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Κατεύθυνση : Φυσικοθεραπεία

MANUAL THERAPY VS LOCALIZATION (TACTILE SENSORY TRAINING) IN PATIENTS WITH NECK PAIN: A RANDOMIZED CLINICAL TRIAL

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ΠΑΤΡΑ 2020

DECLARATION

I hereby declare that this dissertation has been composed solely by myself and that it has not been submitted, in whole or in part, in any previous application for a degree. Except where states otherwise by reference or acknowledgment of original sources, the work presented is entirely the result of my own.

1.05.20

Eleftheria S. Thomaidou

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PREFACE

The aim of the master thesis project is to continue to provide the clinician with an integrated and realistic approach to the evaluation and therapeutic intervention in patients with cervical pain.

Reliable and documented evidence has been collected from the worldwide literature to provide effective information and insight on the research topic. One of the popular approaches for managing cervical problems is manual therapy, including mobilization techniques to the cervical and upper thoracic spine for pain relief effectiveness and movement improvement. Interestingly, a novel approach for the treatment of spinal pain is considered to be the tactile sensory training (localization) approach. This intervention without movement involves the patient concentrated, attempting to identify the location and type of stimulus applied by the therapist and receiving feedback on correctness, thus educating the patient.

The purpose of the present study was to investigate and compare the immediate effects of manual therapy versus localization by tactile sensory training on pain intensity and mobility of the neck in patients with neck pain, through a randomized clinical trial. The results of the study will provide insight on the best treatment approach for managing cervical pain, which is a leading cause of disability worldwide.

ABBREVIATION LIST

AP Anteroposterior
BMI Body Mass Index
Cx Cervical Spine
Ext Extension
HADS Hospital Anxiety Depression Score
Fl Flexion
GROC Global Rating Scale of Change
LFl Lateral Flexion
MT Manual Therapy
MWM Mobilization with Movement
NDI Neck Disability Index
NP Neck Pain
NPRS Numeric Pain Rating Scale
ROM Range of Motion
PA Posteroanterior
PAIVM Passive Accessory Intervertebral Movement
PAG Periaqueductal Grey Matter
PNE Pain Neuroscience Education
PPT Pressure Pain Threshold
SNAG Sustained Natural Apophyseal Glide
Tx Thoracic Spine
TPD Two Point Discrimination

ABSTRACT

Background: The concept of tactile sensory localization, involving small contact area, is a discriminatory sensory training technique thought to "sharpen /re-organize" and "refocus" sensory homunculus, cortical representation, thus improving range of movement (ROM) and decreasing pain intensity in spine.

Purpose: To investigate the immediate effects of manual therapy (MT) versus localization on pain intensity and cervical ROM for neck pain.

Methods: Thirty eligible volunteers, with neck pain, consented and were randomly allocated to a MT or to a motionless, localization group. A single three-minute treatment session was delivered to each group's cervico-thoracic area by two therapists (one for each group). Localization involved tactile sensory stimulation, applied randomly in one out of a nine-block grid. Subjects were asked to identify the number of the square being touched. Manual therapy involved three-minute anteroposterior glides and SNAG techniques, applied to hypo-mobile levels. Pre- and post-intervention pain intensity, using a pressure pain threshold (PPT) algometer and numeric pain rate scale (NPRS), was assessed. Neck ROM was recorded with a bubble inclinometer. Intra-rater reliability of ROM and PPT reliability measurements were established prior to use (ICC ranges for ROM and PPT: 0.894-0.97 and 0.748-0.903, respectively).

Results: Statistical analysis found small improvements in ROM and self-reported pain, in both groups ($p<0.001$). PPT scores decreased equally between groups ($p>0.05$). The MT group showed small, but greater improvements in ROM, compared to the localization group ($p<0.005$).

Conclusion: Tactile sensory training (localization) was as effective as MT in producing short-term decreases in neck pain; however MT resulted in larger improvements in mobility.

Implications: Localization training can be beneficial in reducing neck pain.

Keywords: neck pain; localization; tactile sensory training

Ethical Approval was provided by University of Patras Bioethics Committee

GENERAL PART

CHAPTER 1

1.1 INTRODUCTION

Neck pain (NP) is one of the major public health musculoskeletal problems in modern society, which has a great impact on people's lives, with high prevalence and occurrence rates (Fejer et al.,2006; Rahmani et al.,2013) leading to global disability (Hoy et al.,2014). At the same time, its associated costs are continuously increasing (Vos et al.2015). According to the Global Burden of Disease 2010 Study, neck pain is ranked as the 4th highest problem in terms of disability out of 291 conditions studied in, as measured by YLDs (Years Lived with Disability), and is 21st in terms of overall burden (US Burden of Disease Collaborators,2013).In a recent review conducted again in US, it was estimated that the cost per year of low back pain and neck pain was as high as $ 87.6bn (Dieleman et al.,2016).Interestingly, Enthoven et al. (2004) reported that a significant proportion of patients may continue to seek for health care resources for up to 5 years after the initial onset. Approximately 5% of people experiencing neck pain report severe disability (Philadelphia,2001).Substantial evidence indicates that neck pain represents a significant contributing factor to medical care seeking, disability, reduced work productivity and work absenteeism due to sickness (Cote et al.,2000; Kaaria et al.,2012).

1.2 Epidemiology

Approximately two thirds of the population will suffer from it at least once over the course of their lifetime, whereas the point and annual prevalence is about 23% (Hoy et al., 2010) and 37.2% respectively (Fejer et al., 2006). Of these, 1.7 to 11.5% report limited activity due to pain (Hogg-Johnson et al., 2008). Prevalence is generally higher in women, in high- income countries and in urban areas (Stranjalis et al., 2011). It has been proven that there is a high incidence of neck pain in individuals in middle age (Fejer et al., 2006), after which the risk begins to decline. The estimated annual incidence of neck pain from available studies ranges between 10.4 and 21.3% with higher incidence noted because of sedentary life style in office and computer workers (Cote et al., 2004). In a cross sectional study conducted to 1000 Greeks living in the capital and other urban centers of the country, it was found that neck pain is presented in high annual

prevalence (29%) in the general population with mean duration of pain 12 days, however, relatively few patients seek medical advice (Stranjalis et al.,2011).

In most cases of acute neck pain, patients recover from symptoms with or without treatment. The pain exacerbates and fades periodically and in 50-80% of patients having neck pain symptoms do not fully resolve (Cote et al.,2004), leading to recurrence and chronicity and impacting the quality of life (Cote et al.2004).The findings of a review exploring the course and prognosis of neck, found that more than half of people who experienced a neck episode, will report pain in the following 1-5 years (Carroll et al.,2008) at least at the same frequency (Hill et al.,2004). The likelihood of remission from neck pain is increased in younger age groups compared with older age groups (Carroll et al.2008).

1.3 Risk factors

Recent evidence supports that previous neck pain, genetics, sedentary lifestyle, obesity, smoking, sleep disorders are commonly associated with neck pain (Hogg-Johnson et al.,2008; Hoy et al.,2010).Moreover, there is a widespread agreement that psychosocial dysfunction, anxiety, depression, poor general health status and work related emotional stress are significant risk factors predisposing to the development of NP (Haldeman et al.,2010, Kaaria et al.,2012, Paksaichol et al.,2015) *(Table 1)* and can influence the course of neck pain (Haldeman et al.,2010).This is explained by the fact that, due to sedentary lifestyle and stress, people are experiencing more strain and tension on the upper thoracic and neck area of the spine (Binder,2007). Regarding degenerative changes, there is no evidence that they constitute a risk factor (Hogg-Johnson et al., 2008).

Table 1.*Risk factors for neck pain*

Risk factors for neck pain
Psychopathology
Low work satisfaction /poor work environment
Female sex
Genetics
Concomitant back pain or other rheumatologic conditions
Poor coping skills
Catastrophization
Trauma/previous neck pain

Poor general health status Sedentary lifestyle Obesity Smoking

1.4 Causes and Classification

Neck pain is commonly described as a diffuse painful sensation at the base of the skull, neck area, upper back, and shoulder region. It usually occurs in the upper thoracic spine and it is commonly due to recent trauma, overuse and poor posture (Yip et al., 2008). The exact mechanism which leads to cervical pain is not well understood even today, and its origin is thought to be multifactorial (Jacobsen and Mariano, 2001). However, in a vast number of cases there is no link between pathology and neck complaints, resulting in the term "non specific" neck pain or mechanical neck pain (Hoving et al., 2002). This definition indicates a musculoskeletal cause of NP without however specific anatomic source. Other potential non-musculoskeletal causes of NP, include inflammation, tumors, infections (Hoving et al., 2002).Neck pain might derive from muscle weakness (Jull et al., 2002), nerves' compression, tendons, muscle imbalances, bones or ligaments. Changes in ligaments or in muscles' length can result in cervical pain. The studies of Jull et al. (2004) and Falla et al. (2004b) found that reduced activation and coordination between deep cervical flexors (longus capitis and longus colli) and superficial muscles (sternocleidomastoid and anterior scalene) is considered to dominate neck pain disorders. However, imaging diagnostics are not a reliable or valid for determining the origin of pain, thus still the exact source is difficult to be identified. (Bogduk and Lord, 1998).

Whilst there is not a single clinical classification system for NP (Hoving et al., 2001), various classification systems have been recognized including:

1. **Duration of symptoms** (acute less than 6 weeks, subacute 3 months or less or chronic at more than 6 months).Acute pain is regarded as a normal response to tissue damage, infection or physical injury, whereas chronic pain is not considered to be a protective mechanism. It was suggested that longer duration of neck pain is associated with poorer prognosis.(Peterson et al.,2012)
2. **Severity.** Pain Task Force (Guzman et al., 2008) suggests a 4 grade clinical classification depending on the patient's pain intensity and functionality.

3. **Etiology/structure.** Cervical pain may be a primary or secondary symptom of a condition or disorder that occurs in the cervicothoracic area (Bliss, Flanders and Saint, 2004). Thus, it can be a component of headache, temporomandibular joint disorder, cervical sprain, fracture, tumor, inflammatory arthropathy or fibromyalgia. Depending on the origin of signs and symptoms, musculoskeletal neck pain is differentiated from non-musculoskeletal nature (secondary other cause, i.e. referred pain from heart or vascular pathology).
4. **Type** (i.e. mechanical vs. neuropathic).Common examples of mechanical pain refer to nociceptive pain due to facet joints dysfunction, discogenic pain and myofascial pain (Kung et al., 2001), whereas neuropathic pain results from injury or disease of peripheral nervous system which involves irritation of nerve roots such as in spinal stenosis, disc herniation or osteophytes (Cohen, 2015). The presence of pain can be unilateral or bilateral and the onset of symptoms is usually insidious but can also be sudden.

1.5 Signs and symptoms

Pain arising from neurological causes almost always involves neural radiation at one (usually) or both (less frequently) upper extremities, usually in a dermatomal distribution and presents more intense exacerbations. It is often accompanied by numbness or paresthesias and leads to muscle weakness or asymmetric reflexes (Cohen, 2015). Patients with neuropathic pain typically describe their pain as burning, electrical-like, shooting or stabbing (Bennett, 2001).

Mechanical pain arising from facet joints, disks, muscles, ligaments is nearly always described as more subtle throbbing or aching (Bennett, 2001). Non neuropathic mechanical pain again may extend to the upper extremity but the referral areas are not dermatomically distributed and are usually more diverse. Mechanical pain is characterized by low intensity pain initially that aggravates with activity (Cohen, 2015). Decreased range of movement, neck muscle strength, neck muscle endurance, muscle thickness and increased muscle spasm are frequent findings in people suffering from NP (Javanshir et al., 2010; Lee et al., 2005).

In more severe, but fortunately more rare cases, presentation of ‘red flags’ are apparent including symptoms of myelopathy, such as lower limb spasticity or uncoordinated gait patterns. Through thorough physical examination, developmental abnormalities (i.e. a lipoma may signify the presence of spinal bifida) or spinal cord abnormalities (i.e. prominent vertebrae can indicate

spondylolesthesis) might be revealed (Cohen, 2015). Severe neurologic weakness or increase of reflex response is a sign of upper motor neuron lesions and demand a vigorous investigation (Cohen, 2015).

1.6 Neck Pain and Cortical Changes in the Brain

The ability of the brain to adapt throughout life, to be reorganized according to the functional demands is known as plasticity and is thought to be a part of normal development and learning. Recently, brain imaging such as fMRIs have provided insight and confirmed structural and functional alterations in people suffering from chronic pain (Butler and Moseley, 2003). The main area of the brain which is mainly affected in relation to pain experience is the primary somatosensory area (S1). Within the brain there is a virtual representation of the body, which is labeled as cortical homunculus.*(Figure 1)* The homunculus is located on the somatosensory cortex on the postcentral gyrus of the anterior parietal lobe (Trepel, 2015) and is associated to sensation. Flor (2003) has found that the cortical representation of the homunculus can be modified, depending on the sensory input. Likewise, changes of the cortical homunculus can be displayed in the event of increased input due to training as well as in case of loss of input due to differentiation. *(Figure 2)*

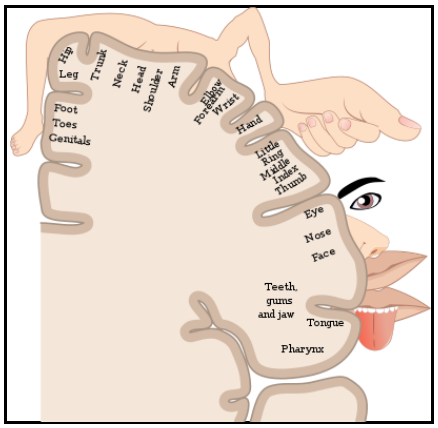


Figure 1 *Cortical Sensory homunculus*

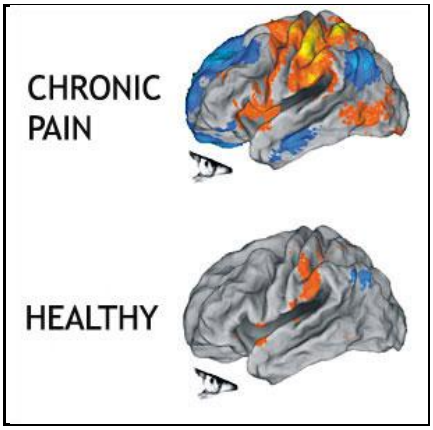


Figure 2 *Changes in cortical activation of S1 in healthy and chronic pain patients*

1.7 Treatment

According to a systematic review of 3.588 citations, conducted in 2017, neck pain is managed by a plethora of treatment options, mostly delivered in primary care settings, including non-pharmacological treatments(self-management advise and pain education, exercise therapy,

manual therapy and psychosocial interventions) complementary treatments (i.e. acupuncture) and pharmacological therapies (analgesics, non-steroid anti-inflammatory drugs (NSAIDS), corticosteroid injections) (Babatunde et al., 2017). Surgical treatments are indicated only in a small proportion of patients, largely when there is a presence of serious pathology and symptoms that are persistent to conservative treatments. Available literature suggests that there is moderate evidence that surgical treatments (nerve root decompression, discectomy, laminectomy,fusion) does provide evidence for pain, but there are no long term benefits for clinical outcomes compared to conservative treatment (Nikolaidis et al., 2010, Map of Medicine,2014).

There is moderate evidence to prove the effectiveness of non steroid anti-inflammatory drugs (NSAIDS) for the management of neck pain (Babatunde et al., 2017). However, it is reported that NSAIDs and opioid analgesics are beneficial for acute musculoskeletal pain relief, but the effects do not last long-term, and the potential adverse effects should be taken into consideration (Babatunde et al., 2017). On the subject of the efficacy of pharmacological injections, as there is a lack of high quality studies, there is no strong evidence to suggest the use of spinal injection for neck pain relief (Babatunde et al., 2017).

Specifically for physiotherapy, various intervention techniques have been explored with better results being provided with therapeutic exercise aiming at cervical muscle strengthening and endurance exercises, posture improvement and re-education, including yoga and Pilates, stretching and proprioception exercises (Hurwitz et al.,2008;Teasell et al.,2010; Kay et al.,2012).

Spinal manipulation and mobilization techniques (Gross et al., 2010) as well as massage have also shown positive results in the neck and thoracic spine but the literature is unclear, since manual therapy is superior when combined with exercise. However, when manual therapy is compared to therapeutic exercise is proven to be inferior. It is suggested that manual therapy can be beneficial for immediate and short term improvements in range of motion, pain levels and function, both in acute and chronic pain patient, as well as those with whiplash (Hurwitz et al., 2008; Teasell et al., 2010; Patel et al., 2012).

The use of therapeutic ultrasound, Transcutaneous Electrical Nerve Stimulation, thermotherapy and laser therapy lacks evidence and it does not offer significant or added benefits over placebo or other conservative treatments (Kroeling et al., 2013; Robertson and Baker, 2001).

The evidence for the effectiveness of aids and devices (such as orthotics, cervical collars) has generally shown small effects with no significant benefits for pain and function (Hurwitz et al., 2008; Teasell et al., 2010; Carroll et al., 2009).

Concerning acupuncture, it was only found to be effective in short term symptom relief, but did not appear to significantly improve the outcomes for neck pain over placebo or other treatments (Trinh et al., 2016).

Lastly, self-management advice and pain education are strongly recommended as a first line treatment option despite the fact that a small effect is shown on pain and function. More specifically, pain neuroscience education (PNE) is a new promising approach in the management of pain, which focuses on teaching people about the neurophysiology of pain (Butler and Moseley, 2003; Louw et al., 2016).

