (Gore et al., 2012; Nijs et al., 2013). Long standing pain, also known as “chronic” pain is associated with neuroplastic changes in the peripheral or central nervous system as a response to nociceptive input (McGreevy, 2011). According to Moseley et al, there are four key points that contributes to the non-straightforward pain mechanism; 1) pain

does not provide a measure of the state of the tissues, 2) pain is modulated by many factors from across somatic, psychological and social domains, 3) the relationship between pain and the state of the tissues becomes less predictable as pain persists 4) pain can be conceptualised as a conscious correlate of the implicit perception that tissue is in danger (Moseley, 2007) .

*Pain cannot exist outside our consciousness* (Moseley and Flor, page 1, 15.02.2012). Changes in the central nervous system detected by imaging data, reveals a bigger role of the brain in the perception of pain. Data suggest that there is lack of consensus between the represented brain area activated during pain perception- and the actual location of the peripheral stimuli (Moseley and Flor, 2012). Changes in the central nervous system is attributed to long term peripheral stimuli or lack of stimuli (Wand et al., 2011c). Yang and Cobs showed a shift of cortical representation in amputee patients (Yang et al., 1994). Patients undergoing arm amputation showed a decreased cortical map of the arm and an increase map of the lip in the somatosensory cortex (Yang et al., 1994). Flor and colleagues showed an increased area of the lower backs representation in the primary somatosensory cortex in patients with long standing low back pain (Flor et al., 1997). The amount of change in cortex reorganization is associated to the duration and chronicity of pain (Flor et al., 1997).

In contrary to the *feeling* of pain, nociception- ("danger- message") can occur outside our consciousness, meaning the one is not depended upon the other (Moseley and Flor, 2012). Besides the fact that we need a brain and cortical function to be able to perceive any feeling, we also need a conscious brain to perceive the feeling of pain. Pain is said to be a sensation, much like vision, hearing and smell. Pain is said to be a feeling, like anger, sorrow or joy. Pain acts like a motivation signal, much like hunger, thirst or tiredness. In persistent pain, we believe that there is a range of perceptual and regulatory dysfunctions of the cortical map and the central nervous system`s regulation of pain and tactile sensations (Woolf, 2011; Roussel et al., 2013; Wand et al., 2013).

### 1.2.1 Postoperative pain

Pain is often a significant issue following many orthopaedic procedures and surgeries (Louw et al., 2013b). Several articles have been published through out the years with regards to preoperative education on alleviating postoperative complications or influencing preoperative health status within the scope of cardiac, abdominal, dental and cancer surgery ((Schoessler, 1989; Shuldham, 1999; Johansson et al., 2005; Johansson et al., 2007; Louw A, 2009; Louw et al., 2013b; Louw et al., 2014). In spite of research investigating pre-surgery education, the persistent degree of postoperative pain and limited effect of medication is still a challenge for clinicians. Pain related cognition is developing in the scope of pre-surgery education, where literature shows pain-related cognition benefitting from pain coping strategies, diversion of attention, cognitive reappraisal and cognitive- behavioural pain management (Moseley and Flor, 2012).

### 1.2.2 Central sensitization influencing long standing pain

During recent time there has been a large body of research to back up the theory behind the phenomenon central sensitization (Nijs et al., 2011; Siddall, 2013). Central sensitization is becoming the "up to date" explanation of various long lasting musculoskeletal complaints; LBP is not an exception (Nijs et al., 2010; Werner et al., 2010; Nijs et al., 2011; Nijs et al., 2013). There is currently a shift in paradigm towards the understanding of long standing pain mechanism (Moseley, 2003a; Moseley, 2003b; Ostelo et al., 2003; Brooks and Tracey, 2005; Linton et al., 2005; Zhuo, 2008; Apkarian et al., 2009; Farmer et al., 2012; Hashmi et al., 2013; Nijs et al., 2013). Decades ago, the findings of sensitized peripheral *nociceptor* terminals after injury explained the reduced threshold for stimuli and hence hypersensitivity (Woolf, 2011). Thus, this could not explain tactile *allodynia*, *temporal summation* of pain nor the result of secondary *hyperalgesia* after an injury. Increased synaptic function triggered within the central nervous system (CNS) by nociceptive inputs led the way to neurobiological explanations

The Biopsychosocial (BPS) model was introduces already in 1987, establishing the bridge between back pain, general distress and lack of movement (Waddell, 1987). The operational of the model was to put focus on active rehabilitation and proactive measures to get the patient to

reduce fear of movement. The following years the BPS model has implemented focus on distress, emotions, and social factors contributing to long-standing back pain, but also with regards to postoperative lumbar surgery (den Boer et al., 2006)

We usually interpret pain as a reflecting presence of a possibly peripheral dangerous stimulus; which indeed can be a critical mechanism for our survival. Central sensitization reveals another dimension to our protective pain experience mechanism. Our CNS can thus change, amplify, and inhibit our conscious experience of pain (Butler et al., 2003; Moseley, 2003a; Moseley, 2007; Moseley and Arntz, 2007). The modulation of the CNS with regards to central sensitization is consistent with biological systems fundamentally designed to adapt according to its use. Adaption can be looked upon as learning, where practise makes perfect – "*we learn to better detect signals of danger".* Moseley and Floor describes the perception of pain as a sensation that emerges according to the apparent danger to body tissues and the need for concerted action, not according to the true danger or damage at a tissue level, meaning that anything that is detectable or accessible to the brain and relevant to the evaluation of danger to body tissue has the capacity to modulate pain (Moseley and Flor, 2012).

Wand and his group showed cortical and neurochemical changes in patients with long standing low back pain (Wand et al., 2011b). Nijs et al describes alterations in the central nervous system processing, and more specifically the responsiveness of central neurons input from *unimodal* and *polymodal* receptors (Nijs et al., 2010). The same author describes an impaired function of descending anti-nosciceptive mechanisms (inhibitory) and over-activity of descending and ascending pain fascilitory pathways within the central nervous system (Nijs et al., 2010; Nijs et al., 2011; Nijs et al., 2013). It is still important to point out that central modulation may evolve from massive peripheral nociception input as trauma, musculoskeletal injuries, and history of several surgeries in particular. The modulation of the central nervous system sensitizes the *somatosensory* cortex and remains highly plastic thus continuing to sustain its aggravated response to stimuli (Nijs et al., 2011). Detectable and objective manifestations as pain *hypersensitivity*, *allodynia*, pressure *hyperalgesia*, *aftersensation* and enhanced *temporal summation* has been described as consequences of central sensitization (Woolf, 2011). The change in cortical mass, described by Rodriguez-Raecke, leads us to understand the powerful

neural plasticity of the brain (Rea Rodriguez-Raecke, 2009). Raecke showed reduced grey matter density in *anterior cingulate cortex*, the *orbifrontal cortex, right insular cortex and amygdala* in patients with longs standing pain due to primary hip osteoarthritis. The latter brain areas are known to be involved in autonomic responses, fear, memory, cognition, self-awareness, cognition and emotions. An increase of gray matter in these same areas was detected post -surgery when these patients had become pain free (Rea Rodriguez-Raecke, 2009). Wand et al supports these findings when stating that there seems to be less neuron matter in the areas of brain stem, posterior parietal cortex and somatosensory cortex in people with LBP compared to healthy controls (Wand et al., 2011b). Wand et al also states that grey matter increases with training of an injury brain, hence the unique plasticity of the brain. (Moseley 2012)

## 1.3 Previous research of Neuroscience Education

Evidence supports the intervention of pain education in patients with low back pain. Education about the neuroscience physiology of pain has been studied in populations with long standing pain, such as LBP ((Louw, 2006; Louw, 2009; Louw et al., 2011; Louw et al., 2012; Louw A, 2012; Louw, 2013).

International publications associated with pain education during the recent years, is much based upon the pioneering work of David Butler and Lorimer Moseley (Moseley, 2002b; David S. Butler, 2003; Moseley, 2003a; Moseley, 2004a; Moseley, 2004c). In later years this has been extended into many other research institutes all over the world (Meeus et al., 2010; Louw et al., 2011; Nijs et al., 2011a; Van Oosterwijck et al., 2011; Nijs et al., 2011; Van Oosterwijck et al., 2011; Nijs et al., 2013).

A survey by Louw et al found evidence of current pre-surgery education content amongst surgeons to be in conflict of what the patient wish to learn (Louw A, 2012). Their study indicates that only 20% of education provided by the surgeons is related to pain topics. Toyone et al showed that almost 50% of the surgeons answering their survey stated that *«Strategies in dealing with pain»*, was not part of the preoperative education (Tomoaki Toyone MD, 2005). What is of interest in the study of Toyone, is the obvious mismatch between the surgeon`s and the patient`s beliefs concerning important content during pre-surgery educating process. While the surgeon

listed *«surgical procedure»* as number one of important subjects; this was ranked as the 9th most important subject of the patient. *«Affection of symptoms»* was ranked highest from a patient`s perspective. *«General aspects of pain»* was among the most important reasons for undergoing lumbar surgery. The pain issue was therefor of higher importance compared to "surgical procedure" in an educative program (Tomoaki Toyone MD, 2005; Louw, 2009; Louw A, 2012). Knowledge, sense of confident, empowerment and control are important factors for a patient in a pre-surgical setting, to better the outcome of a surgery in orthopaedic patients (Johansson et al., 2005; Johansson et al., 2007).

Johansson (2007) states in his study that both written and oral information is an important part of the education process of the patient in a pre-surgical setting. The focus should be put towards development of a tailored education program consisting of bio physiological issues (symptoms and signs), functional issues (ie daily activities), feelings and experiences (Johansson et al., 2007; McGregor et al., 2010; McGregor et al., 2011).

Neuroscience education (NE) has shown significant effects in populations dealing with *chronic low back pain* (Moseley, 2002a; Moseley, 2003a; Moseley, 2004a; Moseley, 2004c; Moseley, 2005; Clarke et al., 2011; Louw et al., 2012; Puentedura and Louw, 2012), *chronic fatigue syndrome* (Meeus et al., 2010), *chronic whiplash disorder* (Van Oosterwijck et al., 2011), *preoperative orthopaedic patients* (Johansson et al., 2005; Johansson et al., 2007; Wong et al., 2010), *patients undergoing THA and TKA* (total hip-and knee arthroplasty) (Louw et al., 2013b), *patients undergoing spinal surgery* (Louw et al., 2013a), *patients undergoing cardiac surgery* (Shuldham, 2001; Shuldham, Fleming, & Goodman, 2002) and *patients with musculoskeletal pain* (Louw et al., 2011).

Wong et al randomized two groups prior to surgery after musculoskeletal trauma, giving one group (experimental group) the cognitive education in addition to usual care, and the other group (control) usual care. Outcome measures like pain, anxiety and self-efficacy were recorded before and after surgery. Statistical significant changes were found in all outcome measures between groups (Wong et al., 2010).

Several studies on NE have shown that one can change a patient´s perception of pain, improve their attitudes about pain, improve their cognition and physical performance related to pain, increase their pain threshold, improve outcomes of therapeutic exercises and reduce widespread brain activity characteristic of pain experience (Moseley, 2002a; Moseley, 2003a; Moseley, 2003b; Moseley, 2004a; Moseley, 2005). Some of these studies also highlight the health professionals' underestimation of patient's ability to understand pain. Attempting to implement NE in patient management may be difficult if the health professions believe that the patient will not understand this kind of information (Moseley, 2003b).

# 2.0 Objective and thesis

## 2.1 Objective

The primary aim of this study was to evaluate the efficacy of Neuroscience Education (NE) in a population of patients waiting to undergoing spinal surgery at Martina Hansen Hospital in Norway. Participants were extracted from the waiting list for spinal surgery. The waiting list for spinal surgery reaches from 14-20 weeks. Surgery for spinal fixation had an estimated waiting time pending from 20 weeks and surgery for spinal stenosis was pending from 14 weeks (Hospital, 2013). We included a group from the same waiting list that received standard hospital pre surgery information.

## 2.2 Thesis

***Is Neurophysiology Education (NE) in a preoperative phase, an effective measure to relieve disability, pain, anxiety, and fear of movement; in patients currently on the waiting list to undergo spinal surgery, compared with a standard hospital preoperative protocol at MHH?***

# 3.0 Method

This master thesis is written according to guidelines from the Department of Global Public Health and Primary Care, University of Bergen. The research protocol for this study was finished early December 2013 due to the need of approval from REK (Norwegian Ethics Committee). The University of Bergen had its own deadline in the middle of February 2014. There was made two different research protocols, one that would fit the criteria of REK and one to fit the criteria of the University.

An application was sent to the Norwegian Ethics committee (REK) the 10.12.2014. According to the protocol; baseline measurements were suppose to start the 1st of March 2014 after on-going inclusion of participants during January/February 2014. A declined application was returned from REK the 26.01.2014 (appendix 3). This postponed study start and inclusion of participants. The research protocol, info letter and letter of consent (appendix 4) was revised according to the feedback from REK, and a new application followed late February 2014. The study was approved by REK mid March and we were able to commence immediately.

## 3.1 Study design

A multiple single-case design (Single Study Experimental Design-SSED) consisting of three phases (A1-B-A2) was used. The main aspect of a study design like this is to answer this question: "*Does this treatment work*?"(Carter R, 2011). A SSED may be used on one or more participants and can provide data to formulate and validate new interventions or in validating existing theories (Backman et al., 1997).

The chosen study design is often used to systematically evaluate new treatments for a specific group of patient population (Carter R, 2011). These studies often serve as a prerequisite for larger randomized control trials (RCT). The critical feature of a single case design is doing continuous measurements throughout different timeframes in the management of the patient in a controlled environment. Continuous measurements enable us to attribute change in outcome measures to the independent variable (NE treatment). Multiple baseline measurements in advance to the intervention let us control the internal validity. This also enabled us to use each patient as his or her own control (Backman et al., 1997; Carter et al., 2011). The intervention was fully validated

in several mentioned studies and did not bring harm to the participants (appendix 5).

As an analogue study to confirm consensus with regards to our neuroscience education paradigm, Louw also pointed out six sections in focus of NE: (1) Decision to have back surgery; (2) The nervous system anatomy, physiology and pathways; (3) Peripheral nerve sensitization; (4) Environmental influence of nerve sensitivity; (5) Down regulation of the nervous system; and (6) Recovery after back surgery (Louw et al., 2013a). All measurement tools were highly validated and tested for reliability and responsiveness.

We aimed at manipulating the independent variable of the participants in the study, and by having reliable measurement instruments we were able to draw conclusion whether changes actually occurred. A single subject study resembles much the clinical setting where one can adjust the intervention according to the patient. Experimental studies with group design are often measuring one time at baseline and one time during post intervention phase. The result of such study may be attributed to normal variation of symptoms and not necessarily reflect the change due to intervention (Backman et al., 1997) .