1.8 Relationship of Cervical and Upper Thoracic spine

There seems to be a definite association between cervical and upper thoracic spine. The upper thoracic spine is ergonomically related and closely involved to the physiological motion of the neck (Tsang et al., 2013; Jull et al., 2008). From the functional viewpoint, since the movement of the cervical spine includes the movement of the upper thoracic (1st thoracic to 4th thoracic) (Potterfield and De Rosa,1995; Tsang et al.,2013), hypo mobility of the upper thoracic can lead to pain in the cervical spine (Cx) because of compensation and excessive movement in Cx, resulting in increased fatigue of neck muscles (sternocleidomastoids, anterior scalenes and upper trapezius muscles), change of the neck postures and decreased range of motion (Kapreli et al.,2008).Furthermore , a positive correlation between hyper mobility of the upper thoracic spine (Tx) and neck pain has been documented by Lau et al. (2011).The application of treatment to the upper thoracic spine may significantly increase neck range of motion (Kim et al.,2011) as well as has been reported to have a positive effect (often immediate) on cervical spine dysfunction and on pain relief (Cleland et al.,2007;Jung and Moon,2015). Krauss et al. (2008) also found that upper thoracic manipulation, when performed to 22 neck pain patients, relieved cervical pain as well as improved patients' range of motion. The study of Gonzalez-Iglesias et al. (2009) reported similar findings with thoracic spine manipulation resulting in superior clinical outcomes that last beyond the 1-month follow-up period for patients with acute neck pain. There is also available evidence to suggest that cervical spine when accompanied with thoracic mobilization as an intervention

might be more effective than cervical mobilization alone (Lee et al., 2013).The improvement of function in the neck area, which is due to therapy being applied on the upper thoracic, supports the concept of regional interdependence between these two neighboring areas (Wainner, 2001).

CHAPTER 2

2.1 Manual Therapy

Conservative interventions for neck pain and its associated disorders may include treatment by physiotherapists who are using methods such as manual therapy to intervene neck pain (Cleland et al., 2007; Suvarnnato et al., 2013). Manual therapy is defined as "skilled hand movements and passive movements of joints and soft tissue with the intent to improve tissue extensibility, increase range of motion, induce relaxation, modulate pain, and reduce soft tissue swelling, inflammation or restriction"(American Physical Association,2014). It includes massage therapy, joint mobilization and manipulation and has been embodied in clinical guidelines for chronic neck pain (Blanpled et al.2017), especially in multimodal study protocols that include exercise (Kay et al., 2005). Gross et al.(2010) in their systematic review have suggested that joint biased therapies have immediate or short term pain relief effectiveness for mechanical neck pain. Similarly, Vernon et al. (2007) estimated that the effect of manual therapy in mechanical chronic neck pain, clinical evidence is of moderate to high quality. Surprisingly, there is lack of conclusive evidence regarding the effectiveness of these interventions (Gross et al.,2004;Bronfort et al.,2010; Kroeling et al.,2013) especially when used alone. Furthermore, no particular manual therapy intervention was proven to be superior to other (Hurwitz et al.,2008).This uncertainty may relate to high heterogeneity of parameters regarding small sample sizes, different comparison groups, lack of long-term measurements and use of subjective outcome measures , thus increasing the need for larger and high-quality future randomized controlled trials (Franke et al.,2015).However, it is worth noting that adverse effects are more likely to be reported after cervical spine manipulation than mobilization (Hurwitz et al.,2005).

Maitland (2005) describes spinal mobilizations as passive rhythmical oscillation performed at the beginning, within, or at the limit of range. Mobilizations are widely used by physiotherapists to treat pain and stiffness is 5 grades (*Table 2*). The aim is to use small or large amplitudes of movement to relieve pain, correct muscle imbalance and restore functional movements (Maitland, 2005; Grieve et al., 2015).

Table 2 .*Maitland's grades of passive oscillatory mobilization*

Maitland's grades of passive oscillatory mobilization
Grade I: Small amplitude movement at the beginning of available range of motion
Grade II: Large amplitude movement within the midrange of motion
Grade III: Large amplitude movement at the end of the range of motion (into resistance)
Grade IV: Small amplitude movement at the end of the range of motion (into resistance)

Maitland mobilization Grade III and IV for the treatment of the cervical and upper thoracic spine significantly decreases neck disability index and the pain index (Cleland et al., 2007), as well as increases the range of motion (Suvarnnato et al., 2013). Sandow demonstrated that by applying joint mobilization in the thoracic spine, the risk due to cervical mobilization, which involves cervical rotation (Sandow, 2011) is reduced. The application of the joint mobilization to the upper thoracic spine has been reported to have a positive effect sometimes immediately on cervical dysfunction, in conjunction with the provision of pain relief (Cleland et al., 2007).

An anteroposterior mobilization technique involves vertebral pressure being applied over the vertebral segment that produces passive accessory movement without active participation of the muscles related to that movement in an anteroposterior direction with the patient in supine position. Egwu' study (2008) showed significantly greater pain reduction in subjects receiving ipsilateral AP mobilizations when compared to transverse oscillatory or cervical oscillatory rotation mobilizations, but no significant difference when compared to ipsilateral PA mobilizations.

Furthermore, Mulligan in the field of manual therapy firstly introduced in 1987 the Sustained Natural Apophyseal Glides (SNAGs), whereas an increasing number of clinical texts provide its effectiveness on neck pain (Grieve, 1991; Boyling and Palastanga, 1994; Petty and Moore, 1998). Cervical (thoracic) SNAG is a group of painless techniques known as mobilization with movement (MWM), which Mulligan developed to restore unrestricted movement (Mulligan, 1999).

A cervical/thoracic SNAG is applied with the patient in sitting position (Petty and Moore, 1998) and thus the spine is in weight bearing position, which is considered more functional.

The concept of SNAGs involves a combination of therapist passive sustained glide of one articular surface (within a joint) and an execution of the patient's symptomatic active movement simultaneously (*Figure 3a, b, Figure 4*). Usually, the therapist applies a sustained passive

accessory zygoapophyseal glide postero- anteriorly towards the facet joint direction (along the plane of the facet joint) (Exelby, 2001).

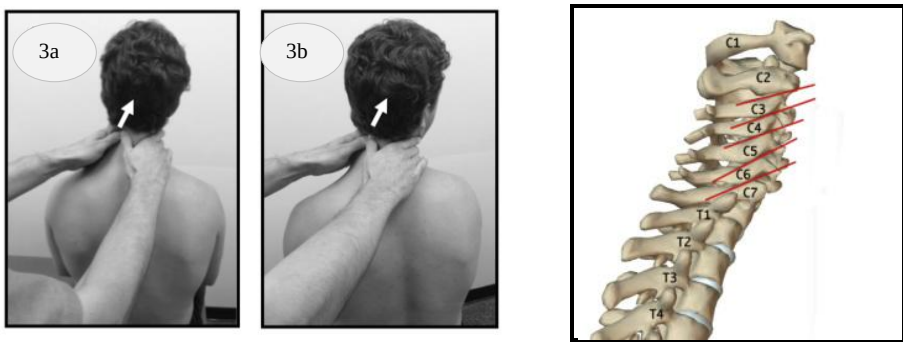


Figure 3.a *Application of SNAGs technique and* ***3.b*** *execution of the patient's symptomatic active movement simultaneously*

Figure 4 *Direction of sustained passive accessory zygoapophyseal glide along the plane of the facet joint*

This "glide" is maintained as the patient moves actively to the desired range of physiological movement and then whilst sustaining the end range position for few seconds applying overpressure. The glide is released by the therapist as the patient returns to the starting position for the active movement (Exelby, 2002). The active physiological movement is nearly always in the direction of symptomatic movement loss-rotation, flexion, side bending (Mulligan, 1994) but all movements both accessory and physiological are in a full pain free range of motion (Mulligan 1994a, 1999).

Existing knowledge suggests that the mechanisms of action of manual therapy include a mix of three mechanisms- biomechanical, neurophysiological and/or placebo effects (Bialosky et al., 2009; Bishop et al., 2011).Despite the evidence to support the possible effects of each one of the above mentioned mechanisms (Coppieters and Butler, 2007; Calloca et al., 2006; DeVocht et al., 2005), current literature presents a failure to determine their potential interaction.

The biomechanical factors of manual therapy involve the effect on joints, articular structures, muscles, nerves or connective tissue, such as improving ROM, over passing restrictions, reducing stiffness etc.(Calloca et al.,2006; Coppieters and Butler,2007) aiming to correct potential dysfunctions detected during the physical examination. Such theoretical concepts include "the intervertebral disc pathology hypothesis" (Mckenzie and May, 2003)," "trigger point, "spinal stiffness" (Edgecombe et al, 2013). It has been reported that manual therapy techniques may lead to structural changes, such as fluid uptake, resulting in improvements in ROM and pain relief

(Beattie et al., 2010). Through massage, the pressure applied on muscles and soft tissue is hypothesized to increase tissue extensibility and thus increasing joints' range of motion and blood flow (Weerapong et al., 2005). However, the effectiveness of MT associated only with biomechanical factors is questionable, so additional mechanisms may be pertinent relevant.

The neurophysiological mechanisms of action involve effects mediated through the peripheral nervous system, spinal cord and higher centers. The exact neurophysiological mechanism underpinning the effects of spinal mobilization, has been well documented, however, still remains unclear. With regard to spinal cord hypoalgesic effects, it is suggested that MT act as "modulator" of pain (Boal and Gillette, 2004) as is speculated to provide a sensory input via large A beta fibers to the central nervous system (dorsal horn of the spinal cord).

Melzack and Wall's (1965) pain gate theory suggests that, within substantia gelatinosa in the dorsal horn of the spinal cord there is "a gate", where the transmission of the sensory information from the primary afferent neurons to transmission cells, occurs. It is considered that spinal mobilization stimulates large A beta fibers which impede the transmission of nociceptive impulses; thus, 'blocking the gate (Melzack and Wall, 2003).

With regard to peripheral mechanism, manual therapy approach can decrease the concentration of inflammatory substances such as cytokine (Teodorczyk-Injeyan et al.,2006) and increase pain mediator substances such as serotonin and β -endorphins (Degenhardt et al.,2007) or endogenous cannabinoids (McPartland et al.,2005) following a musculoskeletal injury.

Finally the literature suggests the involvement of supraspinal systems in mediating the treatment effects of manual therapy. Wright (1995) highlights another theory of hypoalgesia; the descending pain inhibitory system, which is recently the most dominant one for manual therapy. This theory suggests there are two descending pain control systems, sympatho excitation and sympatho inhibition, projecting from the Periaqueductal Grey matter (PAG) of the midbrain that can be activated upon spinal mobilizations. The former system provides an immediate hypoalgesic effect and utilizes noradrenalin as its neurotransmitter, which is non opioid and originates from the dorsal PAG. The sympatho inhibition provides a delayed hypoalgesic effect and utilizes serotonin; an endogenous opioid (Degenhardt et al., 2007). This system originated from the ventral PAG. Bialosky et al., (2009) also reported that the neurotransmitter of the descending inhibitory systems activate receptors at the interneuronal level in the dorsal horn of the spinal cord, inhibiting the release of substance P, blocking pain transmission to CNS. The

combined effect of these two systems, along with the pain- gate theory, may help to explain immediate and longer term pain relief from spinal mobilizations.

Traditionally, manual therapy approach to the tissues is thought to involve bottom up mediated factors, like stimulus intensity, but recently greater attention has been given on top down mediated factors, like patients' beliefs and expectations (Gifford, 2013; Tiemann et al., 2015).Placebo treatment, patients' expectations and psychosocial factors may be relevant to the effectiveness of manual therapy. In other words, manual therapy intends to provide input into the nervous system, as well as to activate the cortical areas of the brain to modulate its integral role in producing pain experience. This possible mechanism of action in this study is also categorized in neurophysiological effects of manual therapy related to supraspinal descending system.

2.2 Tactile Sensory training or Localization

Tactile acuity measured by two- point discrimination (TPD), is referred as the perceived ability to identify the location and type of a tactile stimulus and is regarded to be altered in people suffering from chronic pain (Moseley and Flor, 2012). Tactile acuity has been widely used in the clinical practice to assess nerves' injuries and evaluate patient's progress and response to treatment (Lundborg and Rosen, 2004).Tactile sensory information arises from sensory organs located on the skin (cutaneous mechanoreceptors responding to mechanical stimulus including pressure, vibration), ascends through synapses of afferent neurons (Ab large myelinated fibers) in the dorsal column nuclei and lastly is sent to the somatosensory cortex of the brain (Cheung et al.,2008).The most known area of brain referred to as representation of the physical body of a person by a network of neurons is the primary somatosensory cortex (S1) (Flor, 2000; Stavrinou, 2007).It has been reported that patients suffering from pain manifest different representation compared to healthy individuals (Flor et al., 1997; Moseley et al., 2008) and a correlation between shape and size of the above area with pain and disability was found (Flor et al., 1997; Lloyd et al., 2008).In other words, it is shown that the cortical representation of body maps in S1 expands or contracts as a result of neglect and decreased use of the painful body part (Marinus et al.,2011) leading into more decreased movement and increased pain (Flor,2000).Areas which are normally devoted to specific body parts may start to overlap and the disrupted representations

become blurred. Butler and Moseley call this phenomenon “Smudging of the virtual bodies” as seen in the Figure 5 (Butler and Moseley, 2003).

Figure 5 *Smudging in the virtual hand (Butler, 2003)*

The results pooled by a systematic review with metanalysis showed that patients suffering from chronic pain, including low back, limb pain demonstrated altered tactile acuity, whilst the two-point discrimination threshold was increased. The lack of ability to determine the sense of touch (loss of tactile acuity and increased TPD) is dependent not only on reduced tactile detection (Moseley, 2008; Wand et al.2010) or impairment in transmission via neural pathways (van Rijh et al., 2009) but also on a manifestation of altered somatosensory processing. Thus, persistent pain was associated with cortical disruptions of the painful area (Catley et al., 2014). Noticeably, a recent study of Harvie et al. (2018) has shown that tactile acuity is affected in people suffering from chronic neck pain. More specifically, the impairment in discriminative ability is thought to reflect cortical changes of the neurons and their synaptic mechanisms in the primary somatosensory cortex (S1) (Flor, 2003; Maihofner et al., 2004) of the painful body part. The deficits in TPD are not only present in the painful area but can be localized to different body sites remote from the region of pain (Catley et al., 2014; Harvie et al., 2018). The adaptations in the brain that are associated with chronic pain, include brain neurochemistry, structural changes/ grey matter density, functional changes in the cortex (i.e. location, intensity and activation) often called “cortical reorganization” (Wand et al., 2011; Catley et al., 2014) and have been reflected by structural and functional brain imaging data on chronic low back pain (Flor et al.,1997, Wand et al.,2011) complex regional pain syndrome (Maihofner et al.,2003; Pleger et al.,2006) or phantom limb pain (Falla et al.,2007). Further to the above findings on chronic pain, Adamczyk et al. (2018) and Holla et al. (2018) suggested that similar reduction in tactile acuity (increased

TPD) was found when assessed patients with acute low back and neck pain respectively. Interestingly, there is preliminary evidence to suggest that there is a negative correlation between the number of days of onset of pain and tactile acuity in patients with acute mechanical pain in the neck (Holla et al., 2018)

Based on these neuroplastic changes, physiotherapy has focused on techniques to enhance sensory afferent stimuli to the Central Nervous System and aiming to normalize these altered cortical representations, reverse the sensory impairment and alleviate pain. Various strategies have been studied to induce patients develop an increased acuity of their altered body mapping, including two point discrimination, graphaesthesia (Moseley, 2007; Moseley, 2008) termed "Tactile Sensory training".

Tactile Sensory Training is a promising treatment option for disorders that are associated with maladaptive plasticity or disrupted synaptic connectivity, as in painful conditions. Localization, which involves tactile sensory training without physical movement is thought to "sharpen" or "refocus" the homunculus' representation on the cortex of the brain and thus, improve the movement and decrease the levels of pain (Moseley 2008; Louw et al., 2011). Haggard et al. (2013) in their review, defines it "as somatosensory sharpening". Several studies have been conducted in amputees (Flor et al.,2001) and in complex regional pain syndrome (Pleger et al.,2005; Moseley et al.,2008), revealing decrease of pain, enhance of function and body image, presumably due to reorganization of the somatosensory cortex in the well known primary somatosensory area (S1)(Flor,2000; Stavrinou, 2007). Although the exact mechanisms relating S1 remapping and pain relief remains of a matter of conjecture (Di Pietro et al.2016), a possible explanation might be that stimulus over the skin associated with attention and localization tend to activate mechanical receptors (i.e. Meisner corpuscles and Merkel's discs (Chung et al.,2013; McGlone and Reilly,2010), thus providing a sensory input to the CNS, stimulating the fast myelinated A beta fibers and inhibiting the transmission of nociceptive signals through slow, non-myalinated C fibers, resulting in analgesic effects (Nijs et al.,2010). Another proposed mechanism of action underlying this phenomenon could be the cortical reorganization through cognitive educational approach. The tactile sensory training involves the patient concentrated, attempting to identify the location and type of stimulus applied by the therapist and receiving feedback on correctness, thus, educating the patient. In other words, tactile sensory training is a mentally challenging approach, for which concentration and continuous feedback raises the

attentional control and positively influences pain and movement (Moseley et al.,2008).The last decades, greater attention has been reported in hands-off approaches, known as pain neuroscience education or PNE (Moseley, 2002; Louw et al.,2015; Louw et al.,2016; Puentendura and Flynn,2016) aiming to change patients' cognition (Moseley and Butler,2015), pain relief and decrease dysfunction (Louw et al.,2011) by educating them about neurophysiological and neurobiological processes of pain. In recent studies, it was reported the effectiveness of pain education through cognitive behavior approaches with functional resonance (Flor, 2008) and transcranial magnetic stimulation of motor and sensory cortex (Tsao et al., 2008). Finally, authors have suggested that passive techniques, such as localization technique may have a placebo effect and symptom improvement. The explanation for a short term analgesia effect of placebo is associated to opioid substance release (Simmonds, 2000), occurring through tactile sensory stimulation.

To date only limited pathological conditions have been investigated in terms of tactile acuity and cortical reorganization, such as low back pain (Catley et al .,2014), phantom limb pain(Flor et al.,2001), complex regional pain syndrome (Moseley et al.,2008), neck pain (Harvie et al.,2018,Holla et al.,2018) whilst the positive effects of the sensory training have already been suggested (Flor et al.,2001;Moseley et al., 2008;Wand et al.,2011), there is little evidence on upper spinal area.

2.3 Summary of main findings from literature and scope of study

Review of the literature has shown that the delivery of manual therapy, which is classically considered to be a "bottom-up" or a "hand-on" approach, is beneficial for patients suffering from neck pain (Gross et al., 2010; Kay et al., 2012).It is also believed that manual therapy could re-organize and sharpen the homunculus and improve the mobility so that "top-down" effects in manual therapy could be similar to the localization (Puentendura and Flynn, 2016). Tactile sensory (localization) training, as a new " top down" approach has been reported to have positive effects on improving pain and function (Louw et al., 2015; Kalin et al., 2016) in people with chronic musculoskeletal pain.

Despite this growing interest, to the best of our knowledge, there is a lack of consensus about the effectiveness of tactile sensory treatment (localization) and the difference of interventional effect between the manual therapy and localization in patients suffering from neck pain. Thus, the aim

of this research is to investigate and compare the effects of manual therapy versus localization training by tactile stimulus on pain intensity and mobility of the neck.

SPECIAL PART

CHAPTER 3

3. METHODS

The purpose of the present study was to investigate the outcomes of neck pain treatment and compare the immediate effects of manual therapy versus localization training by tactile stimulus on pain intensity and mobility of the neck, after a single treatment session.

3.1 Hypotheses:

Null hypotheses

1. There is no significant difference of the interventional effect between manual therapy and localization group
2. There is no significant difference of pain levels and cervical range of motion between pre and post intervention to cervico thoracic spine

Hypotheses

1. There is significant difference of the interventional effect between manual therapy and localization group (Group Factor)
2. There is significant difference of pain levels and cervical range of motion between pre and post intervention to cervico thoracic spine (Time Factor)

Independent variable

The independent variable for this study was the group either manual therapy or tactile sensory training group, in which each participant was randomly assigned to.

3.2 Ethical Approval

Prior to the commencement of the study, ethical approval (Number 12144/1.04.19) was gained through application of the research protocol to the Student Project Bioethical Committee of University of Patras and according to the ethical standards of the Declaration of Helsinki (*APPENDIX A*).

3.3 Study Design

A single-blind randomized clinical trial was conducted at the Clinical Rehabilitation Laboratory of the Physiotherapy Department of the University of Patras, which is based in Aigion campus.

3.4 Data storage

Any paper copies with participants' personal information were held in the supervisor's office and the electronic data was kept in a password protected computer and were only accessible to the research supervisor and the postgraduate student. Data will be stored for 5 years after the project completion and will be destroyed in line with the University of Patras protocols on confidential waste.

3.5 Recruitment Strategy

Volunteer adults suffering from neck pain have been invited to participate in the study. Recruitment was performed by verbal announcements, via social media and local newspaper adverts (i.e. posters have been displayed on notice boards at the Aigion Campus of the University as well as on University's social media page with details and information related to the study (*APPENDICES D, E*). Additionally, the project supervisor sent an email to staff and students, inviting individuals to participate in the study. All those who expressed an interest, received an email in response with attached information, enabling them to self-exclude themselves (if they were not eligible for participation) (*APPENDICES C, F*). Eligible subjects were invited for an initial screening and self report of demographic and a health history questionnaire was also recorded (*APPENDICES G, H*).

3.6 Inclusion and Exclusion criteria

Eligible patients had to present with neck pain for at least 1 week prior to their recruitment. Patients were excluded if they could not read or understand spoken /written Greek, were under the age 18 and over 65, had undergone spinal surgery in the area of focus, had any skin condition preventing them from receiving tactile stimuli, had any contraindications to manual therapy (vertebral arteries insufficiency, spinal instability, steroid medication use, malignancy) (Dewitte et al.,2014) present any symptoms related to neurological conditions altering sensation (i.e. peripheral neuropathy, multiple sclerosis, diabetes), had diagnosis of radiculopathy with high irritability (*Table 3*). All participants were required to completed and pass, a health questionnaire (*APPENDIX F*). This ensured each participant was clear of contraindications, 'red flags' and any other additional factors included in the exclusion criteria (Hutting et al., 2018).Given the absence of red flags signs, no imaging was required or indicated according to relative guidelines (Haldeman et al., 2010).

Table 3.*Inclusion and Exclusion Criteria*

Inclusion Criteria	Exclusion Criteria
Participants should suffer from neck pain for at least 1 week	Trauma/surgery to the CxTx in past
Participants must be between the ages of 18-65, including both males and females	Skin allergies/ irritation/ dermatological conditions (dermatitis, eczema)
Participants able to understand spoken and written Greek	Neurological disorders such as altered sensation, peripheral neuropathy, multiple sclerosis
Participants must be able to give informed consent	Vertebral arteries insufficiency
No previous adverse effects to manual therapy	Steroid medication use
	Spinal instability
	High irritability
	Radiculopathy
	Malignant neoplasm
	Cervical myelopathy
	Those who answered YES to any of the questions in the health screening questionnaire, suggesting having contraindication on treatment

3.7 Sample size

There was no relevant previous research available in neck pain to suggest the minimum number of subjects required for adequate statistical power to detect a treatment effect. Based on previous studies in different areas of focus which have applied tactile sensory training, they have used between 15 and 60 participants (Barker et al.,2008;Louw et al.,2015; Ryan et al.,2014; Harvie et al.,2018).Due to time restrictions and sample availability, researchers aimed for a convenience sample of 30 participants. Subjects were eligible to take part if they met the inclusion criteria (*Table 3*).

3.8 Informed Consent

Prior to participation the study informed consent took place by the principal investigator (Master's student) and all subjects were able to ask questions before their written consent according to the ethical standards of the Declaration of Helsinki. The researcher gave explanation of the procedure and participants were reminded at this point that they are free to withdraw from the study at any point. The participants were asked to sign two copies of the consent form (*APPENDIX B*) one for themselves to keep and one for the researchers to retain in the University's file. Participants were reminded that the data gathered/analyzed will be confidential, thus maintaining patient's anonymity. Anonymization was achieved by assigning all participants a numerical identity (healthy subjects in the pilot study #P1-#P20 and study participants #T1-#T30) corresponding to the order in which they arrived. This was to reduce assessor bias and to maintain confidentiality.

3.9 Pilot study

It took approximately 2 weeks to design and pretest the study protocols and forms and design the 9 block grid (required for the localization intervention) (*Figure 8*). A pilot study, using 20 healthy subjects incorporating the series of intervention and measurement relevant to the study was carried out two weeks prior to the data collection of the patient population, to standardize the timings, logistics of the procedure, use of equipment, standardization of the instructions and patient comfort. Leon et al. (2011) found that pilot studies are necessary in the planning and design of a larger trial. Also, pilot studies reduce measurement error, confirm that the treatment dose is appropriate and provide the opportunities to make amendments in the methodology of the

main study, so as to enhance the rigor, by pinpointing any potential problems in the method (Thabane et al., 2010). More specifically, the 20 healthy participants were seen twice within two weeks, in order to undertake a test retest reliability study on neck ROM measurements and on algometer testing performed by the tester. During the first visit, the postgraduate student measured the mobility of all neck movements (flexion, extension, lateral flexion and rotation) using the bubble inclinometer. Each movement was measured three times and an average out of the three trials was calculated and recorded. Three PPT measurements using the algometer were also screened, one centrally (in the middle of 5^{th} square of the 9 block grid) one on the left (in the middle of 4^{th} square) and one on the right (in the middle of 6^{th} square) in order to define the area tested and ensure repeatability. (*Figure 16*) During the second visit, the following week, the same measurements were performed by the same assessor. Additionally, a trial of the sensory training (localization) technique, using the 9 block grid, was conducted for 1 minute to standardize the instructions for the main study. Results from the pilot study were used to calculate the intra examiner reliability of the assessment tools, the bubble inclinometer and the algometer.

3.10 Randomization

Prior to data collection, the participants were randomly assigned into either the tactile sensory stimulation group or the manual therapy group, with mobilizations and, using a randomized number table designed by an on line software (www.randomizer.org) in a private room in the Clinical Rehabilitation lab, to reduce allocation bias (Nunan et al.,2018)

3.11 Blinding

Assessors' blinding was not possible, due to the researcher and therapist being involved in collecting and analyzing the data. On the other hand, participants' blindness was feasible as we ensured that the participants were not informed about the hypotheses of the research treatment approaches and the expected outcome.

3.12 Outcome Measures

In the present study both patient-reported outcomes (PRO) and clinical based outcomes (CBO) were used to monitor aspects of neck pain as well as to monitor the effectiveness of the interventions. The use of various outcome measures and assessment tools assessed many dimensions of neck pain including pain intensity, disability, functionality, general health status as well as psychosocial aspects (Bombardier, 2000).

Self reported neck and thoracic pain intensity was evaluated using 0-10 **Numeric Pain Scale (NPRS),** as it is commonly used in various spinal pain studies (Moseley,2002; Moseley,2003; Moseley 2005b) and clinical practice .In this 11-point numeric linear scale, higher scores indicate greater pain intensity. Patients were asked to rate their average pain intensity, their pain at best and worst, ranging from '0' representing "no pain" to '10' representing the "worst pain imaginable" (Hawker et al., 2011). Cleland et al. (2008) found that the minimum detectable change (MDC) and minimal clinically important difference (MCID) for the NPRS to report a true difference were 2.1 and 1.3 points, respectively, in patients with mechanical neck pain.
The NPRS has previously shown adequate reliability and validity in patients with chronic pain conditions, including neck pain (Childs et al.,2005; Cleland et al.,2008; Hawker et al., 2011).The NPRS has good sensitivity, high responsiveness and generates data that can be statistically analyzed (Pöntinen ,1998) (*APPENDIX G*).

Pain Pressure Threshold (PPT) is defined as the minimal amount of pressure for which a stimulus is perceived as painful (IASP, 2012), measured through an algometer kg/cm^2 and it is also used to objectively measure pain. Potter et al. (2006) found algometry a stable and ideal tool to objectively measure an individual's pain. Chesterton et al. (2007) concludes that pressure algometry, when used with correct technique is a highly reliable measurement of PPT. Walton et al. (2011) indicates that the algometer is reliable and has an excellent intra rater reliability of ICC=0.94-0.97 and an inter rater reliability of ICC=0.79-0.90.PPT is measured either with an electronic or analog handheld algometer (*Figure 6*).It is generally accepted that even simple devices are considered sufficient for clinical purposes (Ylinen et al., 2007). According to Andersen et al. (2002) neck and shoulder pain is associated with low-pressure pain threshold (PPT) values. The minimum detectable change (MDC) for PPT to report a true difference in the

upper trapezius muscle in subjects with NP has been determined in 47.2 kPa = 0.48 kg/cm^2 (Walton et al., 2011).

Range of motion is the measurement of movement around a joint and is one the many outcome measures used in clinical practice (Everrett and Kell, 2010) during the clinical examination of individuals with cervical spine problems. Goniometry is a method of objectively measuring active or passive movement and can determine patient baseline, clinical decision making and intervention effectiveness (Gajdoosik and Bahannan, 1987). Manual goniometer technique includes visual estimation, universal goniometer, and inclinometer, whereas digital means include electrogoniometers photographic images (Norkin and White, 2017). Each goniometer method has varying levels of measurement reliability (Akizuki et al., 2019) which affects its effectiveness for therapists within the clinical environment.

Bubble inclinometer is a valid instrument that assesses the range of motion of the cervical spine and it is found that the inter-examiner reliability ranged from 0.80 to 0.93 ("good to excellent") (Williams et al., 2010), whereas the minimum detectable changes were large for neck flexion and extension (13 to 21°). (*Figure 7*)

Neck Disability Index (NDI) is a patient-completed, condition-specific functional status questionnaire with 10 items including pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation to evaluate disability in patients with neck pain (Vernon and Mior, 1991).Each section is scored from 0 to 5 and the total score is expressed in a percentage (Vernon and Mior,1991) The NDI has sufficient support and usefulness to retain its current status as the most commonly used self-report measure for neck pain throughout the word. It is a valid and reliable tool (Howell, 2011) designed to measure function, it has been translated in Greek with high internal consistency (Cronbach alpha: 0.85) and very good test-retest reliability into Greek (ICC: 0.93) (Trouli et al., 2008). The minimum detectable change is reported at 5 points out of 50, and it is recommended that 7 points is the minimum clinically important difference (MacDermid et al., 2009). However, the NDI was used only at baseline, to estimate the amount of disability of each subject. Due to the short term treatment utilized in the study (only cross-sectional data) NDI could not be justified to have changed the sample's disability levels (*APPENDIX J*).

Hospital Anxiety and Depression Scale (HADS) has been firstly introduced by Zigmond and Snaith (1983) to provide clinicians with an acceptable, reliable, valid, practical tool for identifying and quantifying depression and anxiety. The HADS showed evidence of reliability and validity in population with neck pain (Bicer et al., 2004).The HADS questionnaire has been translated and widely used in over 25 countries and consists of 14 questions rated on a 4-point Likert scale (range 0-3). It is designed to measure anxiety and depression (7 items per subclass) and the score is obtained for each subcategory separately but also from the sum of all 14 questions. In this clinical study the validated Greek version by Michopoulos et al. (2008) was used, which showed good psychometric properties (*APPENDIX I*).

Global Rating of Change Scale (GRoC) is very commonly used in clinical research, particularly in the musculo-skeletal area (Jull et al., 2002; Kay et al., 2005; Koes et al., 1992). It is designed to quantify a patient's improvement or deterioration over time, usually either to determine the effect of an intervention or to chart the clinical course of a condition .GRoC is a 7-point scale ranging from 1(a great deal better), through 0 (no change),to +7 (a very great deal worse)(Tseng et al.,2006). It is widely used to evaluate change in neck pain (Tseng et al.,2006; Izquierdo Perez et al.,2014) because of its validity and clinical relevance(Kamper et al.2009).Participants were requested to complete the questionnaire at baseline (*APPENDIX K*).

3.13 Assessors

The main researcher of this study, who is a postgraduate physiotherapy student with fifteen years of clinical experience, explained the procedure to the participants and collected the information at baseline. All the measurements and data recording pre and post intervention, were performed by the main researcher, after being trained on the assessment tools. In addition, the latter was the therapist who applied the localization intervention to the tactile sensory training group. The therapist throughout the manual therapy intervention was the project supervisor, who is an experienced manual therapist with more than 20 years of clinical experience.

CHAPTER 4

4. Experimental Procedure

4.1 Materials

The Pain Pressure Threshold was measured with an analog handheld algometer (Wagner FDX-20 device) with a surface area at the round rubber tip 1cm^2. The algometer probe tip was applied vertically to the skin at a rate of Kg/ cm^2/s. (*Figure 6*).

Figure 6*.Handheld Analog Pressure Algometer*
Wagner Instruments, FDK-20

The cervical range of motion was measured using a Baseline Bubble inclinometer (*Figure 7*).

Figure 7.*Bubble inclinometer*

A 9 block grid was designed for the experimental procedure using cardboard. The size of the paper was based on the minimal two point discrimination in the neck area. According to Elsig et al. (2014) the mean two point discrimination threshold is 2.975 cm at C2 and 3.27 cm at C7. Catley et al. (2013) and Harvie et al. (2017) have reported a mean of 4.59 cm and 3.5cm respectively. Therefore, the distance between the middles of the blocks should be greater than the 2 point discrimination figures so as to be perceived, it was agreed at 5 cm. (*Figure 8*)

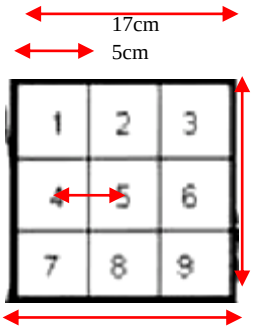


Figure 8.*Localization 9 -block Grid design*

In addition, a standard plinth, a Stopwatch and a stylus pen was used in the study procedure.

4.2 Assessments

Two assessments were performed to each patient; pre and immediately post intervention. These assessments included measurements of pain (NPRS and PPT), and neck ROM in order to quantify their pain, level of mobility and function. These post treatment measurements were taken immediately after intervention, hence providing data regarding the effect of the pain gate theory and sympathoexcitation movement system within the descending pain inhibitory system. Self demographic information (gender, age, occupation, height, weight as well as self-reported questionnaires (history, NDI, GRoC and HADs) were completed at baseline only, to determine participants' function , general health, depression and anxiety levels.