Our study consisted of 3 baseline measurements when no intervention was taking place (A1 phase). The goal of such testing was to describe the natural variability of the patient's present state and predict future conditions of the patient without treatment intervention (Ottenbacher and York, 1984; Backman et al., 1997). In this phase we were able to detect normal variance in both NE group and standard hospital routine group (control) due to the fact that no intervention had taken place.

### 3.1.1 Ethical aspects of the study

All patients included in the study were able to withdraw at any given time. The patients were given a written letter of information prior to the question to consent. The orthopaedic department at MH Hospital supervised all intervention. The intervention done in this study was fully validated in several mentioned studies and would not bring harm to the participants. All participants were approved from the MH hospital prior to participation. All mail correspondence was anonymous.

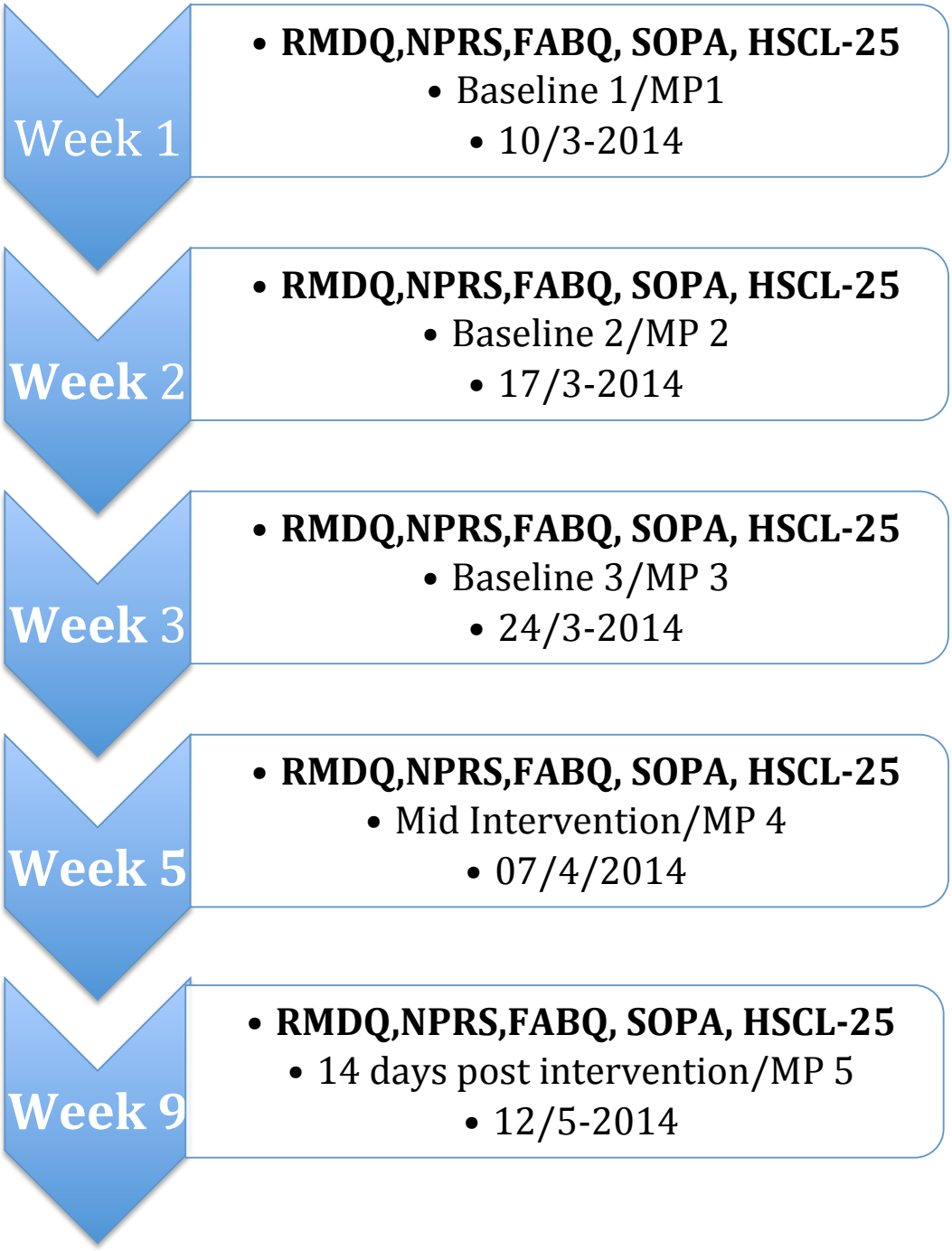


**Figure 1: Flow chart of study duration and outcome measures. The dates indicate time of fulfilled outcome measurement for the control group.**

## 3.2 Participants

Patients (from now on "participants") currently on the waiting list (January 2014) for decompression or fixation back surgery were reviewed for eligibility to the study in advance to the approval from REK. A phone call from research leader (from now on: RL) to the potential participants was done to explain the current application process and study duration, intervention and goal. Patients were told that the RL was to re-establish contact when the approval from REK arrived. At the point where REK approved the research plan, all patients eligible for the study received a new phone call from RL. The info letter and letter of consent was sent out to all patients who orally agreed to receive and read the mentioned information. Inclusion to the study was done when letter of consent was returned.

### 3.2.1 Inclusion criteria

1. Patients Age 18-70
2. Patients LBP
3. Patients currently approved for surgery at the MH Hospital.
4. Patients living in a geographic location 50k within the range of MH Hospital AND/OR Hans & Olav physical therapy centre in Oslo, Norway.
5. Patients able to both read, write, speak and understand spoken Norwegian.

### 3.2.2 Exclusion criteria

1. Patients not eligible for surgery
2. Patients uncertain of surgery
3. Patients with further geographic location than 50k from MH Hospital AND/OR Hans & Olav physical therapy centre in Oslo, Norway.
4. Patients with a diagnostic psychological disorder (patients would be referred to specialist in psychological healthcare).
5. Patients with acute spinal surgery due to trauma (<3months after trauma).
6. Patients with severe pathology of the spine i.e; malignancy, fracture, infection, or inflammatory joint or bone disease

### 3.2.3 Participant Access

The patient journals were obtained in the Hospitals secure journal system "DIPS" (Distributed Information and Patient data System in Hospitals). Msc Elisabeth Thornes (ET), PhD at MHH, performed the allocation of participations from the waiting list. ET extracted participants from the current waiting list, and forwarded information to RL. MHH had several other on-going research projects, which to some degree restricted participant accessibility from the waiting list.

The intervention of the participants was logged in the hospitals records, so that ET could keep track of study progress.

## 3.3 NE Intervention and standard hospital regime (control) group allocation

Randomization is the process where one ensures that participants have an equal chance of being assigned to any group (Kang et al., 2008; Carter et al., 2011). The patients on the waiting list were allocated to either NE or standard hospital regime by RL flipping a coin. Tails would assign first patient on the list to NE and head that would assign first on the list to standard hospital regime. First patient was assigned to hospital regime (head of coin), and every other participant on the list was dictated thereafter, resulting in equal size of groups.

After blinded allocation of participants into NE intervention mode after receiving letter of consent, RL matched the participants' number with personal details to be able to set up appointments for intervention. The number was put on all measurement outcomes and return-envelopes so that the personal details and numbers were kept separate and locked securely within the boundaries of MHH. This was all according to protocol, so that the answered outcome measures could not be matched with a specific person. All data analysis was done with no matching of personal identification and thereby kept anonymous.

All participants were informed by phone with regards to allocation of the two groups. The non-intervention group (standard hospital regime) were informed of the opportunity to receive the NE intervention post surgery if necessary. Participants in both group agreed on receiving surgery before 1$^{st}$ of July, and for some of them this resulted in a reduced time spent on waiting list. This

ethical situation was discussed and decided after an agreement between the Msc Thornes, RL and the Chief of the surgical department at MHH.

## 3.4 Collection of Data

The outcome measurements were retrieved during baseline and intervention period by a sealed pre-paid and anonymous envelop, with only a number in order to match earlier responses. Every week during baseline and intervention, each patient was contacted via telephone to ensure follow up with regards to the responsiveness of the screening tools (remembering to send the envelop back to researcher).

The baseline and intervention data was summarized for each patient. The mean values were calculated for each patient alone. Obtaining power of a statistical significance as an outcome measure (P=<0.05) was not in the scope of this study. Primary data (baseline assessment) and secondary data (patient journal) were provided differently. Secondary data was obtained from the MH hospital. Primary data was collected by the RL during the project by mail correspondence.

Data was obtained in locked cabinet at Martina Hansen Hospitals policlinic department under the supervision of ET.

### 3.4.1 Rationale for choice of outcome measures

Choice of outcome measurements should reflect the credibility regarding validity and reproducibility. The measurement instrument should measure what it is intended to measure and thus validate the instrument (Ostelo and de Vet, 2005). Reproducibility reflects the amount of error, which is accepted within the properties of the instrument when repeating the measurement.

When assessing low back pain, it is essential to assess pain intensity and its contribution to disability in everyday life as multiple factors contribute to LBP (Ostelo and de Vet, 2005). It is well recommended to assess fear avoidance beliefs, attitudes towards pain and level of disability due to prediction of long lasting pain and coping mechanism (Boersma and Linton, 2005; Linton et al., 2005; Ostelo et al., 2005; Boersma and Linton, 2006).

### 3.4.2 Roland Morris Disability Questionnaire

The RMDQ was designed to assessment functional health status and disability due to LBP. It has been designed for the use in research and in the clinic and focuses on a limited range of physical functions such as; walking, bending over, sitting, lying down, dressing, sleeping, self care and daily activities (Roland and Fairbank, 2000). The RMDQ has shown test-retest reliability and the Norwegian version has also shown validity for assessing self reported functional status of Norwegian- speaking pateints ith LBP (M. Grotle, 2003). RMDQ is designed so that patients places a check mark next to a statement that applies for them that specific day. In this way, the design can pick up short-term changes in back pain. Results are calculated by adding up the number of checked items- and the items are not weighted meaning that they grade form 0(no disability) to 24(maximum disability). The design is easy to understand for the patient since it is short and simple with daily known phrases ((Roland and Fairbank, 2000; M. Grotle, 2003; Grotle et al., 2013).

### 3.4.3 SOPA- Survey Of Pain Attitudes

The brief Survey Of Pain Attitudes has been used in several studies as a sensitive and valid measure of attitudes and beliefs about pain (Strong J, 1992; Moseley, 2004b; Clarke et al., 2011; Louw et al., 2011). The study of Moseley (2004) showed that a session of NE could alter the SOPA factors and hence consider positive if it occurred in the same direction as targeted in the pain education program (Moseley, 2004a; Louw et al., 2011). An increase in the SOPA score is associated with increased knowledge regarding pain, and hence a better understanding of pain provocation modulation.

### 3.4.4 FABQ- Fear Avoidance Belief Questionnaire

In patents with long standing low back pain, the fear avoidance model is seen as a central psychological mechanism in the maintenance of pain (Wand and O'Connell, 2008). The FABQ is developed to measure beliefs about physical activity and work (Waddel, 2004). The FABQ consists of 16 statements concerning physical activity and work, and the patient gives score from 0= Completely disagree- to 6= Completely agree. A higher score indicates higher fear avoidance beliefs so we urge for a low score. The scores are calculated by adding the points for question

6,7,9-12 (FABQ-Work) and question 2-5 (FABQ-Physical Activity) independently. A maximal score for FABQ-W is 42 and FABQ-PA 24, there are no standard scores for high or low value, but George et al. have used a cut off for FABQ-PA>29 and FABQ-W >14 as indicators for high score with bad prediction (George et al., 2003; George et al., 2005).

### 3.4.5 NPRS – Numeric Pain Rating Scale

Pain description can be detected by using NPRS (Jensen, 1992). In research concerning interventions that will affect pain, the NPRS- an 11point scale has shown to be a valid tool (Louw et al., 2011; Louw et al., 2012). In several studies detecting pain during the intervention of NE, the NPRS has shown as a valid and reliable measure of pain (Moseley, 2002a; Moseley, 2003a; Moseley, 2005). A reduction of 2-3points or 30% has show to detect clinical significant change from baseline measures (Ostelo et al., 2008).

The NPRS measures pain severity by asking the patient to select a number (from 0 to10(101)) to represent how severe the pain had been over the last 2 weeks (Jensen et al., 1986)NPRS is more reliable than the visual analogue scale, especially with less educated patients (Ferraz et al., 1990).

### 3.4.6 HSCL25- Hopkins Symptom Checklist-25

HSCL-25 is a well-established tool used for capturing indications of unspecific psychosomatic complaints (Sandanger, 1998). The screening tool consists of 25 questions concerning the presence and intensity of depression and anxiety symptoms from last week. The questions are being scored on a scale from 1-4, where 1 equals “not bothered” and 4 equals “extremely bothered”. One should add all scores and divide it by questions answered to get your HSCL-25 score. Score >1,75 indicates a high frequency regarding the use of health services (Derogatis LR, 1974; Winokur et al., 1984).

# 4.0 Results

## 4.1 Population

A total of 20 potential participants from the medical consultant waiting lists were contacted. A total of five people did not meet the criteria, while another four people declined participation. The remaining 11 patients fulfilled all criteria, and were invited to participate in the study. Two patients did not respond to the info letter in spite of confirming orally via telephone in advance. one patient declined after reading info letter. Eight patients provided written informed consent, and entered the study. One participant withdrew during baseline measurement and One participant received all NE sessions but did not complete outcome measures. A mix up during allocation due to drop outs and lack of responsiveness resulted in participant 11 being assigned to NE.

This left six participants completing all questionnaires in the study, two men and four women randomly allocated to NE intervention in addition to hospital regime or to hospital regime only. The two men were aged 67 years and the four women were aged 61,67,67 and 69 years. Mean values for the group during baseline when no intervention had been introduced was 7 (NPRS), 11 (RMDQ), 13 (FABQ-PA), 1,59 (HSCL-25) and 1,46 (SOPA). One participant in the NE-Intervention group did not complete all questionnaires after receiving all 4 NE-Intervention sessions. This person's data was excluded from the data statistics shown in this paper.

| **Baseline** | **P1** | **P2** | **P3** | **P5** | **P6** | **P11** |
|---|---|---|---|---|---|---|
| **Age** | 67 | 67 | 67 | 69 | 61 | 67 |
| **Gender** | Female | Male | Male | Female | Female | Female |
| **Mean NPRS** | 7 | 7 | 9 | 8 | 7 | 5 |
| **Mean FABQ-PA** | 13 | 16 | 12 | 16 | 13 | 10 |
| **Mean FABQ- Work** | - | - | - | - | 10 | - |
| **Mean RMDQ** | 8 | 12 | 16 | 7 | 10 | 10 |
| **Mean HSCL-25** | 1,35 | 1,82 | 2,11 | 1,41 | 1,41 | 1,43 |
| **Mean SOPA** | 1,75 | 1,16 | 2,03 | 1,13 | 1,00 | 1,67 |

**Table 1: Baseline demographics and self reported variables.**

The participants included in the study was extracted from the same waiting list and screened by inclusion and exclusion criteria.

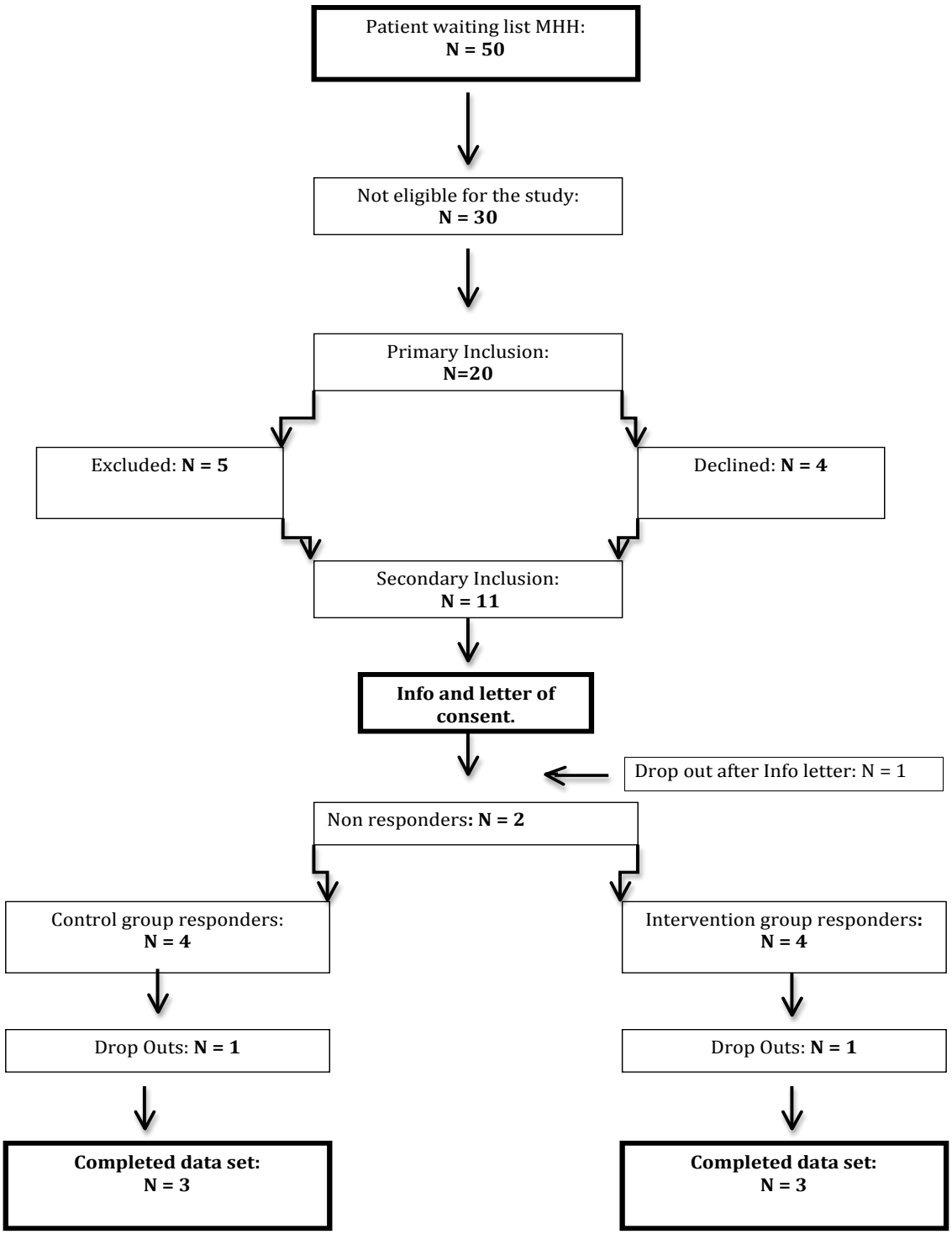


**Figure 2: Flow chart of inclusion and drop out during study period**

## 4.2 Implementation of the study

The intervention sessions lasted from 30min to 1,5h individually and spread out from two to six weeks. One patient underwent NE intervention sessions twice a week for two weeks in order to complete the study before time limit was due. One patient received intervention two weeks in a row and then two times during the following third week. One participant received intervention two weeks in a row and had a break for two weeks and then received the two last interventions the following two weeks. The NE was given through a one-on-one setting. A fourth participant received all NE interventions four weeks in a row, but did not complete outcome measures on time. This came to our attention after intervention was completed and matching of data was done.

During phase A1 (duration 1 month), baseline measurements were assessed and no intervention took place. Self-reported baseline measures of pain and functional disability (see section ”measurements”) were collected for ALL participants on three occasions one week apart. During phase B, four of the participants were treated with NE while four were not given any intervention, just monitored (*See flow chart figure 2*). Duration of phase B lasted a from two to six weeks. An intervention session varied in a pragmatic manner from 30min to 1,5hour, all in relation to patient understanding and cooperation. At the mid point of phase B, all outcome measures were completed once again. Final outcome measures were obtained two weeks after ending the NE Intervention (A2 phase). The A2 phase (SSED= A1-B-A2) was not long enough to determine a new baseline after intervention due to time restrictions and availability of patients. The A2 phase was based upon 1 outcome measure 14 days after intervention and may not be sufficient to detect a true A2 phase.

Total study duration/intervention of nine weeks was according to the research plan. The goal was to finish before the 17$^{th}$ of May, to guarantee operation for all participants within a month after completed intervention. The surgery had to take place before 1$^{st}$ of July 2014 due to summer closing of Martina Hansen Hospital.

All patients who fulfilled the data set underwent surgery during May/June 2014.

## 4.3 Outcome measures

All three patients in the NE intervention group showed an increase in pain understanding SOPA. These results are consistent with the findings of Louw and Puentedura in their latest multicentre study regarding NE in patients with CLBP and in Louw's case report regarding NE in CLBP. (Louw et al., 2012; Louw et al., 2014).

One out of three patients in the NE intervention group reported a drop in all outcome measurements. All three patients in the intervention group showed consistency in increasing their SOPA score which reflects a positive increase in understanding pain.

Outcome measures for the controlled group only receiving hospital standards protocol showed a natural variance and will not be discussed individually.

Figure 3, 7, 11, 16 and 20 will show the score of all participants. The participants undergoing NE are illustrated with a thicker line than the other participants who received standard hospital regime. This was a SSED study and no comparison is done within group, the figures are included in order to illustrate the large variance in outcomes during the study. Mean and SD in the figures illustrating the individual graphs of NE participants are calculated from the values of the concurrent 5 participants in the study. Calculation is explained in next section.

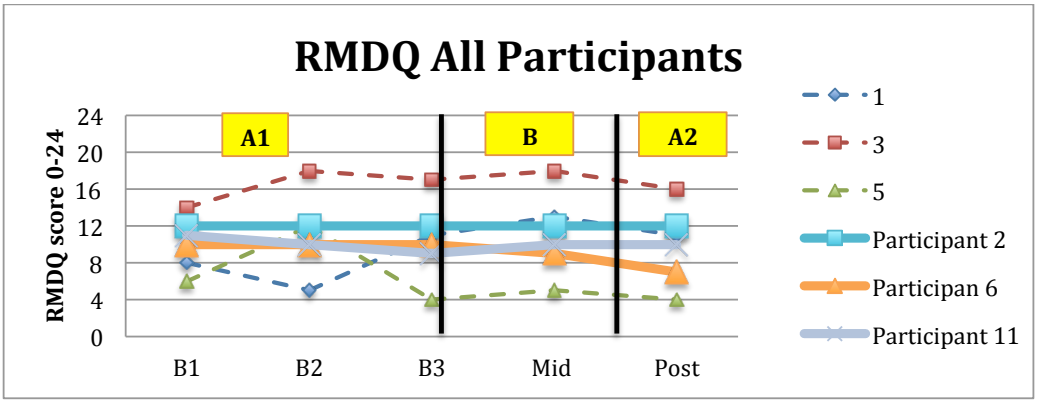


**Figure 3: Outcome measures of Roland Morris Disability Questionnaire in all participants. Participants 1,3 and 5 (dotted lines) did not receive any NE while participant 2, 6 and 11 received NE in addition to hospital guidelines. An increase in RMDQ score indicated a poorer functional health and increased disability.**

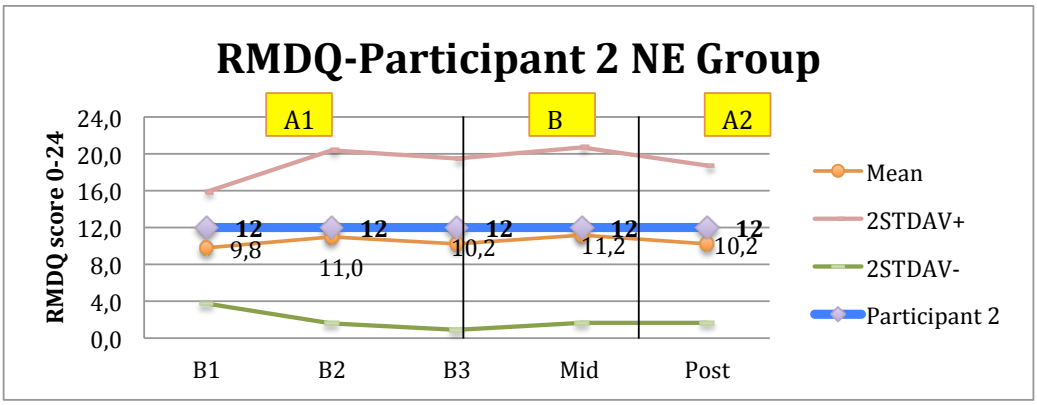


**Figure 4: Outcome measures of Roland Morris Disability Questionnaire in participant 2. P2´s values are excluded from the group´s mean and SD calculation.**

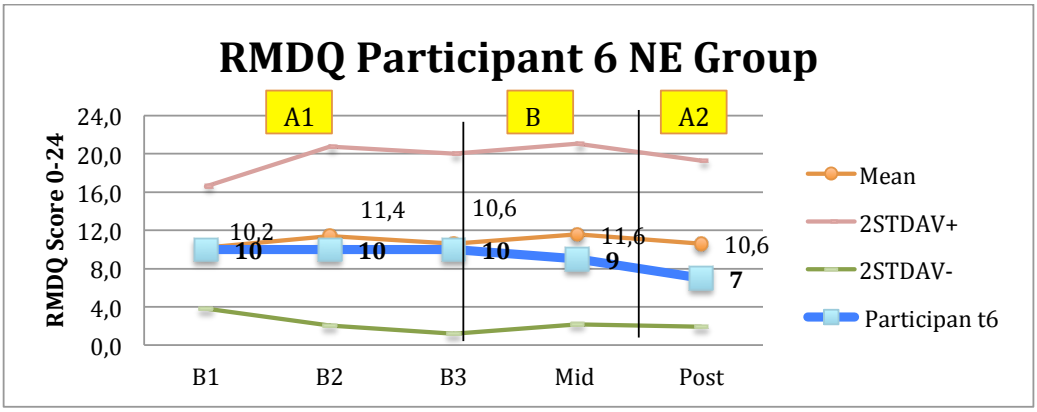


**Figure 5: Outcome measures of Roland Morris Disability Questionnaire in participant 6. . P6´s values are excluded from the group´s mean and SD calculation.**

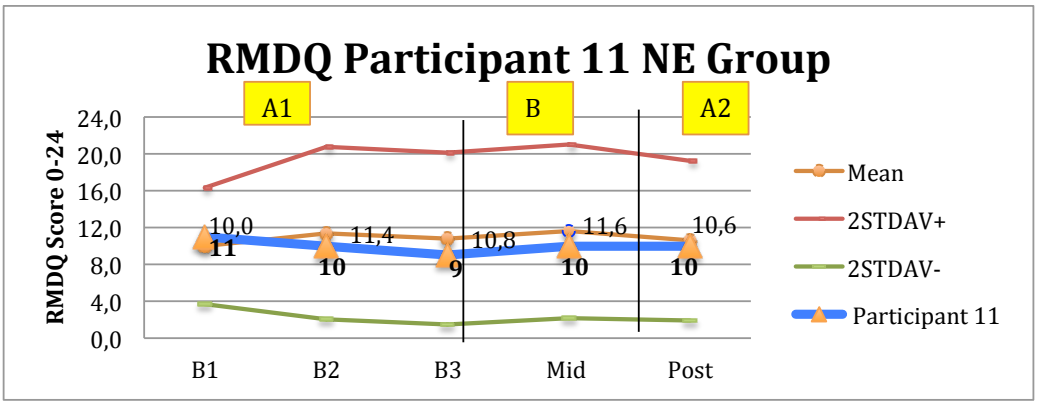


**Figure 6: Outcome measures of Roland Morris Disability Questionnaire in participant 11. P11´s values are excluded from the group's mean and SD calculation.**

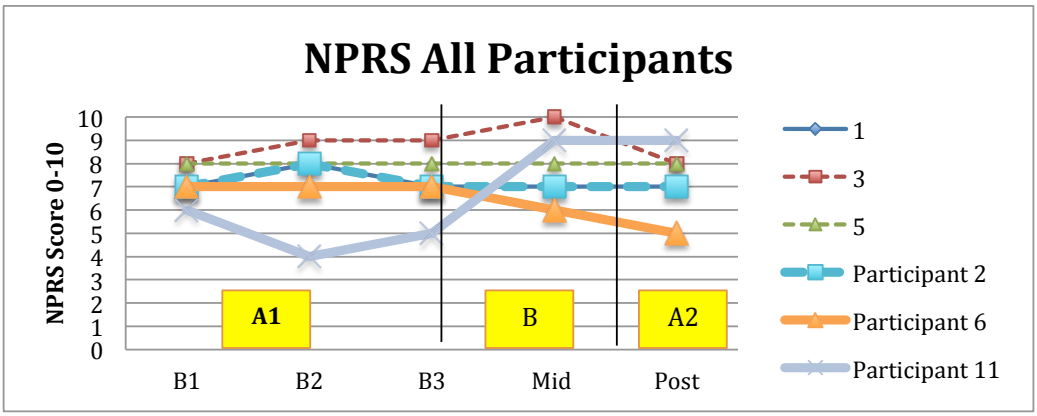


**Figure 7: Baseline, intervention and post intervention measure point of Numeric pain rating scale in all participants. Participants 1,3 and 5 (dotted lines) did not receive any NE while participant 2, 6 and 11 received NE in addition to hospital guidelines. An increase in score indicates an increase in pain.**