The PPT was measured by a trained physiotherapist, with a Wagner FDX-20 device (Wagner Instruments, Greenwich, CT) with a surface area at the round rubber tip 1cm^2. The algometer probe tip was applied perpendicularly to the skin at a rate of Kg/ cm^2/s on the muscle tissue. With the patient seated three points were marked on the participants' skin with a pencil to ensure that the second measurement will be recorded from the same area as the first to increase reliability. The number 5 (of the 9 block grid), one point at the right (6th square of the grid) and one point at the left (4th square of the grid).These criteria ensured the experiment can be repeated and furthers researchers would have detailed knowledge of the methodology. After providing standardized instructions, the examiner applied force via the algometer until the participant felt that pressure sensation turned into an unpleasant feeling, the participant pressed a hand switch when this is felt or stated "stop" and the score was noted. The PPT of the participants was assessed by the same

examiner to reduce inaccuracies when collecting data. Two measurements (pre and within 1 minute immediately post intervention) were recorded at the previously described sites in the same order, starting centrally (5), left (4) and ending right (6) (*Figure 9*).

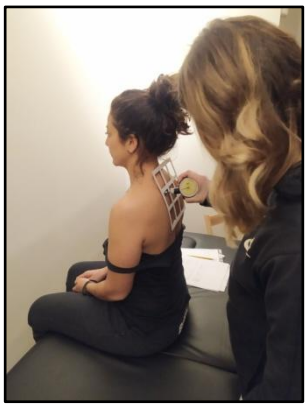


Figure 9 *Pressure Pain Threshold measurements using an algometer, pre and post intervention*

Prior to neck ROM measurements all patients were requested to carry out all neck movement to familiarize themselves with the procedure and to reduce the creep phenomenon (Farooq et al., 2006). Patients were given consistent verbal instructions and were asked to perform active movement as possible up to the beginning of pain otherwise to the fullest extent of mobility of flexion, extension, lateral flexion to the right, lateral flexion to the left (in sitting upright position with the arms relaxed on the plinth and feet on the floor horizontally and head in a neutral position) (Christensen and Nilsson, 1999). Left and right cervical rotations were performed with the patient lying supine. These movements were performed three times each; the scores were recorded and averaged. Neck mobility measurements were conducted pre and post treatment.

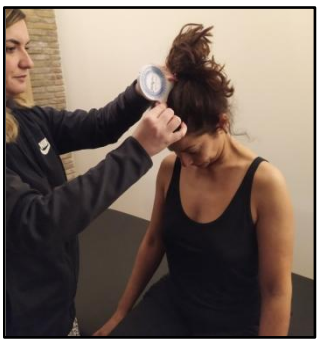


Figure 10.a *Cervical Flexion /* ***b.*** *Extension ROM measurements* ***Figure 11.*** *Cervical Lateral Flexion ROM Measurements*

The cervical flexion /extension ROM was measured with the patient in sitting- upright position unsupported, with hips and knees flexed 90^{o} degrees, feet resting on the floor and arms at the side. The assessor positioned the bubble goniometer in the saggital plane in the midline of the participant's head. The patient should have a starting point in the middle position, which was corrected by the therapist. (*Figure 10a, 10b*)

The cervical lateral flexion ROM was measured with the patient in sitting- upright position unsupported, with hips and knees flexed 90^{o} degrees, feet resting on the floor and arms at the side. The assessor positioned the bubble goniometer in the frontal plane in the midline of the participant's head. The patient should have a starting point in the middle position, which was corrected by the therapist. (*Figure 11*)

The cervical rotation ROM was measured with the patient in supine without a pillow behind the head, with the legs extended and the arms relaxed at the side of the trunk. The assessor positioned the bubble goniometer between the eyebrows in the center of the participant's forehead. The patient should have a starting point in the middle position, which was corrected by the therapist. (*Figure 12*)

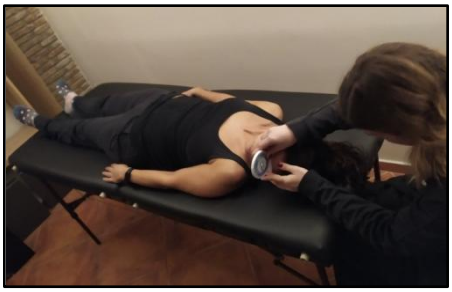


Figure 12*.Cervical Rotation ROM measurements*

4.3 Interventions

4.3.1 Manual Therapy Group

Following baseline assessment, participants assigned into manual therapy group received a single session of MT including, one minute AP technique in the C7-T1 vertebral segment and 2 minutes SNAGs rotation into T1-T2 and T3-T4 level.

With the subject lying supine on an adjustable plinth the researcher palpated and marked the C6,C7,T1,T2,T3,T4 vertebral segments in an attempt to enhance reliability and validity of palpation. The therapist held C6 and applied AP mobilization (as described by Maitland et al., 2005) in C7-T1, Grade II or Grade III for 1 minute, at a frequency of 2 HZ (metronome) following the movement plane of the cervical zygapophyseal joints (downslope or upslope) (Dewitte et al.,2014; McNair et al.,2007). The amount of treatment to the right or left was based on patients' symptoms, identified hypermobility and therapist's clinical reasoning and decision making. (*Figure 13*) Then, with the patient in a sitting position at the edge of the plinth and with feet touching the floor, the therapist located the T1-T2 level and placed her hand unilaterally. Afterwards, the participant was asked to actively rotate to the right for 30 seconds and to the left for 30 seconds (approx 10 times each) while the therapist gently guided the glide through the movement, thus performing a SNAG in rotation. (*Figures 14 a, b, c*). The T3-T4 segment SNAGs mobilization followed, as described in *figure 15*, with the same dosage into right and left rotation. The force was applied parallel to the facet plane (Exelby, 2002) (*Figure 3*) and at the end of the available pain free range an overpressure was administered. SNAGs technique was chosen, as it is suggested for painful movement dysfunctions and in contrast to other manual therapy techniques is performed with the spine under normal load bearing conditions. Further, it includes active and passive elements of physiological movements with accessory glides, within the available range of movement and it is under patient's control. During the application of SNAG technique, the participant should be pain free and was instructed to stop in case pain was produced.

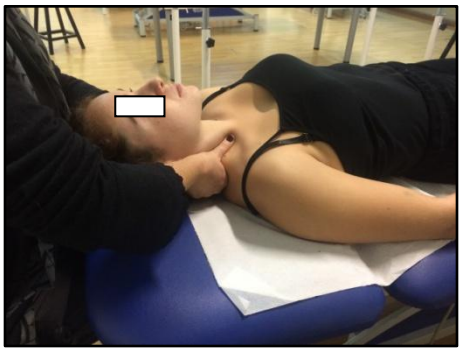


Figure 13*.Application of AP manual therapy mobilization technique to C7-T1*

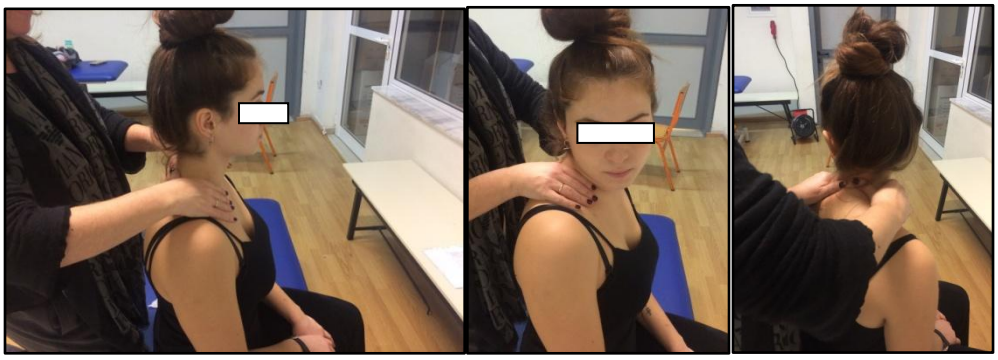


Figure 14.*Application Mulligan SNAGs mobilization technique to TI-T2 spinal level*
a) *Starting position* ***b)*** *rotation to the right* ***c****) rotation to the left*

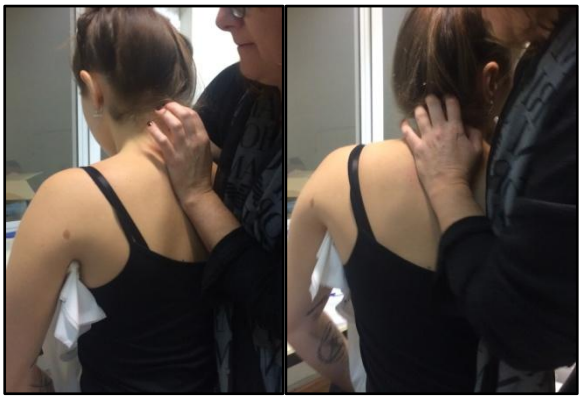


Figure 15.*Application Mulligan SNAGs mobilization technique to T3-T4 spinal level*
a) *Starting position* ***b****) rotation to the right*

4.3.2 Tactile sensory training (Localization) group

For the localization group a paper with a 9 block grid on a body chart was designed (*Figure 8*) for the cervicothoracic area. The localization training was performed for 3 minutes, in order to be in accordance with the first's group treatment duration.

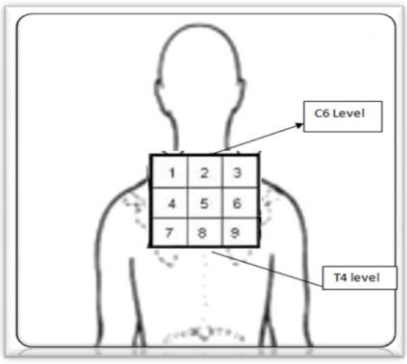


Figure 16 *Application of the 9 block grid in the cervicothoracic area for localization training group*

Participants were asked to sit in normal relaxed position shirtless or with straps removed. The therapist applied the 9 block grid between C6 and T4 (*Figure 16*).At first, the staff taught the participants, viewing the body chart and the 9 block grid, which square (1-9) was being touched by a pen in order to familiarize them with the procedure. Subsequently, whilst the therapist touched randomly one of the 9 grids on the lower cervical- upper thoracic spine, the participant was requested to answer which number was being touched, and gave continuous verbal feedback as to the location of the stimulus. With a successful identification of the grid, the therapist proceeded and the next area was tested *(Figure 17*). In the event of incorrect response, the same grid was touched again, and then the therapist identified the correct stimulated grid, in essence helping the patient to develop greater attention and localization ability. The sequence of areas stimulated was at random and decided upon discretion of the therapist. In order to limit the effect of therapist and patient interaction on treatment outcome, patients in both groups were asked about discomfort and symptom reproduction during interventions.

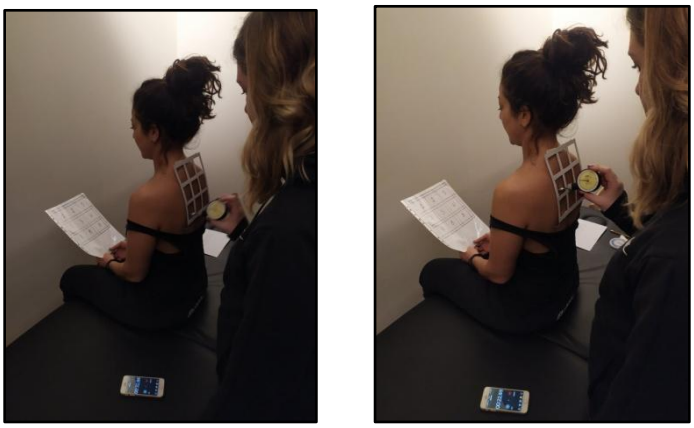


Figure 17a, b. *Tactile sensory (localization) training*

4.4 Data Analysis

Collected data was manually entered into Microsoft Excel 2007 and then a statistical testing was carried out using the IBM Statistical Package for Social Science (SPSS) Software (version 24) Chicago, IL).

Descriptive data was reported as mean, range, minimum, maximum and standard deviations for continuous variables and in frequencies and percentages for nominal data. The results were illustrated through graphs, figures and tables.

For the testing of intra rater reliability of test- retest measures of ROM and PPT, performed in the pilot, reliability was reflected by Intraclass Correlation Coefficients (ICCs) via a two- way random model.

For the data normality, a Shapiro Wilk's test was conducted to determine if the row data was normally distributed. Then, the non parametric normative data was tested for statistical significance utilizing Wilcoxon statistical test within group and or Mann Whitney U test between groups. Statistical significance was accepted at $p<.05$ (in line with the other studies of similar nature).

Assuming parametric data and homogeneity between groups, the independent samples t-test was performed between the two groups (manual therapy versus localization group), and the paired sample t-test was conducted for the within-group comparisons of the measurements before and after the interventions. Null hypotheses of no difference were rejected if p-values were less than 0.05.

Two way Mixed Analysis of Variance (ANONA) was performed for the comparison of interaction of time (pre and post treatment) and group (localization and manual therapy group). Null hypotheses of no difference were rejected if p-values were less than 0.05.

4.5 Declaration of Interest

The researchers and author of this project declare to have no conflicts of interest.

4.6 Funding

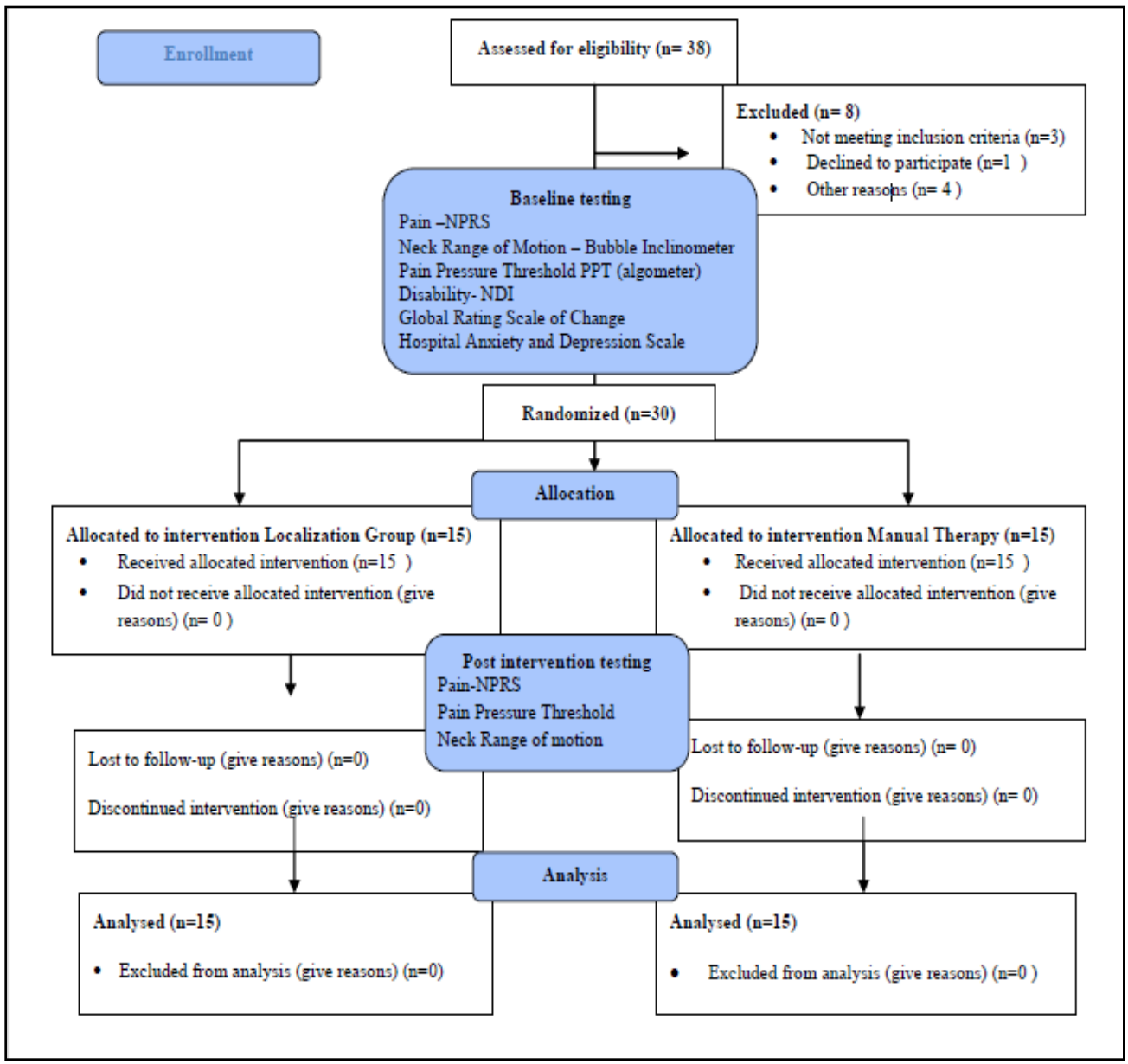
No specific grant from funding agencies in the public, commercial or not- for profit sectors was received for this study.

CHAPTER 5

5. RESULTS

In this randomized single blind clinical trial the extent of change in NPRS, PPT and neck mobility was compared between patients with neck pain who underwent manual therapy or tactile sensory (localization) training. Patients' recruitment and data collection took place between November and December 2019.Thirty eight patients were recruited, out of which four patients were excluded as not meeting the eligibility criteria, one patient declined to participate and 4 for other reasons (*Diagram 1*) such as lack of time, difficulty in transportation and personal reasons.