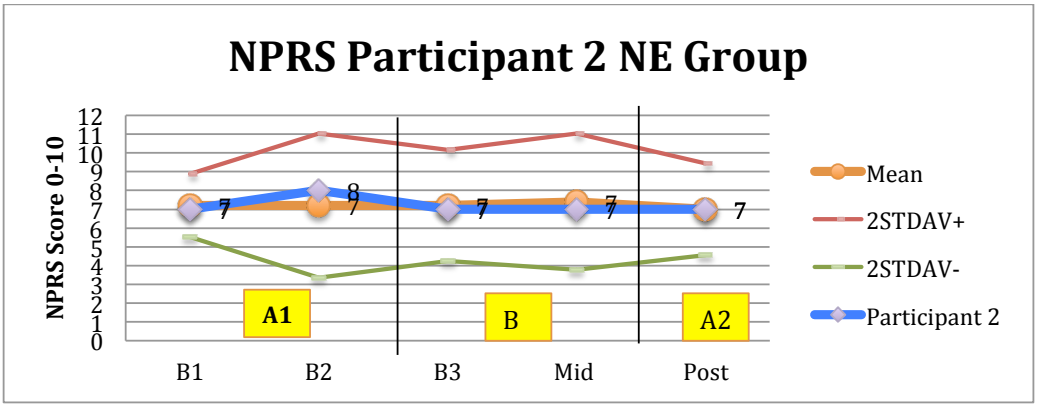


**Figure 8: Outcome measures of Numeric Pain Rating Scale in participant 2. The NPRS scale 0-10 has in this figure increases due to calculation of 2SD band. No higher score than 10 is possible to achieve on a NPRS scale. P2´s values are excluded from the group's` mean and SD calculation.**

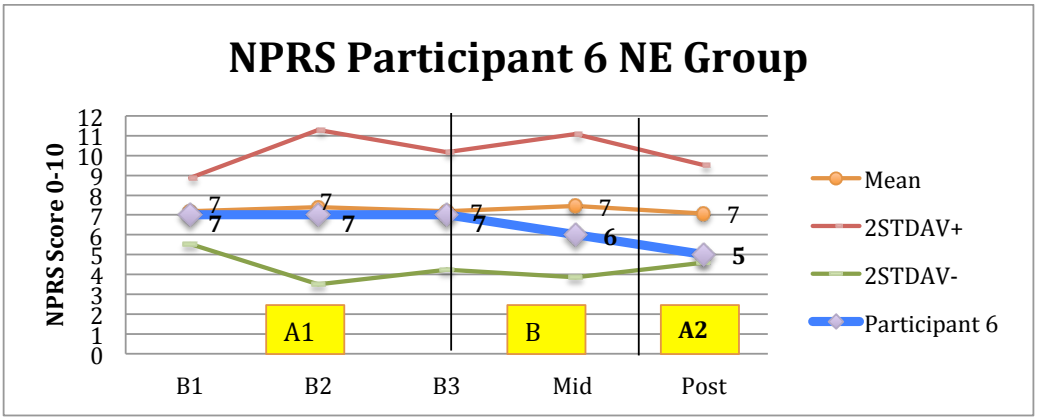


**Figure 9: Outcome measures of Numeric Pain Rating Scale in participant 6. The NPRS scale 0-10 has in this figure increases due to calculation of 2SD band. No higher score than 10 is possible to achieve on a NPRS scale. P6´s values are excluded from the group's` mean and SD calculation.**

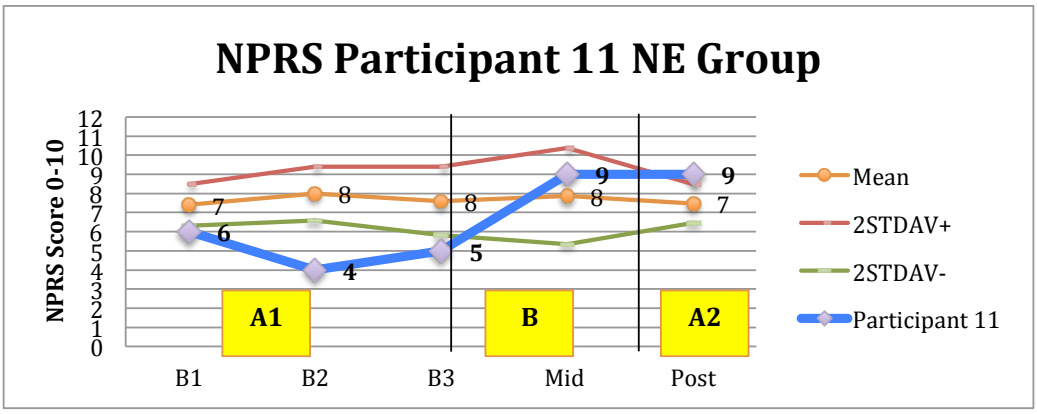


**Figure 10: Outcome measures of Numeric Pain Rating Scale in participant 11. The NPRS scale 0-10 has increased due to calculation of 2SD band. No higher score than 10 is possible to achieve on a NPRS scale. P11´s values are excluded from the group's mean and SD calculation.**

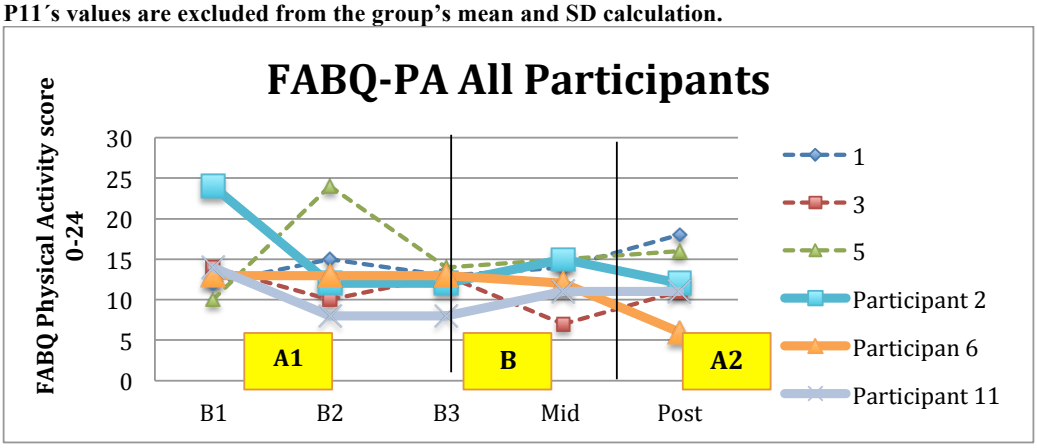


**Figure 11; Outcome measures of Fear Avoidance Beliefs Questionnaire regarding Physical Activity in all participants. Participants 1,3 and 5 (dotted lines) did not receive any NE while participant 2, 6 and 11 received NE in addition to hospital guidelines. Reduced score indicates less fear of physical activity.**

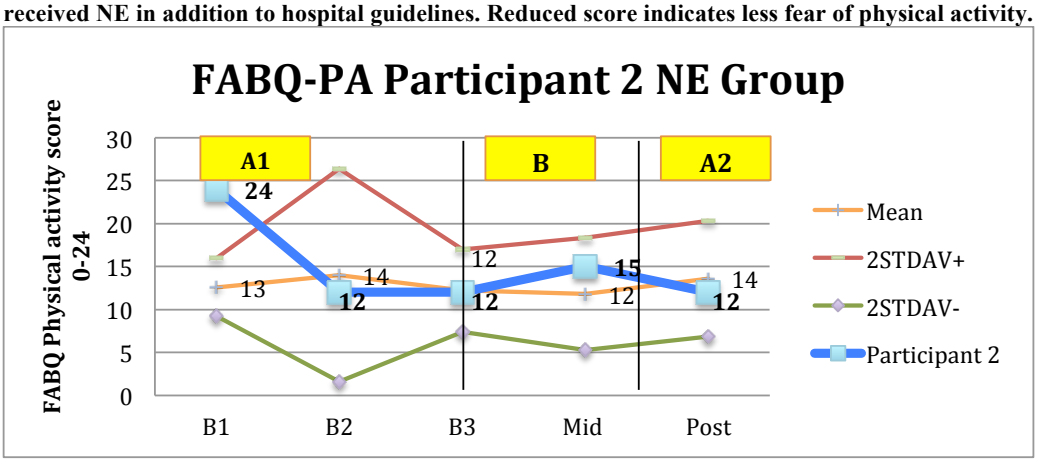


**Figure 12: Outcome measures of Fear Avoidance Beliefs Questionnaire regarding physical activity in participant 2. The increase of scale beyond 24 points is because of the 2SD calculation. P2´s values are excluded from the group's mean and SD calculation.**

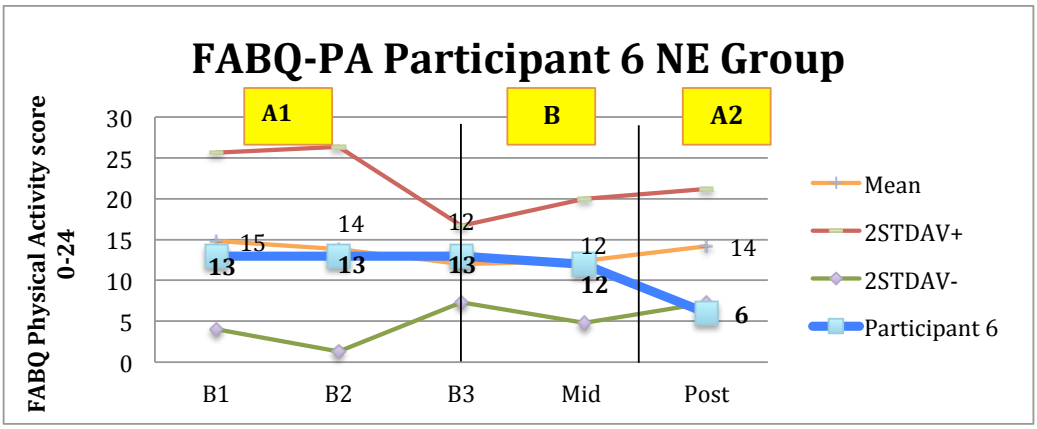


**Figure 13: Outcome measures of Fear Avoidance Beliefs Questionnaire regarding physical activity in participant 6. The increase of scale beyond 24 points is because of the 2SD calculation. P6´s values are excluded from the group's mean and SD calculation.**

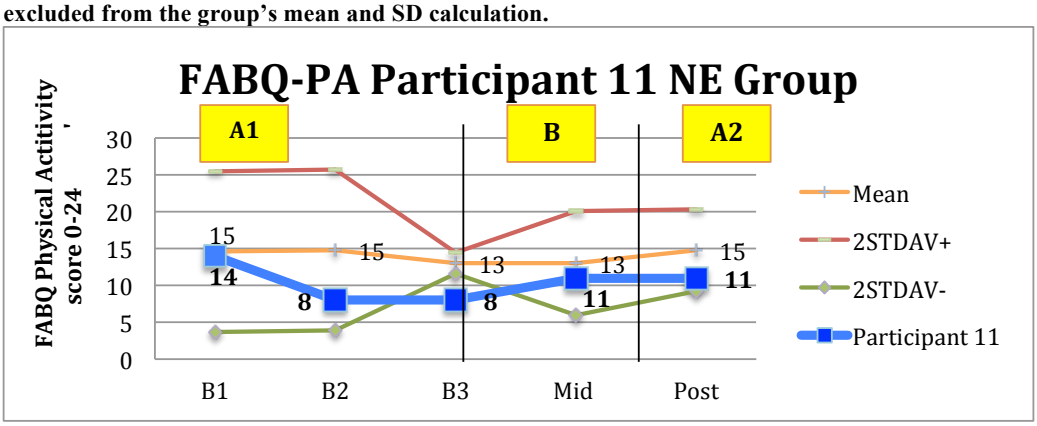


**Figure 14: Outcome measures of Fear Avoidance Beliefs Questionnaire regarding physical activity in participant 11. The increase of scale beyond 24 points is because of the 2SD calculation. P11´s values are excluded from the group's mean and SD calculation.**

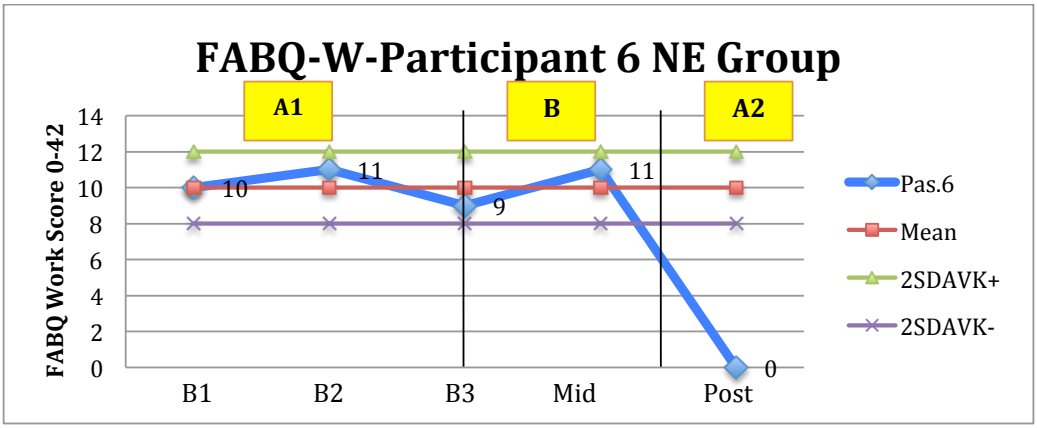


**Figure 15: Outcome measures of Work related Fear Avoidance Beliefs Questionnaire for participant 6. Participant six was compared with its own mean and SD calculated during baseline. Participant 6 was the only participant who had a full time job. Reduced score indicates a reduction of fear and avoidance related to work. P6´s values are compared with itself.**

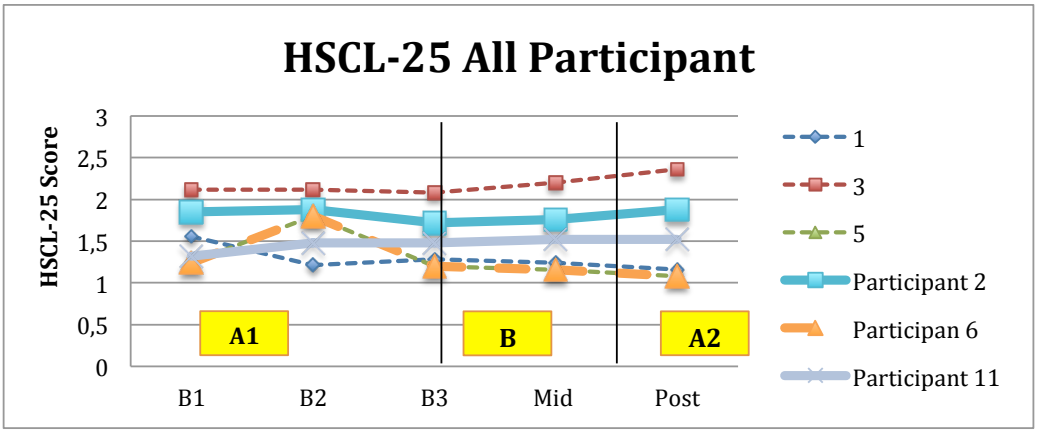


**Figure 16: Outcome measures of Hopkins Symptom Checklist-25 in all participants. Participants 1, 3 and 5 (dotted lines) did not receive any NE while participant 2, 6 and 11 received NE in addition to hospital guidelines. An increase in score indicates a higher use of health services.**

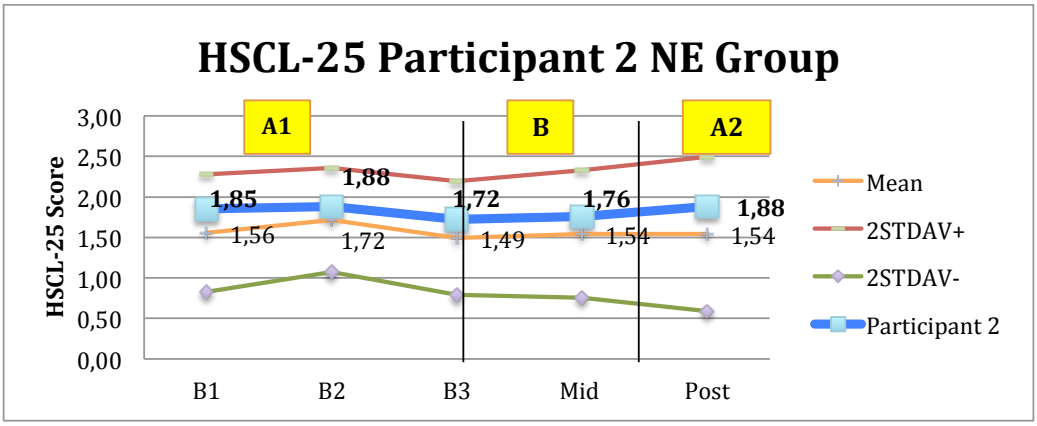


**Figure 17: Outcome measures of Hopkins Symptom Checklist- 25 in participant 2. P2´s values are excluded from the group's mean and SD calculation.**

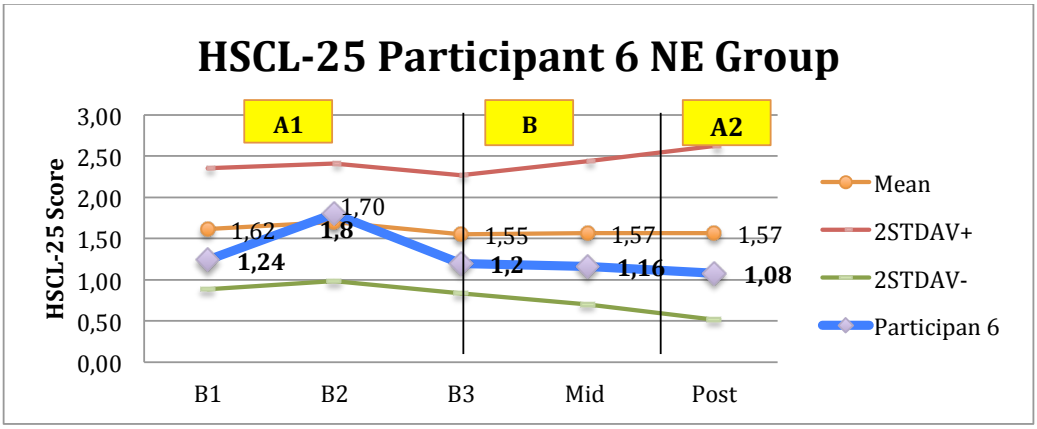


**Figure 18: Outcome measures of Hopkins Symptom Checklist- 25 in participant 6. P6´s values are excluded from the group's mean and SD calculation.**

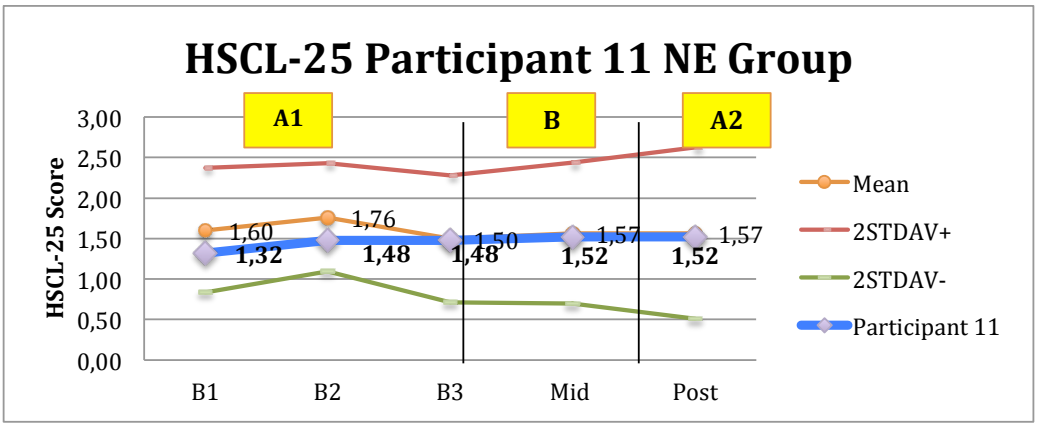


**Figure 19: Outcome measures of Hopkins Symptom Checklist- 25 in participant 11. P11´s values are excluded from the group's mean and SD calculation.**

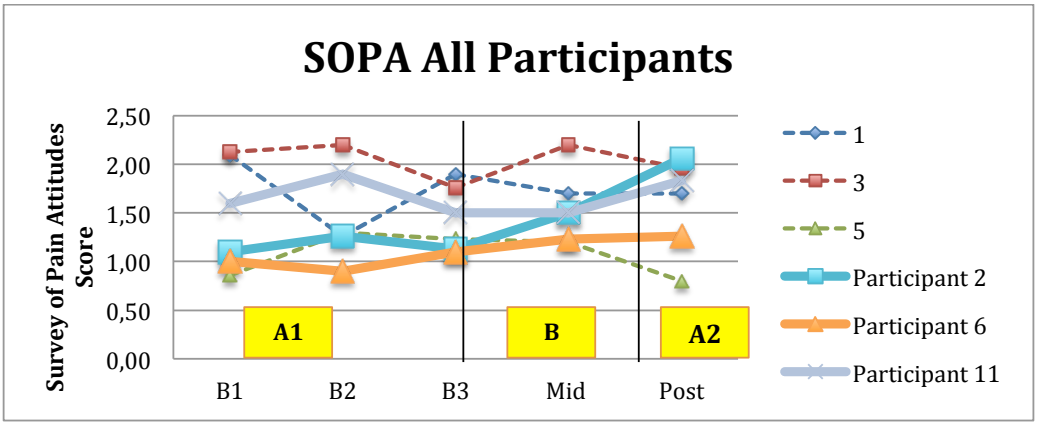


**Figure 20: Outcome measures of Survey Of Pain Attitudes in all participants. Participants 1, 3 and 5 (dotted lines) did not receive any NE while participant 2, 6 and 11 received NE in addition to hospital guidelines.**

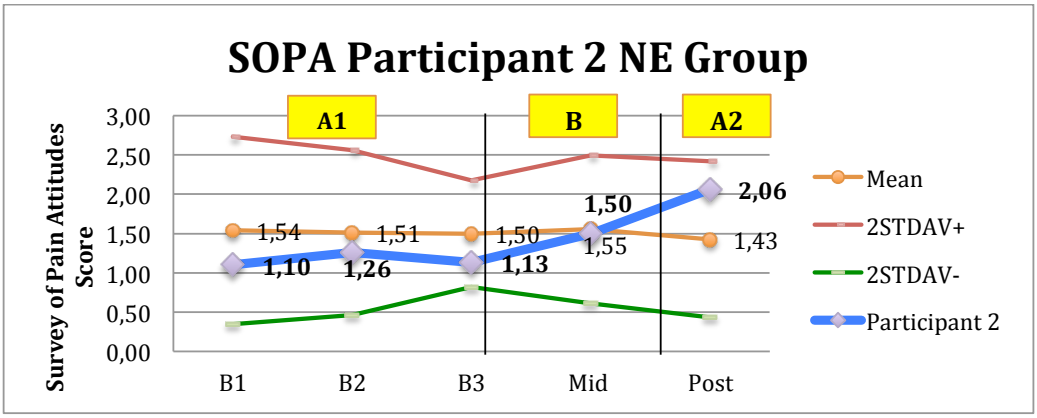


**Figure 21: Outcome measures of Survey Of Pain Attitudes in participant 2. P2´s values are excluded from the group's mean and SD calculation.**

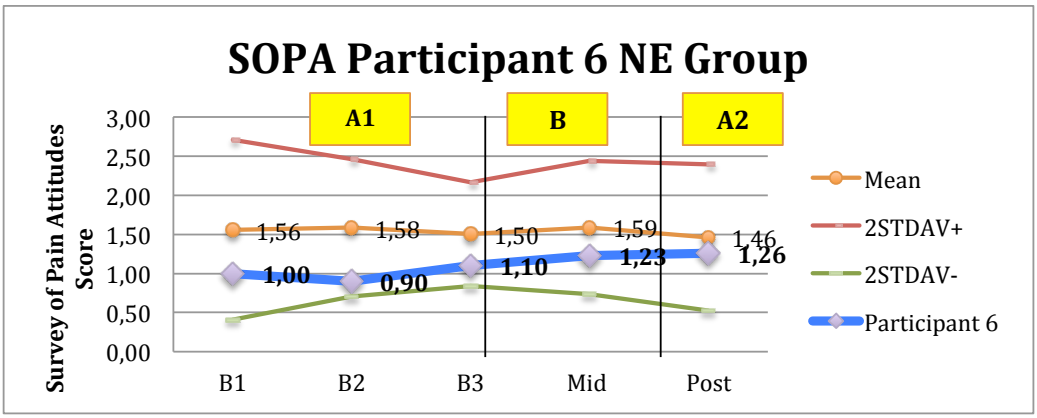


**Figure 22: Outcome measures of Survey Of Pain Attitudes in participant 6. P6´s values are excluded from the group's mean and SD calculation.**

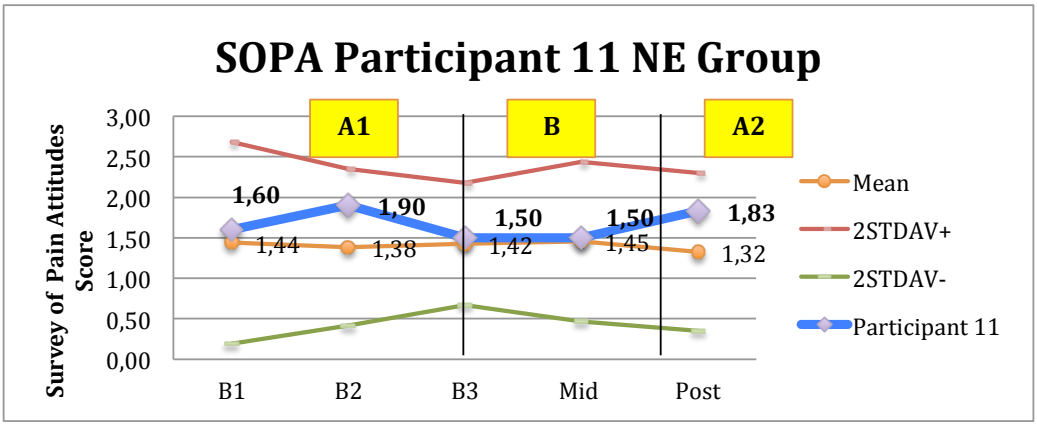


**Figure 23: Outcome measures of Survey Of Pain Attitudes in participant 11. P11´s values are excluded from the group's mean and SD calculation.**

## 4.4 Individual outcome measures

The figures illustrating each of the individual NE participants values is within a frame together with the mean and SD from the resulting five participants. The two participants in the NE group were included in these values by calculating mean and SD from baseline and extrapolate these to the intervention and post intervention values. In this way the NE effect is withdrawn in these two participants and the value replaced indicates the normal progress from baseline. Each participant's outcome measure at each time point is marked with the blue line. The group mean is represented with an orange line, and SD is illustrated with the red and green line. Mean and SD per time point of measurement for all participants reflects the normal variance for this population.

### 4.4.1 Participant 2

In figure 4, 8, 12, 17 and 21 we can observe the individual results for participant 2, who underwent NE intervention. No indications regarding effect of treatment is found in any outcome measures besides SOPA. We can observe an increase in SOPA score in figure 21 after a stable baseline. Participant two had all NE interventions at MHH with one session of 1,5h per week, 4 weeks in a row.

### 4.4.2 Participant 6

In figure 5, 9, 13, 15, 18 and 22 we can observe the individual results for participant 6 who underwent NE intervention. Stable baseline was observed in RMDQ, NPRS, FABQ-PA and SOPA, this can attribute effects to the intervention. A clinical significant drop was seen 14 days after intervention in RMDQ and NPRS with a reduction of three and two scores respectively. A reduction of 50% in FABQ-PA from mean baseline to assessment 14 days after intervention and 100% score reduction in FABQ-W from baseline to post intervention can be observed in figure 13 and 15 respectively. In fig 15, mean and SD are calculated from baseline of p6´s values only, because this was the only person with a full time job. A trend of increasing score can be observed in SOPA (figure 22). No effect of NE is seen in assessment of HSCL-25 either during intervention or after (figure 18). Illustrations of mean and 2SD shows that despite the improvements of the scores for participant 6, these results are still within the normative values of the entire group. Intervention was done at MHH with a mean duration of 1h each session, one session per week for two weeks and then two sessions during one week at the end due to time restrictions.

### 4.4.3 Participant 11

In figure 6, 10, 14, 19 and 23 we can observe the individual results for participant 11, who underwent NE intervention. In RMDQ, FABQ- PA, HSCL-25; figure 5, 14 and 19 respectively, this participant shows stable measurements. NRPS increases during intervention (figure 10). We cannot observe a stable baseline during SOPA score, but still a trend of increased score during and after NE intervention (figure 23). All NE sessions was done at the Hans &Olav physical

therapy clinic where RL had his daily practice. This was arranged due to logistic reasons. The NE lasted approximately 1h each time, two following weeks with one intervention per week, two weeks with no intervention followed by two weeks of intervention.