Diagram 1 *Flow Diagram of patient recruitment and retention (modified Consort 2010 Flow Diagram)*



5.1 Sample Characteristics (N=30)

A sample of 30 patients (23 females, 7 males) aged 28.63 ± 12.49 years (ranging between 18-64 years) with neck pain, who met the inclusion criteria were randomly assigned into 2 equal groups(n=15). In particular, 11 females and 4 males aged 26.4±9.66 years were randomly allocated in localization group and 12 females and 3 males aged 30.87±14.81 years in manual therapy group. There were no differences in participants' demographics (age, height, weight, BMI) between the tactile sensory (localization) training group and manual therapy group (p-values>0.05). *Table 4* outlines the descriptive characteristics for intervention groups, manual therapy and tactile stimulation training group. *Tables 5* shows sample demographic characteristics concerning marital status, formal level of education, working hours per day, study hours per day, whereas *Tables 6-11* display sample's clinical characteristics such as location, description and 24 h pattern of pain, frequency and chronicity of pain at baseline. The majority of patients reported subacute or chronic neck pain (90%), and only 3 patients (10%) suffered from acute neck pain with the complaint of less than 4 weeks *(Table 11*). A notable percentage of patients responded to Global Rating Scale of Change that their condition has no substantial change (33.33%) or is getting worse (40%) over the past 6 months *(Table 12*). *Table 13* outlines sample's scores in Neck Disability Index and Hospital Anxiety and Depression self reported questionnaires at baseline. *Table 14* describes sample's Descriptive Statistics Pre – Post treatment for all measurements (NRPS, PPT, and ROM).

Diagram 2 *Sample and Groups Demographic Characteristics Gender*

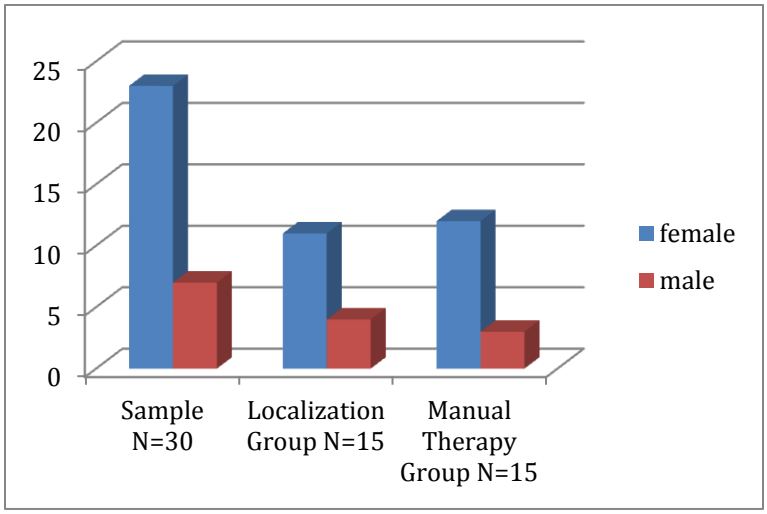


Table 4 *Sample Demographic Characteristics (N=30)*

	Mean(±SD) N=30	Min- Max N=30	Localization Group n=15	Manual Therapy Group n=15	p- value
Age (years)	28.63(±12.49)	18-64	26.4±9.66	30.87±14.81	0.461
Height(m)	1.74(±0.099)	1.54-1.95	1.71±0.09	1.70±0.11	0.746
Weight(Kg)	78.5(±15.40)	50-107	72.26±17.80	70.6±13.17	0.713
BMI(Kg/m^2)	24.61(±3.61)	18.59-33.13	24.40±3.99	24.33±3.33	0.958

SD=standard deviation

Table 5 *Sample Demographic Characteristics (N=30)*

		Frequency	%
Gender	Female	23	76.67%
	Male	7	23.33%
Formal Level of Education	High School	22	73.33%
	University	8	26.67%
Marital Status	Single	24	80%
	Married	5	16.67%
	Divorced	1	3.33%
Working Hours	None	11	36.67%
	Part Time (<8 hours)	8	26.67%
	Full Time(≥8 hours)	11	36.67%
Study Hours/ PC hours	Few (<4 hours)	17	56.67%
	Several(4-8 hours)	11	36.67%
	Many(>8 hours)	2	6.67%

Table 6 *Sample Clinical Characteristics (Pain Location at baseline)*

Pain area	Frequency (%) Baseline
Posterior area of the head Left (1)	4 (13.33%)
Posterior area of the head Right (2)	26 (86.67%)
Posterior area of the neck Left(3)	27(90%)
Posterior area of the neck Right(4)	4(13.33%)
Shoulder Left (5)	4(13.33%)
Shoulder Right (6)	7(23.33%)
Scapular area left (7)	23(76.67%)
Scapular area right (8)	24(80%)
Lower Posterior Thoracic area Left (9)	1(3.33%)
Lower Posterior Thoracic area Right 10)	1(3.33%)
Upper anterior area of the head Left (11)	4(13.33%)
Upper anterior area of the head Right (12)	3(10%)
Lower anterior area of the head Left (13)	4(13.33%)
Lower anterior area of the head Right(14)	3(10%)

Table 7 *Clinical Features/Symptoms at baseline Sample n=30*

	Frequency (%) at baseline
Dizziness	15 (50%)
Vertigo	5(16.67%)
Hyposensitivity	1(3.33%)
Numbness	5(16.67%)
Pins & Needles	5(16.67%)
Weakness	7(23.33%)

Table 8 *Clinical Features/Pain Description at baseline Sample n=30*

	Frequency (%) at baseline
Dull	7(23.33%)
Sharp	9(30%)
Superficial	4(13.33%)
Deep	12(40%)
Diffuse	4(13.33%)
Localized	16(53.33%)
Constant	15(50%)
Intermittent	15(50%)

Table 9 *24h Pattern of Pain at baseline*

	Frequency (%) Sample n=30	Frequency (%) Localization Group n=15	Frequency (%) Manual Group n=15
Wakes me at night	4 (13.33%)	2(13.3%)	2(13.3%)
Difficult to sleep	5(16.67%)	2(13.3%)	3(20%)
Worst in the morning	16(53.33%)	9(60%)	7(46.67%)
Worst in the afternoon	8(26.66%)	4(26.67%)	4(26.67%)

Table 10 *Frequency of Pain at baseline*

	Frequency (%) Sample n=30	Frequency (%) Localization Group n=15	Frequency (%) Manual Group n=15
Rarely	1(3.33%)	0(0%)	1(6.67%)
1-2 days a week	14 (46.67%)	8(53.33%)	6(40%)
5-6 days a week	11(36.67%)	7(46.67%)	4(26.67%)
Everyday	4 (13.33%)	0(0%)	4(26.67%)

Table 11 *Duration (Chronicity) of Pain at baseline*

	Frequency (%) Sample n=30	Frequency (%) Localization Group n=15	Frequency (%) Manual Group n=15
1week-1month	3 (10%)	0 (0%)	3 (20%)
1month-3months	2 (6.67%)	2 (13.33%)	0 (0%)
6months	6 (20%)	3 (20%)	3 (20%)
1 year	7 (23%)	4(26.67%)	3 (20%)
2-5years	10 (33.33%)	4(26.67%)	6 (40%)
>5years	2 (6.67%)	2(13.33%)	0 (0%)
Total	30(100%)	15(100%)	15(100%)

Table 12 *Global Rating Scale of Change at baseline*

	Frequency (%) Sample n=30	Frequency (%) Localization Group n=15	Frequency (%) Manual Group n=15
A very great deal better	0 (0%)	0 (0%)	3 (20%)
A good deal better	4(13.33%)	2 (13.33%)	2 (13.33%)
A little better	4 (13.33%)	4(26.67%)	0 (0%)
No change	10 (33.33%)	3 (20%)	5 (33.33%)
A little worse	9 (30%)	3 (20%)	6 (40%)
A good deal worse	3 (10%)	3 (20%)	0 (0%)
A very great deal worse	0 (0%)	0 (0%)	0 (0%)
Total	30(100%)	15(100%)	15(100%)

Table 13 *Neck Disability Index (NDI) and Hospital Anxiety and Depression scale at baseline (N=30)*

	Sample N=30 Mean(±SD)	Min- Max	Localization Group n=15 Mean(±SD)	Min – Max	Manual Therapy Group n=15 Mean(±SD)	Min -Max	Significance P value
NDI score	21%(±0.09)	4%-44%	22%(±0.10)	10%-44%	19% (±0.08)	4%-36%	0.359
HADs Total	11.83(±5.91)	5-24	12.07(±6.11)	5-24	11.60(±5.91)	5-21	0.838
HADs Anxiety	7.97(±3.92)	2-15	8.07(±4.15)	2-15	7.87(±3.81)	4-15	0.902
HADs Depression	3.87(±2.67)	0-11	4(±2.62)	1-9	3.73(±2.81)	0-11	0.624

5.2 Sample Data Analysis Pre and Post Intervention

All data was assessed by Shapiro Wilk's test to ensure normal distribution. Statistical analysis Paired t test or Wilcoxon Matched Pair Signed- Rank test pre and post intervention were conducted to all sample participants to investigate the effectiveness of the time in dependant variables of NRPS, PPT and neck ROM.

There is evidence to suggest that "my pain now" was less post treatment (3.47±1.43) than pre treatment (4.63±1.40) in the study sample (p-value<0.001).

With regard to PPT, the paired t test demonstrated a numerical decrease of the pain pressure threshold in the study but the changes were not statistically significant (p>0.05).

The statistical analysis paired t or Wilcoxon test pre and post intervention revealed statistical differences (p<0.001), and, in conjunction with the descriptive data, demonstrated that neck range of motion improved in all directions. Most of the movements had an increase of more than 3^{o} between pre and post intervention evaluations, still not enough for a detectable change in bubble inclinometer *(Table 14)*.

Table 14 *Sample Descriptive Statistics Pre – Post treatment*

Measurements ALL patients N=30	**PRE INTERVENTION All patients (N=30)**		**POST INTERVENTION All patients (N=30)**		
	Mean(±SD)	**Min- Max**	**Mean(±SD)**	**Min- Max**	**p- values**
NRPS best	1.5(±1.57)	0-5			
NRPS worst	7.2(±1.58)	3-10			
NRPS now	4.63(±1.40)	2-8	3.47(±1.43)	1-7	0.000**[a]
PPT central	4.10(±1.25)	2.2-7	3.93(±1.34)	1-7.6	0.359[a]
PPT right	3.94(±1.34)	1.6-7.6	3.89(±1.35)	1.4-7.8	0.569
PPT left	3.92(±1.36)	1.4-7.6	3.99(±1.25)	1.4-7.6	0.514
ROM Rotation R	74.78(±6.41)	64-90	78.42(±4.93)	70-90	0.000**[a]
ROM Rotation L	72.11(±9.05)	46-86	76.20(±8.62)	55-90	0.000**
ROM Lateral Flexion R	40.67(±7.27)	25-51	45.78(±7.55)	30-60.67	0.000**[a]
ROM Lateral Flexion L	37.98(±8.16)	22-53	41.68(±7.86)	25-55	0.000**
ROM Flexion	47.80(±9.21)	24.33-65	50.54(±8.88)	32-67.33	0.000**[a]
ROM Extension	49.49(±10.42)	26.67-70	52.14(±9.03)	35-68	0.002**[a]

**statistical significant (p<0.05), **very statistical significant (p<0.001)*

a. The difference scores for OMs pre and post were not randomly distributed, as assessed by ShapiroWilks test-, thus a nonparametric Wilcoxon Test for related samples was conducted.

5.3 Reliability Measurements (pilot study)

During the pilot study, test-retest reliability results in a week interval, were used to calculate and ensure the within experiment intra-examiner reliability for the neck ROM goniometer (bubble inclinometer) and Pressure Pain Threshold (algometer). Reliability was calculated using the two way random average measures, reflected by Intraclass Correlation Coefficient (ICC) for absolute agreements. For the interpretation of reliability scoring it was considered as excellent if ICC was >0.75, satisfactory to good 0.40- 0.75 and poor <0.40 (Fleiss, 1986). For the pilot study and intra rater reliability testing, 20 healthy participants (8 females, 12 males) aged between 18 and 50 years (mean 22.5±6.95) were recruited. Reliability was excellent for ROM measurements ($ICC_{(2,2)}$ ranging from 0,894-0.97, 95% CI 0.772-0.994, p<0.0001, and very good for PPT measurements ($ICC_{(2,2)}$ ranging from 0,748-0,903 , 95% CI= 0.461-0.960, p<0.0001). Reliability results are summarized in Table 15.

Table 15 *Intra rater Reliability Measurements in healthy participants (N=20)*

	Intra class Correlation (ICC) [b]	**95% Confidence Interval Lower –Upper Bound**
ROM Right Rotation	0.913[a]	0.797-0.964
ROM Left Rotation	0.984[a]	0.960-0.994
ROM Lateral Flexion (R)	0.945[a]	0.867-0.978
ROM Lateral Flexion (L)	0.894[a]	0.744-0.957
ROM Flexion	0.902[a]	0.772-0.960
ROM Extension	0.970[a]	0.927-0.988
PPT central	0.816[a]	0.592-0.923
PPT right	0.748[a]	0.461-0.892
PPT left	0.903[a]	0.772-0.960

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.

5.4 Localization (tactile stimulation) Group (n=15)

11 females and 4 males aged 26.4±9.66 years were randomly allocated in localization group, as outlined in *Diagram 2 and Table 4*. *Tables 9-11* display group's clinical characteristics such as 24h pattern of pain, frequency and chronicity of pain at baseline. The majority of patients reported subacute or chronic neck pain (>85%), and only 2 patients (13.33%) suffered from acute neck pain with the complaint of less than 3 months *(Table 11*). A notable percentage of patients responded to Global Rating Scale of Change that their condition has no substantial change (20%) or is getting worse (40%) over the past 6 months *(Table 12*). *Table 13* outlines group's scores in Neck Disability Index and Hospital Anxiety and Depression self reported questionnaires at baseline. *Table 16* describes group's Descriptive Statistics Pre – Post treatment for all measurements (NRPS, PPT, and ROM).

5.5 Localization (tactile stimulation) Group Data Analysis Pre and Post Intervention

All data was assessed by Shapiro Wilk's test to ensure normal distribution. Statistical analysis Paired t test or Wilcoxon Matched Pair Signed- Rank test pre and post intervention were conducted to localization group participants to investigate the effectiveness of the time in dependant variables of NRPS, PPT and neck ROM.

There is evidence to suggest that "my pain now" was less post treatment 3.73(±1.58) than pre treatment 4.93(±1.33) in the localization group (p-value =0.012).

With regard to PPT, the paired t test demonstrated a numerical decrease of the pain pressure threshold in the localization group, but the changes were statistically significant (p>0.05).

The statistical analysis paired t or Wilcoxon test pre and post intervention revealed statistical differences, and, in conjunction with the descriptive data, demonstrated that neck range of motion improved in all directions. Most of the movements had an increase of more than 3^{o} between pre and post intervention evaluations, still not enough for a detectable change in bubble inclinometer *(Table 16).*

Table 16 *Localization Group Descriptive Statistics Pre – Post treatment*

Measurements Localization Group N=15	**PRE INTERVENTION Localization Group (N=15)**		**POST INTERVENTION Localization Group (N=15)**		
	Mean(±SD)	**Min- Max**	**Mean(±SD)**	**Min- Max**	**p- values**
NRPS best	1.53(±1.46)	0-5			
NRPS worst	7.8(±1.32)	5-10			
NRPS now	4.93(±1.33)	3-8	3.73(±1.58)	1-7	0.012*
PPT central	4.42(±1.28)	2.2-7	4.06(±1.47)	1-7.6	0.073
PPT right	4.09(±1.51)	1.6-7.6	4.07(±1.47)	1.4-7.8	0.846
PPT left	4.17(±1.59)	1.4-7.6	4.10(±1.45)	1.4-7.6	0.681
ROM Rotation R	74.51(±5.70)	64-82	77.62(±4.44)	70-84.33	0.008**[a]
ROM Rotation L	70.91(±10.45)	46-84	75.40(±9.25)	55-90	0.0008**
ROM Lateral Flexion R	42.16(±5.55)	34.33-50.33	47.04(±5.88)	37.67-60	0.00029**
ROM Lateral Flexion L	38.73(±6.97)	22.67-53	40.93(±6.60)	26-54	0.0051**
ROM Flexion	45.09(±9.29)	24.33-60	47.09(±8.06	32-60	0.012*
ROM Extension	52.22(±9.62)	35-70	53.33(±9.17)	35-68	0.073

**statistical significant (p<0.05), **very statistical significant (p<0.001)*
a. The difference scores for OMs pre and post were not randomly distributed, as assessed by Shapiro Wilks test-, thus a nonparametric Wilcoxon Test for related samples was conducted.

5.6 Manual Therapy Group (n=15)

12 females and 3 males aged 30.87±14.81 years were randomly allocated in the manual therapy group, as outlined in *Diagram 2 and Table 4*. *Tables 9-11* display group's clinical characteristics such as 24 h pattern of pain, frequency and chronicity of pain at baseline. The majority of patients reported subacute or chronic neck pain (>80%), and only 3 patients (20%) suffered from acute neck pain with the complaint of less than 1 month *(Table 11*). A notable percentage of patients responded to Global Rating Scale of Change that their condition has no substantial change (33.33%) or is getting worse (40%) over the past 6 months *(Table 12*). *Table 13* outlines group's scores in Neck Disability Index and Hospital Anxiety and Depression self reported questionnaires at baseline. *Table 17* describes group's Descriptive Statistics Pre – Post treatment for all measurements (NRPS, PPT, and ROM).

5.7 Manual Therapy Group Data Analysis Pre and Post Intervention

All data was assessed by Shapiro Wilk's test to ensure normal distribution. Statistical analysis Paired t test or Wilcoxon Matched Pair Signed- Rank test pre and post intervention were conducted to manual therapy group participants to investigate the effectiveness of the time in dependant variables of NRPS, PPT and neck ROM.

There is evidence to suggest that "my pain now" was less post treatment 3.20(±1.26) than pre treatment 4.33(±1.45) in the manual therapy group (p-value =0.003).

With regard to PPT, the paired t or Wilcoxon test did not reveal any statistically significant changes ($p>0.05$).

The statistical analysis paired t or Wilcoxon test pre and post intervention revealed statistical differences, and, in conjunction with the descriptive data, also demonstrated that neck range of motion improved in all directions ($p<0.001$). Most of the movements had an increase of more than 4^{o} between pre and post intervention evaluations, still not enough for a detectable change in bubble inclinometer *(Table 17).*

Table 17 *Manual Therapy Group Descriptive Statistics Pre – Post treatment*

Measurements Manual Therapy Group N=15	**PRE INTERVENTION Manual Therapy Group (N=15)**		**POST INTERVENTION Manual Therapy Group (N=15)**		
	Mean(±SD)	**Min- Max**	**Mean(±SD)**	**Min- Max**	**p- values**
NRPS best	1.47(±1.73)	0-5			
NRPS worst	6.6(±1.64)	3-8			
NRPS now	4.33(±1.45)	2-8	3.20(±1.26)	1-5	0.003**[a]
PPT central	3.77(±1.17)	2.4-6.8	3.80(±1.24)	1.8-6.8	0.385[a]
PPT right	3.79(±1.18)	1.8-6.6	3.71(±1.24)	2.2-7.4	0.530
PPT left	3.68(±1.08)	2.2-6	3.87(±1.06)	2.2-6	0.082
ROM Rotation R	75.04(±7.25)	65-90	79.22(±5.42)	70-90	0.005**[a]
ROM Rotation L	73.31(±7.58)	56-86	77(±7.97)	56-90	0.0034**
ROM Lateral Flexion R	39.18(±8.59)	25-51	44.51(±8.95)	30-66.67	0.0014**
ROM Lateral Flexion L	37.22(±9.39)	22-50	42.42(±9.11)	25-55	0.00024**
ROM Flexion	50.51(±8.59)	34.33-65	54(±8.53)	40-67.33	0.005**[a]
ROM Extension	46.76(±10.79)	26.67-66.33	50.96(±9.04)	36-66	0.003**[a]

**statistical significant (p<0.05), **very statistical significant (p<0.001)*
a. The difference scores for OMs pre and post were not randomly distributed, as assessed by ShapiroWilks test-, thus a nonparametric Wilcoxon Test for related samples was conducted.

5.8 Data Analysis Pre and Post Intervention for each outcome measure (within groups ~paired groups)

Table 18 *Pre Post Intervention p- values within localization and manual therapy group*

	All Sample N=30	**Localization group N=15**	**Manual Therapy Group N=15**
NRPS now	0.000**[a]	0.012*	0.003**[a]
PPT central	0.359[a]	0.073	0.385[a]
PPT right	0.569	0.846	0.530
PPT left	0.514	0.681	0.082
Rotation Right	0.000**[a]	0.008**[a]	0.005**[a]
Rotation Left	0.000**	0.0008**	0.0034**
Right Lateral Flexion	0.000**[a]	0.00029**	0.0014**
Left Lateral Flexion	0.000**	0.0051**	0.00024**
Flexion	0.000**[a]	0.0067**	0.005**[a]
Extension	0.002**[a]	0.307[a]	0.003**[a]

**statistical significant (p<0.05), **very statistical significant (p<0.01)*
a. The difference scores for OMs pre and post were not randomly distributed, as assessed by Shapiro Wilks test-, thus a nonparametric Wilcoxon Test for related samples was conducted.

5.9 Data Analysis Pre and Post Intervention for each outcome measure (between groups ~independent groups)

There were no differences in participants' demographics (age, height, weight, BMI) between the tactile sensory (localization) training group and manual therapy group (p-values>0.05) *(Table 4).*

Neck Disability Index Scores were normally distributed for both localization and manual therapy group as assessed by Shapiro Wilk's test. The comparison of Neck disability scores at baseline, using Independent T test revealed that the mean difference between localization and manual therapy group was 3% and was not statistically significant (p=0.359) (*Table 13).*

The measurement of anxiety and depression levels was conducted through the HADs questionnaire and the results were reflected in total scores and subcategory scores (anxiety and

depression). Hospital Anxiety Depression scores were not normally distributed for both localization and manual therapy group as assessed by Shapiro Wilk's test. The statistical analysis Mann Whitney U Test showed no statistical significant differences ($p>0.05$) between groups at baseline (*Table 13).*

The self reported pain levels at baseline were recorded using Numeric Rating Pain Scale (NRPS), "my pain now", "pain at best", "pain at worst". NRPS scores were not normally distributed for both localization and manual therapy group as assessed by Shapiro Wilk's test. Following Mann Whitney U test, significance level difference between groups for present pain was $p= 0.345$ ($p>0.05$), significance level for "my pain at best was $p=0.713$ ($p>0.05$) and for worst pain, $p=0.056$($p>0.05$). Following one session of treatment, all participants were reassessed for their pain levels, as measured by NRPS to define their present pain which was improved regardless of type of treatment. The average "pain intensity now" after participants had received manual therapy was less 3.20(±1.26) than when they received tactile sensory (localization) training 3.73(±1.58).However, independent t- test showed that the significance level was $p=0.389$, which is above the accepted level of significance ($\alpha >0.05$), thus the difference is not statistically significant between localization and manual therapy group. In both intervention groups the self reported level of pain was decreased and the mean change was statistically significant (F statistic (p- value) 22.80 (0,000**).Irrespective of the intervention groups, the reported reductions in neck pain identified by NRPS, were less than 2.1, thus deemed to provide clinical significance *(Table 19).*

The measurements for Pain Pressure Threshold for each group are displayed in the table below. PPT scores were normally distributed for both localization and manual therapy group as assessed by Shapiro Wilk's test. The Independent t test analysis confirmed that there is no significant statistical difference between the PPT values before treatment between the two groups ($p>0.05$). Similarly, Pressure Pain Threshold measured at 3 points (centrally, right and left) after the intervention between groups, showed no significant difference, with significance level at 0.605,0.367 and 0.629 respectively (all $p>0.05$) *(Table 19).*

Table 19 summarizes the differences in the primary outcome measure range of motion between the two interventions groups at baseline. Neck ROM scores were normally distributed for both

localization and manual therapy group as assessed by Shapiro Wilk's test. The independent t test did not reveal any statistically significant difference within pre test measurements for the two treatment groups (p>0.05). Neck ROM in all directions was improved from baseline to post treatment in both groups (F>12.54, p<0.002).However, between groups, the improvement shown, was not statistically significant post intervention for Rotation, Lateral flexion and Extension (p>0.05) but was in favor of manual therapy group for flexion (p=0.030).

Table 19 *Pre Post Intervention p- values between localization and manual therapy group*

Measurements Pre and Post Intervention between Groups	PRE INTERVENTION			POST INTERVENTION		
	Localization Group (n=15)	Manual Therapy Group (n=15)	Independent sample test	Localization Group (N=15)	Manual Therapy Group (n=15)	Independent sample test
	Mean(±SD)	Mean(±SD)	P values	Mean(±SD)	Mean(±SD)	P values
NRPS best	1.53(±1.46)	1.47(±1.73)	0.713			
NRPS worst	7.8(±1.32)	6.6(±1.64)	0.056			
NRPS now	4.93(±1.33)	4.33(±1.45)	0.345	3.73(±1.58)	3.20(±1.26)	0.389
PPT central	4.42(±1.28)	3.77(±1.17)	0.161	4.06(±1.47)	3.80(±1.24)	0.605
PPT right	4.09(±1.51)	3.79(±1.18)	0.542	4.07(±1.47)	3.71(±1.24)	0.367
PPT left	4.17(±1.59)	3.68(±1.08)	0.337	4.10(±1.45)	3.87(±1.06)	0.629
ROM Rotation R	74.51(±5.70)	75.04(±7.25)	0.824	77.62(±4.44)	79.22(±5.42)	0.384
ROM Rotation L	70.91(±10.45	73.31(±7.58)	0.478	75.40(±9.25)	77(±7.97)	0.616
ROM Lateral Flexion R	42.16(±5.55)	39.18(±8.59)	0.270	47.04(±5.88)	44.51(±8.95)	0.379
ROM Lateral Flexion L	38.73(±6.97)	37.22(±9.39)	0.620	40.93(±6.60)	42.42(±9.11)	0.612
ROM Flexion	45.09(±9.29)	50.51(±8.59)	0.108	47.09(±8.06)	54(±8.53)	0.030*
ROM Extension	52.22(±9.62)	46.76(±10.79	0.154	53.33(±9.17)	50.96(±9.04)	0.480

**statistical significant (p<0.05), **very statistical significant (p<0.001)*

5.10 Data Analysis Two Way Mixed ANOVA (within subjects interaction *time*group*)

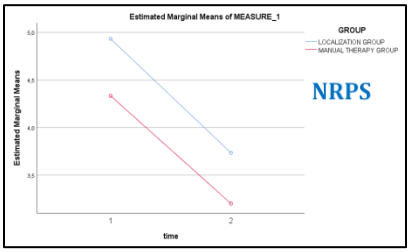
A two way mixed ANOVA was conducted to investigate the interaction between time and group and was found to be statistically significant only for lateral flexion left (F value =5.72, p=0.024*) and in extension (F value=4.24, p<0.05*) favoring manual therapy group.

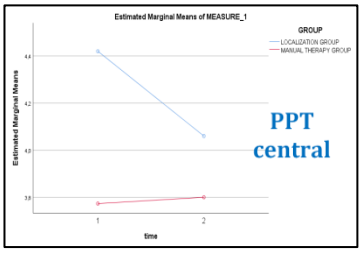
The two way mixed ANOVA did not reveal any statistically significant differences for Present pain intensity (p>0.05), PPT (p>0.05) and other neck ROM directions (p>0.05).Table 20 summarizes the significance values of the primary outcome measure NRPS, range of motion and PPT assessed by two way mixed ANOVA test and graphs illustrate the changes of the above mentioned outcome measures in both groups.*(Diagrams 3a-3j)* More specifically, the improvement in lateral flexion left (from M=37.22^0 SD=9.39 pre intervention to M=42.4^0, SD=9.11post intervention) in manual therapy group was more statistically significant than in localization group (from M= 38.7^0, SD=6.96 pre intervention to M= 40.9^0, SD 6.60). *(Table 19)* In extension the improvement in manual therapy group (from M= 46.756^0, SD=10.78 pre intervention to M= 50.96^0, SD=9.04 post intervention) was statistically greater than in localization (from M= 52,22^0 SD=9.62 pre intervention to M= 53.33^0, SD= 9.17 post intervention) *(Table 19)*

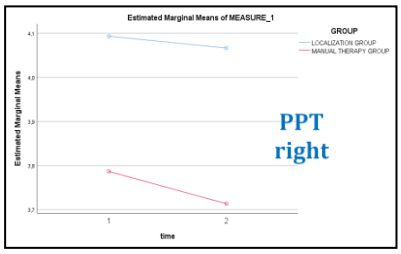
Table 20 *Two- way Mixed ANOVA results, factor=time between localization and manual therapy group*

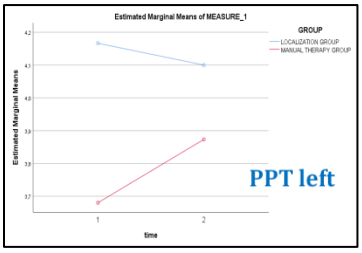
	Interaction Time*Group *F (p values)*
NRPS now	0.02(p=0.892)
PPT central	3.21(p=0.084)
PPT right	0.07(p=0.793)
PPT left	1.89(p=0.180)
ROM Rotation R	0.48 (p=0.495)
ROM Rotation L	0.29(p=0.595)
ROM Lateral Flexion R	0.07(p=0.794)
ROM Lateral Flexion L	5.721(p=0.024*)
ROM Flexion	1.34(p=0.256)
ROM Extension	4.24(p=0.049*)

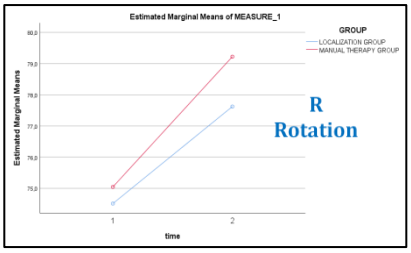
Diagram 3a.*NRPS* ***3b.****PPT central* ***3c.****PPT right* ***3d.****PPT left* ***3e.*** *Right Rotation* ***3f.****Left Rotation* ***3g.****Lateral Flexion R* ***3h.*** *Lateral Flexion L* ***3i.*** *Flexion* ***3j.****Extension*

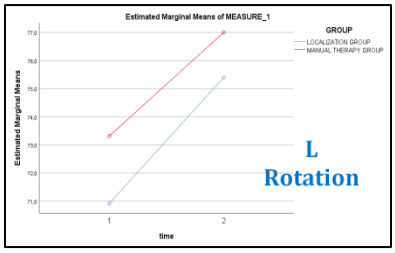


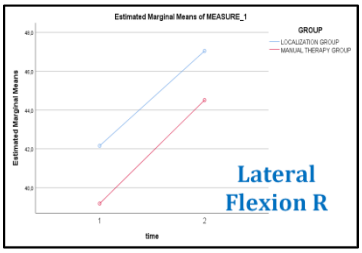


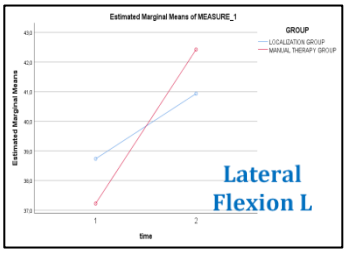


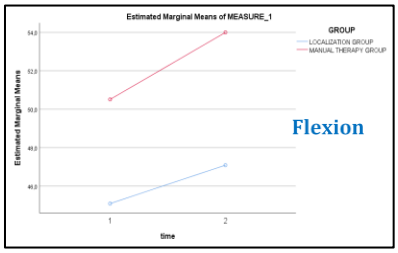


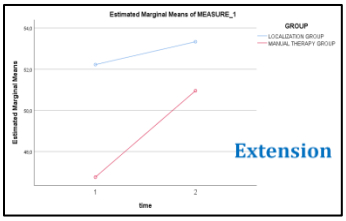












CHAPTER 6

6.1 DISCUSSION

To the best of author's knowledge this is the first randomized clinical trial investigating the effects of manual therapy versus tactile sensory training (localization) on pain and neck mobility in patients with neck pain. 30 patients (23 females, 7 males) mean age 28.63(±12.49), with neck pain who met the inclusion criteria were randomly assigned into 2 intervention groups (n=15 each). In the present study, the results suggest that a single session of tactile sensory (localization) training in the cervicothoracic area resulted in similar outcomes as a single session of manual therapy in patients with neck pain. Both groups made significant improvements on the levels of pain and neck mobility from baseline to immediately post intervention.

Obviously, the prevalence of women compared to men reflected in this clinical trial (76.67% females, 23.33% males) confirms the available evidence from the literature, that neck pain prevalence is higher in women (Hogg-Johnson et al., 2008).With a view of generalization of the results, it should be mentioned that the average age of participants was relatively young (28.63±12.49). However, descriptive statistic analysis regarding the age (years), height (m), weight (kg), BMI (kg/m^2) of the study sample allocated in localization and manual therapy group ensured homogeneity at baseline ($p>0.05$).Similarly, the sample randomization did not show any differences in measurements/scores of NDI, NRPS, HADs, ROM, PPT at baseline (all $p>0.05$), thus ensuring homogeneity across groups.

Our patient baseline data revealed low initial self reported pain (4.63±1.40) and disability scores (21%±0.09). It is not unreasonable to assume that this would limit the significant improvement or influence the outcome compared to a more acute or higher pain /disability sample.

The data from the current trial identified that manual therapy, involving mobilizations and sustained natural apophyseal glides, had an immediate statistically significant as well as clinically significant effect in reducing cervical pain and increasing range of motion, which is in line with the findings of several studies (Cassidy et al., 1992; Sterling et al., 2001; Kanlayanaphotporn et al., 2009; Lopez-Lopez et al., 2015) but contrasts with the results of others (Kanlayanaphotporn et al., 2010; Snodgrass et al.,2014). In fact, the mechanisms by which manual therapy improved

ROM can be attributed mainly to mechanical effects, such as change in the length of connective tissue structures-ligaments, facets' joints capsule and muscles- stretching adhesions (Hearn and Rivett, 2002).The reason for this could be the short duration of treatment on moderate patients' levels of pain. The observed improvement in cervical ROM followed the pattern described in the literature after manual therapy using mobilizations in patients with NP. Likewise, the magnitude of changes in ROM of the above mentioned studies varies, and it could be influenced by the type and method of the applied manual therapy technique. Cassidy et al. study (1992) applied muscle energy technique as mobilizations, whereas we have done anteroposterior oscillations and SNAGs technique. Another reason could be the different type of assessment tool used in the other trials, often the active cervical rom.