# 5.0 Discussion

This master thesis was written according to guidelines from the Department of Global Public Health and Primary Care, University of Bergen, which limit both the duration, and size/scale of the study. A2 phase was not long enough to establish a new baseline after intervention, so we are unsure with regards to the stability of our results.

The aim of this study was to see the effect of applying NE in patients waiting to undergo spinal surgery. Presenting theses findings in figures along with the result of assessment both during and after the NE intervention makes it possible to determine and illustrate if the NE intervention actually contributed to changes or improvements (Ostelo et al., 2008; Van Oosterwijck et al., 2011).

## 5.1 Recruitment

The initial goal was to include a total of 20 participants in this multiple SSED study. 10 would be allocated in the NE intervention group and 10 would follow standard hospital routines. 20 participants was an estimation too low to achieve a significant power of RCT, but enough to show clinical effect in a "within subject "comparison during this SSED. Postponed approval from REK, logistic problems regarding transport, deadlines at MHH and UIB may have been reasons for not reaching a total amount of 20 participants included in the study. Other research projects at MHH in parallel to this study restricted extraction of patients from the waiting list. Declined responses and dropouts are described previous in this paper. In an SSED, the author needs only one participant to discuss results. The participant is compared with itself, and would not be representative for generalization. Reaching 20, 10 or three participants undergoing NE should not affect how we attribute our effect, due lo lack of statistical power in the SSED format.

Participants were taken from the same population and were similar in relation to age, duration of pain and underlying pathology implying surgery. Age and pain duration can therefore be thought as representative in some extent to the population currently on waiting list for spinal surgery. Few participants in this study imply that we should conclude with caution.

## 5.2 Outcome measures

### 5.2.1 Hospital regime group

None of the three participants receiving only hospital preoperative routines showed stability in outcomes during the study, except in NPRS. An unstable baseline and fluctuations in perceived disability, fear of movements, pain attitudes and perceived psychosomatic illness may reflect the natural variations of symptoms in this group.

NPRS seemed somewhat stable throughout all 5 measurements in the group receiving standard hospital regime (fig 7). The results indicate a more fluctuating functional and cognitive response to pain depending on context when observing figure 3(RDMQ) and figure11 (FABQ). Wand et al has shown that RMDQ and self reported measure of function correlates with levels of distress, depression and anxiety, but seeing how the HSCL-25 is more or less stable in this group, this does not imply a correlation. The same author states that there is a misconception between self-reported disability and performance -based assessment (Wand et al., 2010). As we did not perform any functional assessment, this is difficult to relate to our findings. Physical performance assessment in either group should be of interest for further studies. Research describes a strong relationship between present pain intensity (NPRS) and RMDQ score (Wand et al., 2010), although earlier research have found no association of the latter (Jensen and Karoly, 1992). Several studies point out that perceived pain is not consistent with amount of tissue damage, and this may be why the other outcome measures vary more than NPRS in this population (Hrudey, 1991; Melzack et al., 2001; Apkarian et al., 2005; Tracey, 2005; Moseley and Arntz, 2007; Ossipov et al., 2010; Wand et al., 2010; Melzack and Katz, 2013).

### 5.2.2 NE Intervention Group

All three participants in the NE group showed an increase in the Survey Of Pain Attitudes (SOPA), indicating they had an increase in their pain attitudes and understanding of pain. One out of three participants in the NE group, clinically improved outcome measures of pain, disability, and fear of movement in physical activity and work context. Literature provides evidence of clinically detectable change if score is of 30% improvement from baseline testing (NRPS, RMDQ, Fear Avoidance, SOPA) (Ostelo et al., 2008; Wand et al., 2011a).
The outcome measure of work related fear avoidance was difficult to assess because only one participant (participant 6) was working full time.

#### 5.2.2.1 Participant 2

Participant number 2 had the greatest increase in SOPA outcome. The same participant showed no change in either RMDQ, NPRS, HSCL-25 which is consistent with the results from other studies (Louw et al., 2014). This person had formerly received conservative treatment at several physical therapy institutes with no increase of function. The multiple tries of conservative treatment may interfere with beliefs regarding ability to increase function in spite of pain. The mother language for this person was not Norwegian, so this can imply to some extent that not all information was understood. After NE sessions, this person responded “what about my pain?” and “but the surgeon said.” which reflected not a fully understood message of NE.

#### 5.2.2.3 Participant 6

Participant 6 shows a stable baseline with a drop of 3 points in RMDQ from baseline to post intervention outcome (fig 5). This is a clinical significant score reduction which can reflect an effective intervention (M. Grotle, 2003; Ostelo et al., 2008). A stable baseline strengthens the attribution of effect to NE, ergo validating the independent variable (Carter et al., 2011). The participant was an active listener throughout the whole intervention. She asked critical questions, demanding practical examples of the theoretical claims and came back to each session with reflective questions from last time. The participant met first appointment with no prejudgements of this type of intervention and showed an open mind regarding new explanatory models.

We observed a stable baseline measure in the FABQ Physical Activity and Work (figure 13 & 15). There are no known cut-off score for the FABQ, yet literature states that a reduced score equals a reduction in fear of movement (Waddell et al., 1993).

This participant showed a drastic reduction in work related fear avoidance. The post intervention outcome measure was verified through phone contact with the participant in order to confirm the 100% reduction rate. Observing figure 15 (FABQ-W), it may seem that this participant changed her attitude towards pain in certain contexts. During the NE sessions, information with regards to "context dependent pain" was highlighted. Participant 6 was self employed and able to control her own working environment. The ability to take control and change her working environment with regards to pacing, stress and expectations may have contributed to this reduction of fear and disability, as pointed out in other studies (Linton et al., 2005). The importance of coping skills has been accentuated in earlier studies. Coping skills are of importance in management of work and health related complaint (den Boer et al., 2006; Ree et al., 2013)

FABQ-PA (fig 13) indicates effect of NE. After intervention the score drops to six and even though it is not possible to detect a significant statistical effect of this, the clinical significant is obvious. The author questions the delayed effect when observing no change during intervention phase. Was it parts of NE that was more effective than others, or did the participant need a certain amount of time to reconceptualise the message given during intervention? The effect is still consistent with the results from Louw et al. verifying that reconceptualization might be efficient in reducing fear of movement, but not necessarily in reducing the perceived pain in a numeric pain rating scale (Louw et al., 2014). Even though this participant only showed a slight improvement of pain understanding (fig 22- SOPA), she seemed to embrace the fact that pain could arise elsewhere than from tissue only. She spent time during intervention asking for alternative explanations when she did not seem to understand the message. This may have contributed to the overall effect in spite of only a slight increase in SOPA. NPRS (fig.9) dropped 2 scores, and we attribute the reduction of pain to NE due to the stable baseline.

This participant had a strong social network and the only in the NE group with a full time job, this made her more dependent on functioning in daily life. During the NE she was able to create examples of "pain without tissue damage"- like mourning, grief and also "tissue damage without pain" in example- an injured soldier in war. The cognitive ability of this patient to really reflect over the perception of pain may have contributed to the change in outcome measures.

Patient therapist alliance seemed to be optimal in this particular setting. Studies state that alliance is of importance in order to predict a good outcome for the intervention (Fuentes et al., 2014). Fig 1represent baseline characteristics and age of this participant is somewhat less than the other participants. This may have resulted in a more active coping mechanism in combination with the fact that she was under the age of retirement. Central sentitization may have shifted towards a stronger descending inhibitory modulation in accordance to her ability to cope with pain attitudes.

#### 5.2.2.4 Participant 11

Participant 11 showed no effect with regards to NPRS (fig 10), FABQ-PA (fig 14) or RMDQ (fig. 6) How come that this person who seemingly understood and openly discussed the psychological aspects of thoughts and emotions still not seemed to reconceptualise his/her beliefs concerning pain? The author cannot determine effect of increased SOPA to NE when observing the variation of baseline assessment. A letter was attached when the last outcome measure was received. The letter described a person who found the questionnaires difficult and somewhat not relevant to the participants' situation. The letter was written in addition to the questionnaires in order to explain the benefits this person had achieved from NE intervention. The letter indicated that the participant was now better prepared for surgery and able to handle postoperative pain, if such would sustain. It may seem that the validated questionnaires lacked the ability to pick up relevant changes in this participant.

## 5.3 Understanding Pain versus Perceiving Pain and Daily Function

Moseley states that information about the neurophysiology of pain can be effective in promoting reconceptualization of the problem, but may not be sufficient to obtain behavioural change (Moseley, 2004c). When interpreting our results, there is not sufficient evidence to conclude

overall reduction in outcome measures due to NE.

This information is important and also consistent with the results found in the last multicentre study by Louw et al (Louw et al., 2014) **.** No different in pain or disability outcome between NE and control group 12 months post surgery was detected in the study of Louw et al. The same study showed NE participant to report a significantly different and more positive view of their surgical procedure (Louw et al., 2014). Our study was not able to detect these outcomes due to lack of post-surgery follow up. Looking at the letter received from participant 11 (appendix 6), it may seem that the same effect related to surgical procedure and outcome was obtained.

Moseley et al. showed changes in cognitive and physical performance assessment after NE intervention, but little effect on perceived disability (Moseley, 2004c). In figure 20 we observe that SOPA increases slightly in all intervention participants, but an unstable baseline makes it difficult to attribute effect to NE**.** Our results demonstrate that the provision of information about neurophysiology of pain may be effective in promoting reconceptualization, but continues to demonstrate that in spite of reconceptualization and information, this may be insufficient to change behaviour. This is also concurrent with other studies (Louw et al., 2014).

## 5.4 Study implementation and aspects of intervention

Due to time restriction we were not able to detect changes in outcome measures after surgery. This is a limitation when interpreting the importance of such intervention. The optimal aim of this study would be to detect a post surgery improvement in pain (Louw et al., 2013b).

The therapist (RL) had to rely on his own knowledge and didactic ability in order to perform the NE. Reflecting on current capacity of NE, the RL admits to be biased in the way he preformed the NE intervention. RL had no former experience with pre-surgery NE intervention. Experience and expertise of the RL regarding NE was within the scope of non-specific low back pain. Participants included in this study had long standing pain and they were all convinced both by the surgeon and themselves that the pain was related to organic mechanisms. This is contrary to the aim of neuroscience education where pain is defined dependent on complex neural processing. Trying to send another message compared to what had been given by the authority- the surgeon,

was a huge barrier during communication with the participants. Mal adaption and dysfunction of the nervous system rather than robust spinal pathology is among the explanatory models to pain sensation in NE (Melzack et al., 2001; Zusman, 2002; Moseley, 2004c; Nijs et al., 2010; Woolf, 2011; Moseley and Flor, 2012).

Earlier studies on preoperative NE have attributed the effect when assessing postoperative pain (Louw et al., 2013a). As mentioned in the former section, this study was not able to detect any postoperative effect of the intervention. As a follow up from MHH, it would be optimal to do an assessment of the participant after surgery. The author registered outcome measures only 14 days after ending NE, how would time affect these results? The latest study from Louw et al showed *postoperatively,* that the effect of NE was greatest within the first month after lumbar surgery, then flattening out until no detectable different 12months after surgery (Louw et al., 2014). Would we be able to expect a reduced effect of NE if there were longer time intervals between intervention and post intervention assessment?

### 5.4.1 Study design and Clinical implications

Choosing multiple SSED as a format for this intervention, made it possible to evaluate variations in symptoms both outside and during intervention. Individual differences reflect the importance of studying each participant instead of the group as a whole. A disadvantage concerning study type is that we cannot say anything regarding the effect on group level, nor can the author generalize the results to all patients on a waiting list for spinal surgery.

### 5.4.2 Hospital information

All patients in our study had received information with regards to surgical procedure from the orthopaedic department at the hospital prior to the intervention. Participants had received a biomechanical diagnosis from the hospital based upon structural damage. Studies show that anatomical explanations might increase fear and pain instead of relieving it (Houben et al., 2005a; Louw et al., 2011; Darlow et al., 2012; Louw et al., 2013b; Nijs et al., 2013; O´Sullivan, 2014).

The standardized information given by MHH before the spinal operation and initiation of NE was in certain aspects opposite of what the NE explains with regards to tissue sensitivity and fear avoidance beliefs in relation to pain-related movements. Surgeons focused a lot of their information on the biomechanics of injured body parts. This is concurrent with earlier studies regarding what a surgeon weights important during information (Tomoaki Toyone MD, 2005). Participants in our study had a memory of surgeons commenting, " exercise will not help ease your pain", "do not move into pain, it will make it worse". This may have increased beliefs around movement and increased pain behaviour (Darlow et al., 2012; Darlow et al., 2013). One can reflect whether the outcome would be different if the participants had not seen a surgeon prior to the commencement of the NE intervention?

The author experienced different attitudes and beliefs regarding pain, which made it difficult to implement alternative explanations of pain to participants. Instructions like " do not move into pain provoking positions" were given to patients with LBP. "Stay aware of symptoms in order to not aggravate the pain" was information given to patients by physiotherapist both before and after surgery. These instructions are in strong contrast to the current evidence of how to communicate pain related issues to patients with LBP (Ostelo et al., 2003; Houben et al., 2005b; Darlow et al., 2012; O´Sullivan, 2014).

### 5.4.3 Further research

This study is primarily a hypothesis generating process and may be of help in designing a pilot for a larger study.

Exposing the participant to "fearful" movements and disabilities in a safe environment, rather than on their own, could have been a natural contribution to our intervention. Although the clinical utility of the effects detected in our study is limited when considered in isolation, they are probably more important if they enhance the effect of other strategies; i.e. Physical therapy, exercise therapy or cognitive behavioural therapy.

Surgery versus no-surgery is a subject at hand. Should everyone undergo surgery (Nachemson, 1992; Mannion et al., 2013)?) Should we improve allocation of patients to surgery or cognitive-

neuroscience education based on personal characteristic? We need to look at patient characteristics when introducing either cognitive therapy or neuroscience education to our patients. The neuroscience education in this study was structured into four learning sessions (appendix 5). A shift of NE towards a more tailor-suited intervention may be more efficient in changing the participant`s understanding of pain and transferring this into activities of daily life. NE in combination with physical therapy has shown positive outcome, so for further research this should also be included in the intervention (Moseley, 2002a).

Utilization of NE is increasing and the use of this intervention in a hospital setting should still be thought of as mandatory when looking at the substantial evidence through earlier studies (Louw et al., 2011). We may need to combine NE with other interventions like graded exposure or cognitive behavioural therapy in order to optimize the reconceptualization of pain understanding (Louw et al., 2014). Even though NE has limited effect as an entity alone, it may be beneficial in laying the groundwork for other active cognitive interventions.

## 6.0 Limitations

"To whom", "In what setting" and "At what times"; are essential questions when focusing on generalization of the results in a study (Carter R, 2011). One needs to take in consideration the consumer's perspective in how closely the research participants and intervention setting will match the reader`s clients and setting.