The reduction of pain levels shown in manual therapy group is probably due to biomechanical effects while normalizing the muscle activity and stretching the joint tissues (Sterling et al., 2001); neurophysiological effects while stimulating mechanoreceptors (Melzac and Wall, 1965) and psychological effects (Coulehan, 1985) of mobilization. One possible explanation to understand the impact of the application of mobilization techniques to the cervicothoracic area on pain relief in NP subjects has been the principle of regional interdependence. According to this principle, the subject's pain may be related to a restriction in a proximal or a distal anatomical area (Wainner et al., 2007) which might also support the present observations. The decrease of pain intensity in the manual therapy group in our study was statistically ($p=0.003$) but not clinically significant (< MDC), from 4.33(±1.45) to 3.20(±1.26).Therefore, caution should be exercised when interpreting the results. In other similar studies (Cassidy et al., 1992; Lopez-Lopez, 2015) a more remarkable decrease of pain intensity was reported after mobilizations. However, taking into account the relatively low pain levels, it was interesting to see pain reductions with only one MT session.

Surprisingly, no hypoalgesic effects were showed in the current study. These findings did not agree with previous studies where the results of a double blinded RCT indicated that the anterioposterior cervical mobilization technique grade III, produced a hypoalgesic effect, as revealed by increased pressure pain thresholds on the side of treatment (Sterling et al., 2001). Similarly, in the study of Alonso –Perez et al. (2017) in healthy subjects, PPT values after 5minutes mobilization were increased, indicating local and segmental hypoalgesic effects. This

discrepancy could be potentially explained by the fact that the sample size was underpowered to detect changes in PPT over all points because estimation was only based on available data for the cervical spine. This could also explain why the current study observed changes in neck pain intensity but not in PPT. It should be noted that in the present study, patients only received one session of the intervention. Perhaps more MT sessions are necessary to experience a cumulative effect when dealing with manual therapy techniques directed at the thoracic spine. For example, it has been demonstrated that in a population with acute mechanical neck pain, thoracic spine manipulation does not lead to significant tolerance in regard to pain compared to MDC (Salom-Moreno et al., 2014).

Although the duration of treatment was short (3 minutes), with no follow up measurements, it is suggested that these immediate effects are related to some long term changes and are valid predictors of between-session changes (Whittingham and Nillson ,2001). Previous studies (Cassidy et al., 1992; Hanten et al., 1997; Sterling et al., 2001; Martinez-Segura et al., 2006; Vernon and Humphreys, 2008) have also suggested that a single session of mobilization technique can result in improvements in pain levels and pain pressure threshold, but still the evidence remains inconclusive. In contrast, evidence from the studies of Coronado et al. (2010) and Hegedus et al. (2011) showed that only short term neurophysiological benefits may result following a single treatment session of manual therapy. The duration of the treatment in previous studies also varies between 2 minutes and 6 minutes or longer (Kanlayanaphotporn et al., 2009; Snodgrass et al., 2014; Izquierdo Perez et al., 2014).

The data from the current trial identified that there was a statistically significant improvement of range of motion (flexion, right rotation, left rotation, lateral right and left flexion) ($p<0.008$) and current pain levels ($p=0.012$) in the tactile sensory (localization) training group pre and immediate post intervention. The outcome measure of PPT displayed a numerical decrease, but the changes were not statistically significant ($p>0.05$). A possible interpretation for this difference maybe that both outcomes assess different aspects of the pain experience and that PPT is considered as a neurophysiological outcome, whereas neck pain is a self-reported outcome.

In the current study individuals in both intervention groups (manual therapy and localization treatment) experienced significant reductions in neck pain as measured by the Numerical Pain

Rate Scale post treatment. The differences between-group were not large, likewise could not suggest a clinical effect of one intervention over the other; however, the between-group difference score was close to the reported MCID of 1.3 points, but it did not surpass the MDC of 2.1 (Cleland et al., 2008). A plausible reason for this statistical improvement but still not detectable change in NRPS between studies might be because Cleland et al. included a group of patients with neck pain and symptoms of less than 2 months, whereas the current study included patients mainly with chronic symptoms.

With regards to neck range of motion the interaction between treatment (time) and group was shown to be statistically significant only for lateral flexion left ($p<0.024$)and extension ($p<0.05$) where the manual therapy group was superior. The localization group did not yield any significant difference, thus indicating some inferiority against the MT group for the above ROM. This study provides preliminary evidence as it is the first attempt to compare the effectiveness of these interventions in neck pain.

The present study has been unable to indicate any major clinical differences in pain perception and neck mobility between the two interventions. The findings of the study seem to be congruent with the null hypothesis, that there is no significant difference of the interventional effect between manual therapy and localization group. The very small favorable effect of manual therapy group over tactile sensory may be attributed to the hands on approach and intensive patient- therapist interaction.

This is the first study to investigate the effectiveness of localization training vs. manual therapy in people with neck pain, the results can be compared and discussed with similar studies (Barker et al., 2008; Moseley, 2008b; Wand et al., 2011; Ryan et al., 2014; Louw et al., 2015) although the blinding of subjects/therapists has not always been ensured, therefore increasing the risk of bias. The above studies showed great heterogeneity about the type of intervention and treatment duration. Although, they investigated the effects of tactile sensory training on LBP and CRPS, they did not examine its effect on cortical representation. Likewise, in our study, it was suggested that tactile sensory training improved the pain levels and neck range of motion, but it was difficult to draw conclusions concerning the neurophysiological mechanisms underlying any treatment effect.

The exact physiological mechanism for the effectiveness of tactile sensory training (localization) remains unclear. However, there currently exists much speculation surrounding the mechanisms of tactile sensory training, which potentially includes both the cortical reorganization in the primary somatosensory cortex (Flor, 2003) and pain neuroscience education involvement (Louw et al., 2011; Louw et al., 2016). The training includes not only sensory stimulation but also an active perception, a cognitive demanding task, aiming to educate the patient and modulate the pain.

The findings of this study are congruent with the study of Barker et al. (2008), where a novel device for the tactile stimuli was used for 30 minute-sessions for 3 weeks in 32 patients with LBP and patients were asked to localize the stimuli and received feedback on correctness. Pain levels and function demonstrated an improvement post treatment.

The findings of our study are in accordance with a recent case series of three participants (Wand et al., 2011) with CLBP which found clinically important improvements in pain and function following tactile acuity training for 10 weeks.

The case series of Louw et al. (2015), which was the basis for the design of our experimental protocol for the localization group, also reported improvement in ROM (lumbar spine flexion) following tactile localization training in people with chronic low back pain.

The findings of our study contrast with the pilot randomized trial of Ryan et al. (2014),which reported better outcomes in pain and function in the sham group (only stimulation) compared to intervention (tactile acuity training) after 24 minutes sessions for 3 weeks in patients with chronic low back pain. The reason for the contrasting findings may be related to the different methodology, as the tactile acuity training was delivered by an informal care giver at home and the fact that in our study the other intervention was a manual therapy approach and not a sham treatment. It should also be noted that in Ryan et al. study there was a high dropout percentage (38%) and that patients' pain intensity and disability levels were more severe compared to our study.

6.2 Study Limitations

Although this experiment was carefully organized and delivered, generalisability of the results may be impacted by a number of limitations. Although the duration of the study as well as the sample size was feasible for the purposes of a postgraduate master's research project, the results must be interpreted with caution. The relatively small sample size (n= 30) may limit the validity of the results, leading to inaccurate findings (Hicks, 2009). Despite the study was open to subjects aging between 18-65 years old, the mean age of participants was 28.63(±12.49), and most of them were undergraduate students.

Our patient baseline data revealed low initial self reported pain and disability scores that would limit the significant improvement or influence the outcome compared to a more acute or higher pain /disability sample.

A single treatment session, used in this study, as well as the duration of the treatment (3minutes) was not representative for treating patients with neck pain. Although no available data exists for localization training dosage (Kalin et al., 2016), maybe a greater number of sessions would have possibly revealed greater changes in outcomes or differences between the groups. Additionally, we only included an immediate after intervention follow-up, and we do not know if the findings would be the same at long-term follow-up periods.

Another limitation of this study is that we did not include a placebo group, to explore placebo effects related to the expectations of the patients.

Finally, the lack of double blinding may have influenced the assessor /therapist in this study and biased the results. However, 'hands-on' techniques are traditionally impossible to be doubly-blinded.

6.3 Recommendations for the future

It is recommended that future research should consist of high methodological quality randomized controlled trials ensuring double blinding where possible, larger sample size calculated using a power calculation. It is also important to collect data at a long term follow up period to measure the long term effects of the treatment of focus and to optimize the treatment protocols. Furthermore, future researchers should include measures of tactile acuity and cortical

representations (along with pain and function measures) to explain the neurophysiological mechanisms underlying any treatment effect in short and long term in patients with neck pain. Emerging evidence suggests that including tactile sensory training and coupling with movement therapies might be more beneficial for neck pain.

CHAPTER 7

7. CONCLUSION

To the best of the author's knowledge this is the first randomized clinical trial investigating the effects of manual therapy versus tactile sensory training (localization) on pain and neck mobility in patients with neck pain. The results of this study are supportive of the notion that a single session of tactile sensory training (localization) can be as effective as manual therapy in reducing neck pain and improving neck ROM among participants with neck pain. Working on this research project has deepened the level of our knowledge regarding neck pain, cortical changes and treatment methods that should considered for future research. Tactile sensory training (localization) should be considered to be included in the rehabilitation programmes for patients with neck pain.

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APPENDIX A

ETHICAL APPROVAL LETTER

Τ.Ε.Ι. ΔΥΤΙΚΗΣ ΕΛΛΑΔΑΣ
Πρόγραμμα Μεταπτυχιακών Σπουδών
"Επιστήμες Αποκατάστασης"
Αριθμ. Πρωτ: 1214Η
Ημερομηνία: 1/4/2019

ΕΠΙΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΣΧΟΛΗΣ ΕΠΑΓΓΕΛΜΑΤΩΝ ΥΓΕΙΑΣ ΚΑΙ ΠΡΟΝΟΙΑΣ ΤΕΙ ΔΥΤΙΚΗΣ ΕΛΛΑΔΑΣ

Μετά από έλεγχο των εγγράφων **αριθ. πρωτοκ. 7922/26-02-2019**, το πειραματικό πρωτόκολλο της ερευνητικής εργασίας με θέμα: **«Χειροθεραπευτική Φυσικοθεραπεία έναντι απτικής αισθητικής επανεκπαίδευσης (localization) σε ασθενείς με αυχενικό πόνο: μία τυχαιοποιημένη κλινική μελέτη»** που πρόκειται να διεξαχθεί από τη μεταπτυχιακή φοιτήτρια **Θωμαΐδου Ελευθερία** του Π.Μ.Σ. Επιστήμες Αποκατάστασης του ΤΕΙ Δυτικής Ελλάδας **εγκρίνεται.**

Η Επιτροπή Βιοηθικής:

Δρ. Σταυρούλα Γεωργοπούλου,

Καθηγήτρια Τμήματος Λογοθεραπείας

Υπογραφή:

Δρ. Χαράλαμπος Ματζάρογλου,

Επίκουρος Καθηγητής, Τμήματος Φυσικοθεραπείας

Υπογραφή:

Δρ. Μαρία Μπατσολάκη,

Καθηγήτρια Τμήματος Νοσηλευτικής

Υπογραφή:

APPENDIX B

ΠΑΝΕΠΙΣΤΗΜΙΟ ΠΑΤΡΩΝ
UNIVERSITY OF PATRAS

ΣΧΟΛΗ ΕΠΑΓΓΕΛΜΑΤΩΝ ΥΓΕΙΑΣ ΚΑΙ ΠΡΟΝΟΙΑΣ
ΔΙΑΤΜΗΜΑΤΙΚΟ ΠΡΟΓΡΑΜΑ ΜΕΤΑΠΤΥΧΙΑΚΩΝ ΣΠΟΥΔΩΝ
ΤΜΗΜΑΤΩΝ ΛΟΓΟΘΕΡΑΠΕΙΑΣ, ΝΟΣΗΛΕΥΤΙΚΗΣ ΚΑΙ ΦΥΣΙΟΘΕΡΑΠΕΙΑΣ
«Επιστήμες Αποκατάστασης – RehabilitationSciences»

ΦΟΡΜΑ ΣΥΓΚΑΤΑΘΕΣΗΣ ΣΥΜΜΕΤΟΧΗΣ ΣΤΗΝ ΕΡΕΥΝΑ

Τίτλος Έρευνας : «Χειροθεραπευτική Φυσικοθεραπεία έναντι απτικής αισθητικής επανεκπαίδευσης (localization) σε ασθενείς με αυχενικό πόνο: μια τυχαιοποιημένη κλινική μελέτη»

Όνομα και στοιχεία επικοινωνίας κύριου ερευνητή :

Ελευθερία Θωμαΐδου, email elethom@gmail.com

ΣΗΜΕΙΩΣΤΕ ΜΕ Χ αν ΣΥΜΦΩΝΕΙΤΕ ΜΕ ΤΙΣ ΔΗΛΩΣΕΙΣ

1. Επιβεβαιώνω ότι έχω διαβάσει και κατανοήσει το ενημερωτικό έντυπο (Ημ/νια…….) για την παραπάνω μελέτη και μου δόθηκε η ευκαιρία να κάνω ερωτήσεις. ☐
2. Κατανοώ ότι η συμμετοχή μου είναι εθελοντική και μπορώ να αποσυρθώ από την έρευνα ανά πάσα στιγμή. ☐
3. Συμφωνώ να λάβω μέρος σε αυτή την έρευνα. ☐

4. Κατανοώ ότι τα δεδομένα που θα συλλεχθούν σχετικά με έμενα κατά τη διάρκεια της έρευνας θα είναι ανώνυμα πριν κατατεθούν για δημοσίευση ☐

5. Κατανοώ ότι τα δεδομένα που θα συλλεχθούν σχετικά με έμενα κατά τη διάρκεια της έρευνας δε θα είναι ανώνυμα πριν δημοσιευτούν. ☐

6. Συμφωνώ και επιτρέπω τα δεδομένα συλλογής να χρησιμοποιηθούν σε μελλοντικά ερευνητικά προγράμματα. ☐

7. Συμφωνώ να επικοινωνήσετε μαζί μου σε πιθανή μελλοντική σχετική έρευνα ☐

_____	_____	_____
Όνομα Συμμετέχοντα	Ημερομηνία	Υπογραφή
_____	_____	_____
Όνομα Ερευνητή	Ημερομηνία	Υπογραφή

APPENDIX C

ΠΑΝΕΠΙΣΤΗΜΙΟ ΠΑΤΡΩΝ
UNIVERSITY OF PATRAS

REHAB SCIENCES
Physical therapy

ΕΝΗΜΕΡΩΤΙΚΟ ΕΝΤΥΠΟ ΣΥΜΜΕΤΟΧΗΣ ΣΕ ΚΛΙΝΙΚΗ ΜΕΛΕΤΗ

Τίτλος Έρευνας : < Χειροθεραπευτική Φυσικοθεραπεία έναντι απτικής αισθητικής επανεκπαίδευσης (localization)σε ασθενείς με αυχενικό πόνο: μια τυχαιοποιημένη κλινική μελέτη >.

Πρόσκληση

Έχετε προσκληθεί να λάβετε μέρος σε μία ερευνητική μελέτη με θέμα *"*Χειροθεραπευτική Φυσικοθεραπεία έναντι απτικής αισθητικής επανεκπαίδευσης (localization)σε ασθενείς με αυχενικό πόνο: μια τυχαιοποιημένη κλινική μελέτη*"*. Αυτή η μελέτη διεξάγεται από την Ελευθερία Θωμαΐδου στα πλαίσια της διπλωματικής εργασίας για το Πρόγραμμα Μεταπτυχιακών Σπουδών « Επιστήμες Αποκατάστασης» με κατεύθυνση τη Φυσικοθεραπεία στο Πανεπιστήμιο Πατρών (πρώην Τ.Ε.Ι Δυτικής Ελλάδος). Ο Επιστημονικά υπεύθυνος για τη έρευνα αυτή είναι η Δρ. Μπίλλη Ευδοκία, Αναπληρώτρια Καθηγήτρια Τμήματος Φυσικοθεραπείας, Πανεπιστημίου Πατρών (πρώην ΤΕΙ Δυτική Ελλάδας).

Προτού αποφασίσετε αν θα επιθυμούσατε να λάβετε μέρος, είναι σημαντικό για εσάς, να κατανοήσετε το λόγο για τον οποίο πραγματοποιείται αυτή η έρευνα και τι περιλαμβάνει. Παρακαλώ αφιερώστε λίγο χρόνο να διαβάσετε προσεκτικά αυτή την ενημέρωση και να το συζητήσετε με όποιον επιθυμείτε. Μη διστάσετε να ρωτήσετε την ερευνητική ομάδα για ο,τιδήποτε δεν είναι σαφές ή θα θέλατε περαιτέρω διευκρινίσεις.

Σκοπός

Ο σκοπός της έρευνας είναι να διερευνηθεί και να συγκριθεί η αποτελεσματικότητα δύο σύγχρονων φυσικοθεραπευτικών μεθόδων αποκατάστασης, και συγκεκριμένα, της χειροθεραπευτικής φυσικοθεραπείας και της απτικής αισθητικής επανεκπαίδευσης (localization) στη βελτίωση της έντασης του πόνου και του εύρους κίνησης της αυχενικής μοίρας της σπονδυλικής στήλης σε ασθενείς με αυχενικό πόνο.