The few number of participants is a threat to generalisation of our results. The fact that participants received no compensation for time spent filling out assessment forms, may have contributed to rapid and unreliable answering of forms. We can only compare the participants with themselves in this study format. The external validity was defined from population through the cooperation with MH Hospital who gave permission to intervene with the patients currently on the waiting list for spinal surgery. In a single subject study, the most useful tactic for establishing generality would be of *replication (Carter R, 2011)*. By replication of intervention in this multiple single case experimental study of highly similar participants, the RL was able to establish some generality of the results. It could be reasonable to perform a pilot study before

initiating this current study to test the protocol in relation to challenges like logistics, facilities, and information from surgeons in advance, time aspect, and NE intervention format.

The internal validity should ensure a causal relationship between the independent and dependent variables (Carter R, 2011).(Sigrunn Drageset, 2009). The independent variable (intervention) was 4 NE sessions with the author as the therapist and research leader (RL). The dependent variable was detected through questionnaires; NPRS, RMDQ,FABQ, and HSCL-25, Multiple dependent variables may have confused the participant and contributing to reduced understanding of the targeted outcome effect. The study presented only one standardised independent variable not custom made or tailor suited for the individual participant. The intervention was restricted to NE only, thus exercise therapy or gradual exposure to painful movements was not included in the study. Former educational format emphasize the shift from "therapist as a teacher", to "therapist and patient as a team. Implementation of a structure based upon "education" to begin with-rolling towards a more two-way intervention much like Motivational Interviewing/cognitive therapy could have provided a better patient alliance during intervention (Forsberg et al., 2011; Hall et al., 2012).

We aimed at investigating the effect of NE *prior* to surgery so surgery intervention should not play a role in NE effect. Still, participants were allocated to only two different surgical procedures, being decompression or fixation. We should therefore be careful at extrapolating our results to other patients waiting to undergo lumbar surgery.

## 7.0 Conclusion

Reconceptualising of pain occurred in one of three participants in the NE group who showed an improvement in all outcome scores. Increase in SOPA does not seem to significantly change pain ratings, disability score or fear of movement. Results implicates NE alone, is not efficient of changing pain behaviour. This SSED is hypothesis generating for future research in NE and patient characteristic.

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# 9.0 Appendix

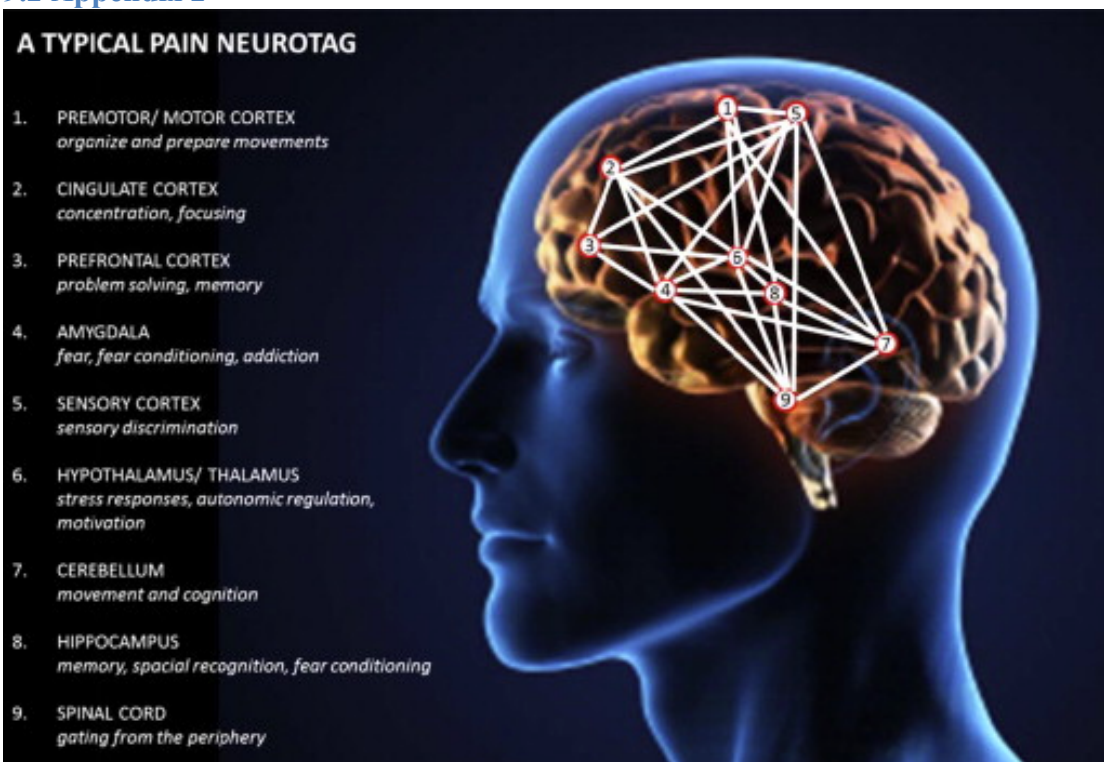
## 9.1 Appendix 1

| | |
|---|---|
| **Pain** | An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. |
| **Allodynia** | Pain due to a stimulus that does not normally provoke pain. |
| **Analgesia** | Absence of pain in response to stimulation, which would normally be painful.<br>*Note:* As with allodynia (q.v.), the stimulus is defined by its usual subjective effects. |
| **Anesthesia dolorosa** | Pain in an area or region, which is anaesthetic. |
| **Hyperalgesia** | Increased pain from a stimulus that normally provokes pain. |
| **Hyperesthesia** | Increased sensitivity to stimulation, excluding the special senses |
| **Hyperpathia** | A painful syndrome characterized by an abnormally painful reaction to a stimulus, especially a repetitive stimulus, as well as an increased threshold.<br>*Note:* It may occur with allodynia, hyperesthesia, hyperalgesia, or dysesthesia. Faulty identification and localization of the stimulus, delay, radiating sensation, and aftersensation may be present, and the pain is often explosive in character. |
| **Neuropathy** | A disturbance of function or pathological change in a nerve: in one nerve, mononeuropathy; in several nerves, mononeuropathy multiplex; if diffuse and bilateral, polyneuropathy |
| **Nociception** | The neural process of encoding noxious stimuli. |
| **Nociceptive neuron** | A central or peripheral neuron of the somatosensory nervous system that is capable of encoding noxious stimuli. |
| **Nociceptive pain** | Pain that arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors, |
| **Nociceptive stimulus** | An actually or potentially tissue-damaging event transduced and encoded by nociceptors. |
| **Nociceptor** | A high-threshold sensory receptor of the peripheral somatosensory nervous system that is capable of transducing and encoding noxious stimuli. |
| **Noxious stimulus** | A stimulus that is damaging or threatens damage to normal |

| | |
|---|---|
| **Hypoalgesia** | Diminished pain in response to a normally painful stimulus. |
| **Hypoesthesia** | Decreased sensitivity to stimulation, excluding the special senses. |
| **Neuralgia** | Pain in the distribution of a nerve or nerves. |
| **Neuritis** | Inflammation of a nerve or nerves. |
| **Neuropathic pain** | Pain caused by a lesion or disease of the somatosensory nervous system. |
| **Central neuropathic pain** | Pain caused by a lesion or disease of the central somatosensory nervous system. *See neuropathic pain note.* |
| **Peripheral neuropathic pain** | Pain caused by a lesion or disease of the peripheral somatosensory nervous system. *See neuropathic pain note* |
| | tissues. |
| **Pain threshold** | The minimum intensity of a stimulus that is perceived as painful. |
| **Pain tolerance level** | The maximum intensity of a pain-producing stimulus that a subject is willing to accept in a given situation, |
| **Paresthesia** | An abnormal sensation, whether spontaneous or evoked. |
| **Sensitization** | Increased responsiveness of nociceptive neurons to their normal input, and/or recruitment of a response to normally subthreshold inputs. |
| **Central sensitization** | Increased responsiveness of nociceptive neurons in the central nervous system to their normal or subthreshold afferent input.<br>*Note:* See note for sensitization and nociceptive neuron above. This may include increased responsiveness due to dysfunction of endogenous pain control systems. Peripheral neurons are functioning normally; changes in function occur in central neurons only. |
| **Peripheral sensitization** | Increased responsiveness and reduced threshold of nociceptive neurons in the periphery to the stimulation of their receptive fields. |

**http://www.iasp-pain.org/Taxonomy?navItemNumber=576, 06.10.2014.**

## 9.2 Appendix 2




**Chapter 1**—A Conceptual Framework for Understanding Pain in the Human

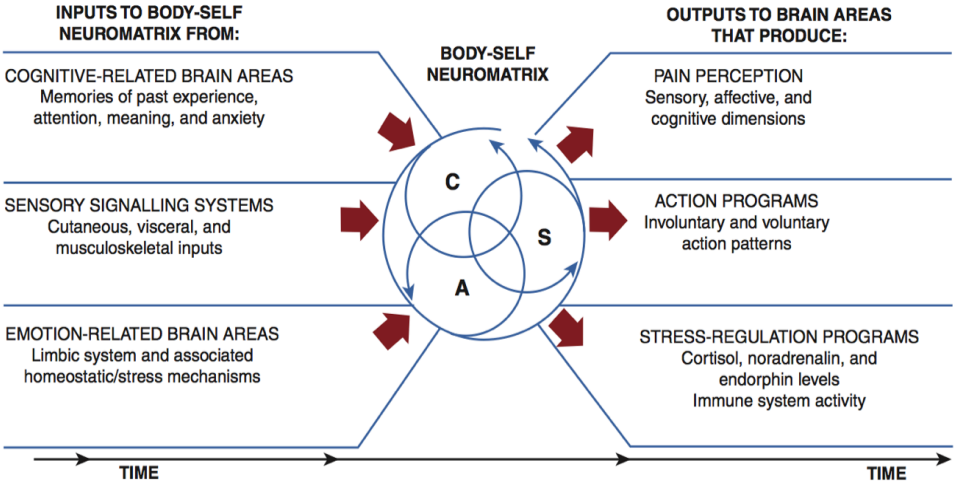



**Figure by Ronald Melzack, Ph.D. in "Pain and the Neuromatrix in the Brain", 2001.**

## 9.3 Appendix 3

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

| Region: | Saksbehandler: | Telefon: | Vår dato: | Vår referanse: |
|---|---|---|---|---|
| REK sør-øst | Anne S. Kavli | 22845512 | 28.02.2014 | 2013/2383/REK sør-øst A |
| | | | Deres dato: | Deres referanse: |
| | | | 09.02.2014 | |

Vår referanse må oppgis ved alle henvendelser

Kjartan Vibe Fersum
Universitetet i Bergen

**2013/2383 Effekt av undervisning i smertefysiologi hos pasienter som skal gjennomgå ryggkirurgi**

**Forskningsansvarlig:** Universitetet i Bergen
**Prosjektleder:** Kjartan Vibe Fersum

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtet 14.01.2014. Det ble fattet et utsettende vedtak. Prosjektleder har besvart komiteens merknader i tilbakemelding mottatt 09.02.2014. Tilbakemeldingen er behandlet av komiteens leder på fullmakt.

Til spørsmål 1 vedrørende beredskap: Det vil etableres beredskap og dersom det avdekkes psykiske lidelser hos pasientene vil de henvises til spesialisthelsetjenesten

Til spørsmål 2 om fordeling til gruppene : Annenhver pasient på ventelisten vil fordeles til hver av gruppene.

Til spørsmål 3 om tilgang til journal: Inklusjon skjer i samråd med behandlingsansvarlig ved MH sykehus og det er derfor ikke nødvendig at prosjektleder har tilgang til journaler.

Til spørsmål 4 om datasikkerhet: Data skal oppbevares ved MH hospital og behandles avidentifisert.

Til spørsmål 5,6 og 7 vedrørende informasjonsskriv: Informasjonsskrivet er revidert i tråd med komiteens merknader. Komiteen har imidlertid fortsatt noen merknader til utformingen av informasjonsskrivet.

I avsnittet under overskriften "Hva innebærer studien" bør man først forklare hva intervensjonen går ut på. Deretter hvordan man fordeler til undervisning før eller etter operasjon, og deretter informere om spørreskjema.

**Komiteens vurdering**

Komiteen anser tilbakemeldingen på komiteens spørsmål som tilfredsstillende, men har følgende merknader til informasjonsskrivets avsnitt "hva innebærer studien":
1 Først må man forklare hva intervensjonen går ut på.
2 Deretter må man forklare hvordan man fordeles til undervisning før eller etter operasjon
3 Og deretter informere om spørreskjema

**Besøksadresse:** Gullhaugveien 1-3, 0484 Oslo
**Telefon:** 22845511
**E-post:** post@helseforskning.etikkom.no
**Web:** http://helseforskning.etikkom.no/

**Vedtak**

Komiteen godkjenner prosjektet på vilkår som beskrevet ovenfor med hjemmel i helseforskningsloven § 33 jf. § 9.

Godkjenningen gjelder til 01.07.2015.

Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren». Personidentifiserbare data slettes straks det ikke lenger er behov for dem og senest ved prosjektets avslutning.

Prosjektet skal sende sluttmelding, se helseforskningsloven § 12, senest 6 måneder etter at prosjektet er avsluttet.

*Klageadgang*
Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Knut Engedal
Professor dr. med.
Leder

Anne S. Kavli
Førstekonsulent

**Kopi til:** ; [redacted] Universitetet i Bergen: postmottak@uib.no

REK feedback

Etter tilbakemelding fra REK ses det på som nødvendig å klare opp i noen punkter vedr protokoll og Informasjonsskriv.

1) *I prosjektet vil det bli brukt spørreskjema som kartlegger psykisk helse. Det var i utgangspunktet ikke beskrevet beredskap for oppfølging dersom dette avdekkes.* Forskningsgruppen setter pris på at komiteen påpeker dette. Forskningsgruppen har i original protokoll satt som et eksklusjons kriteriet (se §3.4.2, s 12 i protokoll), "patients with a diagnostic psychological disorder" og vi beregner da at pasienter med psykiske lidelser blir fanget opp og ekskludert før studiestart. Vi tar videre tilbakemelding fra REK i betrakting og vil nå protokollføre at dersom det blir avdekket ytterligere psykiske lidelser hos pasienter inkludert i studiet, så vil disse bli ekskludert fra videre intervensjon, men fulgt opp med henvisning til spesialhelsetjenesten.

2) *Komiteen ber om redegjørelse for hvordan deltakerne fordeles til intervensjonsgruppe og kontrollgruppe*. Vi takker komiteen for denne opplysningen om mangelfull informasjon og tar det til etterretning. Forskningsgruppen vil selektere pasienter til intervensjon og kontroll ved å ta annenhver pasient på ventelista i hver av gruppene. Dette er nå beskrevet i protokoll og i informasjonsskriv.

3) *Det er ikke gitt noe begrunnelse for hvorfor prosjektleder får tilgang til pasientjournal for å velge ut pasienter. Komiteen ber om at forskergruppen vurderer hvorvidt dette kan gjøres av behandlingsansvarlig ved sykehuset.* Forskergruppen takker for komiteens tilbakemelding vedr saken og har tatt dette i betrakting for revidert protokoll. Forskergruppen har vurdert innsyn for prosjektleder i pasientjournal som ytterligere unødvendig da inklusjon av pasienter skjer i samråd med behandlingsansvarlig ved MH sykehus.

4) *Datasikkerheten i prosjektet er ikke klart beskrevet*. Forskningsgruppen takker komiteen for innsikt i manglende opplysninger og retter opp dette i revidert protokoll. All data innsamlet under prosjektet vil bli oppbevart i låst skap i poliklinisk avdeling på MH Sykehus under oppsyn av Mcs Elisabeth Thornes- Prosjektleders kontakt ved MH. Utfylte skjema vil bli innsendt til MH i allerede adressert og frankerte konvolutter med merket ID nr for pasienten. Ved bruk av ID nr vil pasienten være avidentifisert, men ikke anonym for vår databearbeidelse.

5) *Det er ikke samsvar mellom protokoll, søknadsskjema og informasjonsskriv når det gjelder hvor ofte og på hvilke tidspunkt spørreskjemaene skal fylles ut*. Forskningsgruppen takker for tilbakemelding om presisering ved bruk av spørreskjema. Forskningsgruppen viser til §3.4.3 s 13 i protokollen der det beskrives 3 baseline målinger a 1 gang per uke før intervensjon og videre beskrivelse av hvilke skjema som skal besvares, §3.4.5 s14 i protokollen beskriver hvilke skjema som skal brukes underveis i intervensjonen og § 3.4.6 s14 beskriver hvilke skjema som skal brukes etter ferdig intervensjon. Forskningsgruppen ser at dette kan være beskrevet mer presist, vi vil ta tilbakemelding til etterretning og presisere dette. Forskningsgruppen ser at dette ikke kommer klart frem i informasjonsskrivet og vil rette opp dette.

6) *Det må videre komme klart frem i informasjonsskrivet hva deltakelse i prosjektet innebærer. Hvilke skjema som skal fylles ut, når de skal fylles ut og omtrent hvor lang tid det vil ta.*
Forskningsgruppen ser at behovet for konkretisering av intervensjon og informasjon vedr spørreskjema og utfylling burde forbedres i informasjonsskrivet, og takker komiteen for denne tilbakemeldingen. I informasjonsbrevet vil forskningsgruppen redegjøre for hvilke tiltak som vil bli brukt for intervensjonsgruppen og hvilke tiltak som blir gjort for kontrollgruppen. Forskningsgruppen vil presisere at dersom pasienten er inkludert til intervensjonsgruppen så vil vedkommende bli tilbudt smerteundervisning som et tiltak for å redusere oppfatning av smerte og mål om å øke funksjon i hverdagen. Forskningsgruppen vil presisere at dette skal foregå 1 gang i uken over 4 uker. Forskningsgruppen vil presisere at 3 uker FØR intervensjon med smerteundervisning er det viktig at pasienten fyller ut hjemsendte skjema ukentlig, at dette vil ta ca 30min og gjøres 1 gang i uken (onsdag). Det vil også bli presisert at pasient fyller ut de samme skjemaene 14 dager etter avsluttet smerteundervisning. Forskningsgruppen vil presisere ovenfor pasientene i kontrollgruppen, at de bidrar med relevant informasjon vedr forandring i smerte, funksjon og mental tilstand i påvente av operasjon. Forskningsgruppen må presisere at de ikke vil bli tilbudt smerteundervisning, og at alle spørreskjema fylles ut i hjemmet.

   Forskningsgruppen vil informere om mulighet for tlf kontakt i forbindelse med utfylling av skjema.

7) *Negativ omtale av standard behandling i informasjonsskrivet bør tones ned.*
Forskningsgruppa takker komiteen for tilbakemelding på dette, og vi ser at endringer er nødvendig.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

| Region: | Saksbehandler: | Telefon: | Vår dato: | Vår referanse: |
|---|---|---|---|---|
| REK sør-øst | Anne S. Kavli | 22845512 | 28.02.2014 | 2013/2383/REK sør-øst A |
| | | | **Deres dato:** | **Deres referanse:** |
| | | | 09.02.2014 | |

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Kjartan Vibe Fersum
Universitetet i Bergen

**2013/2383 Effekt av undervisning i smertefysiologi hos pasienter som skal gjennomgå ryggkirurgi**

**Forskningsansvarlig:** Universitetet i Bergen
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2 Deretter må man forklare hvordan man fordeles til undervisning før eller etter operasjon
3 Og deretter informere om spørreskjema

**Vedtak**

Komiteen godkjenner prosjektet på vilkår som beskrevet ovenfor med hjemmel i helseforskningsloven § 33 jf. § 9.

Godkjenningen gjelder til 01.07.2015.

Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

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Prosjektet skal sende sluttmelding, se helseforskningsloven § 12, senest 6 måneder etter at prosjektet er avsluttet.

*Klageadgang*
Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Knut Engedal
Professor dr. med.
Leder

Anne S. Kavli
Førstekonsulent

**Kopi til:** ; [redacted] Universitetet i Bergen: postmottak@uib.no

## 9.4 Appendix 4

MHH
1936

Smerteundervisning v/Martina Hansens Hospital 2014

Forespørsel om deltakelse i forskningsprosjektet

# *"Effekt av undervisning i smertefysiologi hos pasienter som skal gjennomgå ryggkirurgi*

**Bakgrunn og hensikt**
Dette er et spørsmål til deg om å delta i en forskningsstudie for å vurdere om ny forståelse av smerte kan hjelpe personer med langvarige ryggplager som venter på ryggoperasjon. Undervisning om smertemekanismer har i tidligere studier vist seg å være virksomt for personer med ryggplager. Resultatene i studien vill danne grunnlaget for en masteroppgave i Manuell Terapi. 2014, Universitetet i Bergen.

**Hva innebærer studien?**
Studien innebærer at du besvarer et sammensatt spørreskjema totalt 5 ganger i tiden frem mot operasjonen. Halvparten av deltagerne i prosjektet vil så få smerteundervisning på MHH i samme periode. Den andre halvparten/gruppen vil få tilbud om undervisningen i etterkant av operasjonen. Annenhver deltager vil bli fordelt til de to gruppene etter første skjemaet er blitt fylt ut av deg, returnert og mottatt på Martina Hansen Hospital. Smerteundervisningen foregår i 4 møter a 30min-1 t på Martina Hansens Hospital der du og prosjektleder (fysioterapeut og masterstudent [redacted] samtaler rundt fastsatte temaer vedrørende det å leve med smerte i hverdagen. Utfyllingen av skjemaene skal gjøres hjemme 1 gang i uken de 3 første ukene, deretter 2 ganger til med 14 dagers (4de skjema) og 30 dagers (5te og siste skjema) mellomrom før operasjon. Årsaken til utfylling av skjemaene så ofte, er for at vi ønsker å fange opp eventuelle endringer i din helsetilstand i perioden frem mot operasjonen. Skjemaene vil omhandle blant annet hvordan du opplever smertene, dine fysiske restriksjoner på bakgrunn av ryggplagene, fysisk funksjon i hverdagen og eventuelt arbeid, og generell velvære i hverdagen. Det tar omtrent 30 minutter å fylle ut skjemaet som du returnerer i ferdig frankert konvolutt.

**Mulige fordeler og ulemper**
Fordeler med deltagelse i studien kan være at opplever å få nyttig kunnskap om hvordan smerter virker på kroppen, samt hvordan smerter kan håndteres og at du derved kommer deg lettere gjennom operasjonen. En annen fordel kan være den nære kontakten du får med sykehuset. Ulempene er den tiden du bruker for å fylle ut skjema og delta på "smerteundervisningen".

## Hva skjer med prøvene og informasjonen om deg?

All informasjon om deg vil kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres i masteroppgave.

**Frivillig deltakelse**
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Elisabeth Thornes (spesialfysioterapeut MHH) tlf 67 52 18 04.

Med vennlig hilsen

[redacted]
Fysioterapeut/Stud.Msc Manuellterapi
Universitetet i Bergen/MHH

Nikolaos Ikonomou
Seksjonsoverlege Ryggavd.
MHH

# Samtykke til deltakelse i studien (beholdes av deltaker)

Jeg er villig til å delta i studien og har fått mulighet til å stille egne spørsmål

---

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

---

(Signert, rolle i studien, dato)

# Samtykke til deltakelse i studien (beholdes av prosjektleder)

Jeg er villig til å delta i studien og har fått mulighet til å stille egne spørsmål

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(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

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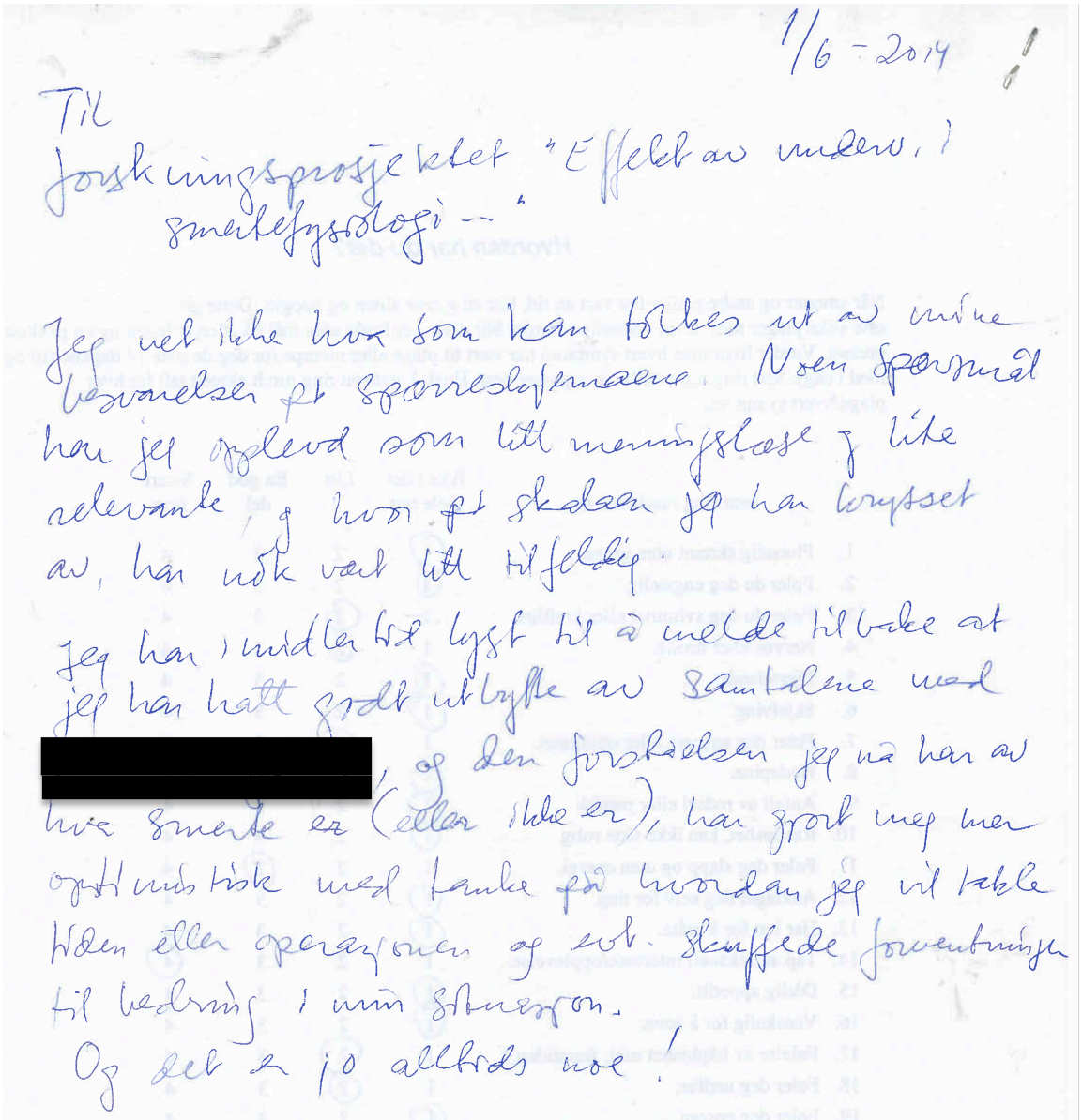
(Signert, rolle i studien, dato)

## 9.5 Appendix 5

| Time of Intervention | Type of Intervention |
|---|---|
| 1st Intervention | Recognising maladaptive pain cognition and addressing fear and perceived threats.<br>Pain Physiology with regards to the Neurone, the synapse and Action Potential<br>Brain Output dependent on perception of danger with regards to emotions, memory, beliefs, thoughts and experience. |
| 2nd Intervention | Control questions detecting patients understanding from first session:<br>o What is pain?<br>o Can we have pain without structural damage?<br>o Can we have structural damage without pain?<br>↓<br>Answer any questions that may have arisen from last session.<br>Descending inhibitory pathways, gate control, wind up, effect of interneuron plasticity.<br>Plasticity of the CNS and cortical changes. |
| 3rd Intervention | Reinforcing last session´s explanation with a true life story example of pain perception and change in surrounding.<br>o Balancing board on the ground v sot top of a building.<br>o Fight or flight response; bus in the street, bear in the woods.<br>Detecting patient's motivation level and coping strategies with focus of internal and external locus of control.<br>How to react based on what you know?<br>o Fight or flight?<br>o Pain related to structure or context? |
| 4th Intervention | Postoperative outcome- expectations and theory of postop pain.<br>o Importance of cognition, movement and lifestyle after surgery with regards to anxiety and provocation of sensitivity.<br>▪ Fixing structural problem, but not sensitized nerves |

## 9.6 Appendix 6



1/6 - 2014 !

Til
forskningsprosjektet "Effekt av undervisning i smertefysiologi --"

Jeg vet ikke hva som kan tolkes ut av mine besvarelser på spørreskjemaene. Noen spørsmål har jeg opplevd som litt meningsløse og ikke relevante, og hvor på skalaen jeg har krysset av, har nok vært litt tilfeldig.

Jeg har imidlertid lyst til å melde tilbake at jeg har hatt stort utbytte av samtalene med [redacted], og den forståelsen jeg nå har av hva smerte er (eller ikke er), har gjort meg mer optimistisk med hensyn på hvordan jeg vil takle både en operasjon og evt. skuffede forventninger til bedring i min situasjon.

Og det er jo alltids noe!