Πρέπει να λάβω μέρος;

Είστε ελεύθερος να αποφασίσετε αν θα συμμετέχετε στην έρευνα ή όχι. Αν απαντήσετε θετικά, θα σας ζητηθεί να συναινέσετε γραπτώς σε ειδική φόρμα που θα σας δοθεί. Είστε ελεύθερος να αποσυρθείτε από τη συλλογή δεδομένων, ανά πάσα στιγμή. Αν θελήσετε να αποσυρθείτε από τη μελέτη, θα κρατήσουμε τις πληροφορίες που έχουμε συλλέξει έως τότε. Δεν υποχρεούστε να δικαιολογήσετε το λόγο της διακοπής και σε καμία περίπτωση αυτό δε θα επηρεάσει τα δικαιώματά σας/ μελλοντική θεραπεία / παροχή υπηρεσίας θα λάβετε.

Τι θα συμβεί αν λάβω μέρος;
Αφού σας δοθεί η φόρμα συγκατάθεσης και θεωρηθείτε κατάλληλος/η να συμμετέχετε βάσει των κριτηρίων ένταξης, θα τοποθετηθείτε τυχαία σε μία από τις δύο πειραματικές ομάδες. Στη συνέχεια θα γίνουν κάποιες μετρήσεις με χρήση ειδικών οργάνων, θα ακολουθήσει η παρέμβαση και κατόπιν θα επαναληφθούν οι μετρήσεις. Η διαδικασία θα λάβει χώρα στο Εργαστήριο της Κλινικής Αποκατάστασης του Πανεπιστημίου Πατρών (πρώην ΤΕΙ Δυτικής Ελλάδος), με έδρα το Αίγιο, οδός Ψαρρών 6, Τ.Κ 25100. Η διεξαγωγή των μετρήσεων θα πραγματοποιηθεί σε μία μόνο επίσκεψη , ενώ η πειραματική συνεδρία θα έχει εντελώς ανώδυνη και δεν θα έχει διάρκεια πάνω από 5 λεπτά.

Ποια είναι τα κριτήρια συμμετοχής στην έρευνα;
Για να ενταχθείτε στη μελέτη θα πρέπει να έχετε πόνο στον αυχένα τουλάχιστον μία εβδομάδα , να είστε ηλικίας από 18 έως 65 ετών , άνδρες ή γυναίκες, να μιλάτε και να διαβάζετε την ελληνική γλώσσα και να είστε σε θέση να συναινέσετε τη συμμετοχή σας. Άτομα που έχουν υποβληθεί σε χειρουργική επέμβαση σπονδυλικής στήλης στην περιοχή ενδιαφέροντος, έχουν δερματικές παθήσεις, νευρολογικά προβλήματα που επηρεάζουν την αισθητικότητα και έχουν αντένδειξη στη χειροθεραπεία δεν θα μπορούν να συμμετάσχουν στη μελέτη.

Ποια θα είναι τα οφέλη αν λάβω μέρος;
Το όφελος μετά από τη συμμετοχή στην παρούσα έρευνα, θα είναι ενδεχομένως να μειωθούν τα επίπεδα του πόνου σας και να βελτιωθεί το εύρος κίνησης της αυχενικής μοίρας της σπονδυλικής στήλης. Αλλά ακόμα και αν δε σημειωθεί κάποιο άμεσο όφελος, θα έχετε συνεισφέρει σημαντικά στην περαιτέρω γνώση και κατανόηση της θεραπείας του αυχενικού πόνου.

Ποιοι είναι οι κίνδυνοι αν λάβω μέρος;
Δεν υπάρχει κανένας απολύτως κίνδυνος από την εφαρμογή των θεραπευτικών τεχνικών , κατόπιν λήψης ιστορικού και καταλληλότητας ένταξής σας στην παρούσα μελέτη.

Ποιος θα έχει πρόσβαση σε πληροφορίες που με αφορούν;
Τα δεδομένα που θα συλλεχθούν, θα είναι προσβάσιμα μόνο από τα μέλη της ερευνητικής ομάδας που αναφέρθηκαν, συμπεριλαμβανομένου και του Επιστημονικά Υπεύθυνου της έρευνας. Κατά τη διάρκεια της έρευνας, τα Προσωπικά Δεδομένα θα αποθηκευτούν σε υπολογιστή του Εργαστηρίου του Τμήματος, που θα προστατεύεται από κωδικό εισόδου, ενώ μετά την ολοκλήρωση της έρευνας θα διατηρηθούν εμπιστευτικά για 6 έτη από την ερευνητική ομάδα, όπως υπαγορεύει ο Γενικός Κανονισμός Προστασίας Προσωπικών Δεδομένων (2018). Με τη συγκατάθεσή σας, τα στοιχεία σας μπορεί να χρησιμοποιηθούν σε μελλοντικές μελέτες, αν το επιθυμείτε , κατόπιν νέας επικοινωνίας.

Πώς θα χρησιμοποιηθούν οι πληροφορίες που με αφορούν;
Τα δεδομένα που θα συλλεχθούν από τους συμμετέχοντες θα διαφυλαχθούν εμπιστευτικά, ανώνυμα και θα συμπεριληφθούν σε αναφορά. Οποιαδήποτε πληροφορία αφορά το όνομά σας, ημερομηνία γέννησης θεωρείται προσωπικό δεδομένο. Τα προσωπικό δεδομένα δεν περιλαμβάνουν στοιχεία που δεν αποκαλύπτουν την ταυτότητα του ατόμου και έχουν συλλεχθεί

ανώνυμα. Για να διαφυλαχθούν τα δικαιώματά σας, θα γίνει προσπάθεια να καταγραφούν ελάχιστα προσωπικά στοιχεία, αν και αυτό δεν είναι πάντα δυνατόν ,λόγω του περιορισμένου αριθμού δείγματος, χώρου διεξαγωγής της παρέμβασης και πιθανής έκθεσης κάποιου εγγράφου.

Πώς θα χρησιμοποιηθούν τα αποτελέσματα της παρούσας έρευνας;
Η παρούσα μελέτη αποσκοπεί στην εκπόνηση διπλωματικής εργασίας στα πλαίσια μεταπτυχιακού προγράμματος σπουδών και φιλοδοξεί να δημοσιευθεί σε Επιστημονικό Περιοδικό ή να παρουσιαστεί σε Επιστημονικό Συνέδριο.

Ποιος χρηματοδοτεί και οργανώνει την έρευνα;
Η παρούσα έρευνα διοργανώνεται από τον μεταπτυχιακό φοιτητή του ΠΜΣ «Επιστήμες Αποκατάστασης» του πρώην ΤΕΙ Δυτικής Ελλάδας. Η έρευνα έχει ελάχιστες οικονομικές απαιτήσεις, στα πλαίσια του εξοπλισμού, που θα καλυφθούν από το Τμήμα.

Αν υπάρχουν απορίες/παράπονα;
Αν έχετε κάποιο προβληματισμό για την μελέτη αυτή, θα μπορούσατε να επικοινωνήσετε στα μέλη της ερευνητικής ομάδας, που θα χαρούν να σας απαντήσουν. Τα στοιχεία επικοινωνίας σημειώνονται παρακάτω:

Ελευθερία Θωμαΐδου (μεταπτυχιακή φοιτήτρια) email: elethom@gmail.com

Δρ. Ευδοκία Μπίλλη (επιβλέπουσα καθηγήτρια) email: evdokiabillis@gmail.com>

Αν θα θέλατε να καταθέσετε κάποιο παράπονο για τον τρόπο προσέγγισης ή μεταχείρισης κατά τη διάρκεια της μελέτης αυτής, παρακαλώ επικοινωνήσετε με τη Γραμματεία του Μεταπτυχιακού Προγράμματος Σπουδών του Πανεπιστήμιου Πατρών (πρώην Τ.Ε.Ι Δυτικής Ελλάδος) «Επιστήμες Αποκατάστασης» .

email: rehabsecretary@teiwest.gr

APPENDIX D

ΠΡΟΣΚΛΗΣΗ ΣΥΜΜΕΤΟΧΗΣ ΣΕ ΕΡΕΥΝΑ

ΈΧΕΙΣ ΠΟΝΟ ΣΤΟΝ ΑΥΧΕΝΑ ΓΙΑ ΤΟΥΛΑΧΙΣΤΟΝ 1 ΕΒΔΟΜΑΔΑ ;

ΕΠΙΚΟΙΝΩΝΗΣΕ ΜΑΖΙ ΜΑΣ

Επόμενη Προγραμματισμένη Συνεδρία Παρασκευή 8 Νοεμβρίου & Δευτέρα 11 Νοεμβρίου 2019

ΣΚΟΠΟΣ

ΣΥΓΚΡΙΣΗ ΑΠΟΤΕΛΕΣΜΑΤΙΚΟΤΗΤΑΣ ΤΗΣ ΧΕΙΡΟΘΕΡΑΠΕΥΤΙΚΗΣ ΦΥΣΙΚΟΘΕΡΑΠΕΙΑΣ ΚΑΙ ΤΗΣ ΑΠΤΙΚΗΣ ΑΙΣΘΗΤΙΚΗΣ ΕΠΑΝΕΚΠΑΙΔΕΥΣΗΣ ΣΤΗ ΒΕΛΤΙΩΣΗ ΤΗΣ ΕΝΤΑΣΗΣ ΤΟΥ ΠΟΝΟΥ ΚΑΙ ΤΟΥ ΕΥΡΟΥΣ ΚΙΝΗΣΗΣ ΤΗΣ ΑΥΧΕΝΙΚΗΣ ΜΟΙΡΑΣ ΤΗΣ ΣΣ

Η ΣΥΜΜΕΤΟΧΗ ΣΤΗΝ ΕΡΕΥΝΑ ΘΑ ΔΙΑΡΚΕΣΕΙ ΠΕΡΙΠΟΥ 15 ΛΕΠΤΑ

ΜΙΑ ΜΟΝΟ ΕΠΙΣΚΕΨΗ ΣΤΟ ΤΜΗΜΑ ΦΥΣΙΚΟΘΕΡΑΠΕΙΑΣ , ΨΑΡΡΩΝ 6 ΑΙΓΙΟ

Η συγκεκριμένη έρευνα δεν χρηματοδοτείται για αυτό και η συμμετοχή σας είναι καθαρά εθελοντική.

ΕΠΙΚΟΙΝΩΝΙΑ

ΕΛΕΥΘΕΡΙΑ ΘΩΜΑΙΔΟΥ (μεταπτυχιακή φοιτήτρια) email: elethom@gmail.com , τηλ: 697 6246965

Αγαπητέ φοιτητή ,

Είμαι μεταπτυχιακή φοιτήτρια του Πρόγραμμα Μεταπτυχιακών Σπουδών « Επιστήμες Αποκατάστασης» με κατεύθυνση τη Φυσικοθεραπεία στο Πανεπιστήμιο Πατρών (πρώην Τ.Ε.Ι Δυτικής Ελλάδος). Στα πλαίσια της διπλωματικής μου εργασίας, θα διεξαχθεί μία τυχαιοποιημένη κλινική μελέτη με θέμα *"Χειροθεραπευτική Φυσικοθεραπεία έναντι απτικής αισθητικής επανεκπαίδευσης (localization) σε ασθενείς με αυχενικό πόνο: μια τυχαιοποιημένη κλινική μελέτη.* Ο Επιστημονικά υπεύθυνος για τη έρευνα αυτή είναι η Δρ. Μπίλλη Ευδοκία, Αναπληρώτρια Καθηγήτρια Τμήματος Φυσικοθεραπείας, Πανεπιστημίου Πατρών (πρώην ΤΕΙ Δυτική Ελλάδας).

Ο σκοπός της έρευνας είναι να διερευνηθεί και να συγκριθεί η αποτελεσματικότητα δύο σύγχρονων φυσικοθεραπευτικών μεθόδων αποκατάστασης, και συγκεκριμένα, της χειροθεραπευτικής φυσικοθεραπείας και της απτικής αισθητικής επανεκπαίδευσης (localization) στη βελτίωση της έντασης του πόνου και του εύρους κίνησης της αυχενικής μοίρας της σπονδυλικής στήλης σε ασθενείς με αυχενικό πόνο.

Οι συμμετέχοντες που αναζητώ για την έρευνα μου θα πρέπει:

- **Να είναι ηλικίας από 18 έως 65 ετών , άνδρες ή γυναίκες**
- **Να μιλούν και να διαβάζουν την ελληνική γλώσσα**
- **Να είναι σε θέση να συναινέσουν τη συμμετοχή τους**
- **Να έχουν πόνο στον αυχένα για τουλάχιστον μία εβδομάδα**

Η συμμετοχή στην έρευνα θα διαρκέσει περίπου 15 λεπτά και θα ολοκληρωθεί σε μία μόνο επίσκεψη στο τμήμα Φυσικοθεραπείας, Ψαρρών 6, στο Αίγιο.

Επόμενη Προγραμματισμένη Συνεδρία Παρασκευή 8 Νοεμβρίου & Δευτέρα 11 Νοεμβρίου 2019

Η συγκεκριμένη έρευνα δεν χρηματοδοτείται για αυτό και η συμμετοχή σας είναι καθαρά εθελοντική.
Επίσης η συμμετοχή σας στην έρευνα θα είναι εμπιστευτική.

Αν επιθυμείτε να λάβετε μέρος στη μελέτη αυτή, θα μπορούσατε να επικοινωνήσετε με τα μέλη της ερευνητικής ομάδας, που θα χαρούν να σας απαντήσουν.

Τα στοιχεία επικοινωνίας σημειώνονται παρακάτω:

Ελευθερία Θωμαϊδου (μεταπτυχιακή φοιτήτρια) **email: elethom@gmail.com**

Δρ. Ευδοκία Μπίλλη (επιβλέπουσα καθηγήτρια) **email: evdokiabillis@gmail.com**

APPENDIX E

Αγαπητέ φοιτητή ,

Είμαι μεταπτυχιακή φοιτήτρια του Πρόγραμμα Μεταπτυχιακών Σπουδών « Επιστήμες Αποκατάστασης» με κατεύθυνση τη Φυσικοθεραπεία στο Πανεπιστήμιο Πατρών (πρώην Τ.Ε.Ι Δυτικής Ελλάδος). Στα πλαίσια της διπλωματικής μου εργασίας, θα διεξαχθεί μία τυχαιοποιημένη κλινική μελέτη με θέμα ***"Χειροθεραπευτική Φυσικοθεραπεία έναντι απτικής αισθητικής επανεκπαίδευσης (localization) σε ασθενείς με αυχενικό πόνο: μια τυχαιοποιημένη κλινική μελέτη.*** Ο Επιστημονικά υπεύθυνος για τη έρευνα αυτή είναι η Δρ. Μπίλλη Ευδοκία, Αναπληρώτρια Καθηγήτρια Τμήματος Φυσικοθεραπείας, Πανεπιστημίου Πατρών (πρώην ΤΕΙ Δυτική Ελλάδας).

Ο σκοπός της έρευνας είναι να διερευνηθεί και να συγκριθεί η αποτελεσματικότητα δύο σύγχρονων φυσικοθεραπευτικών μεθόδων αποκατάστασης, και συγκεκριμένα, της χειροθεραπευτικής φυσικοθεραπείας και της απτικής αισθητικής επανεκπαίδευσης (localization) στη βελτίωση της έντασης του πόνου και του εύρους κίνησης της αυχενικής μοίρας της σπονδυλικής στήλης σε ασθενείς με αυχενικό πόνο.

Οι συμμετέχοντες που αναζητώ για την έρευνα μου θα πρέπει:

- Να είναι ηλικίας από 18 έως 65 ετών , άνδρες ή γυναίκες
- Να μιλούν και να διαβάζουν την ελληνική γλώσσα
- Να είναι σε θέση να συναινέσουν τη συμμετοχή τους
- Να έχουν πόνο στον αυχένα για τουλάχιστον μία εβδομάδα

Η συμμετοχή στην έρευνα θα διαρκέσει περίπου 15 λεπτά και θα ολοκληρωθεί σε μία μόνο επίσκεψη στο τμήμα Φυσικοθεραπείας, Ψαρρών 6, στο Αίγιο.

Επόμενη Προγραμματισμένη Συνεδρία Παρασκευή 8 Νοεμβρίου & Δευτέρα 11 Νοεμβρίου 2019

Η συγκεκριμένη έρευνα δεν χρηματοδοτείται για αυτό και η συμμετοχή σας είναι καθαρά εθελοντική. Επίσης η συμμετοχή σας στην έρευνα θα είναι εμπιστευτική.

Αν επιθυμείτε να λάβετε μέρος στη μελέτη αυτή, θα μπορούσατε να επικοινωνήσετε με τα μέλη της ερευνητικής ομάδας, που θα χαρούν να σας απαντήσουν.

Τα στοιχεία επικοινωνίας σημειώνονται παρακάτω:

Ελευθερία Θωμαϊδου (μεταπτυχιακή φοιτήτρια) email: elethom@gmail.com

Δρ. Ευδοκία Μπίλλη (επιβλέπουσα καθηγήτρια) email: evdokiabillis@gmail.com

APPENDIX F

ΠΑΝΕΠΙΣΤΗΜΙΟ ΠΑΤΡΩΝ
UNIVERSITY OF PATRAS

Nursing
Speech & language therapy
REHAB SCIENCES
Physical therapy

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ ΥΓΕΙΑΣ ΓΙΑ ΣΥΜΜΕΤΟΧΗ ΣΕ ΚΛΙΝΙΚΗ ΜΕΛΕΤΗ

Τίτλος Έρευνας : «Χειροθεραπευτική Φυσικοθεραπεία έναντι απτικής αισθητικής επανεκπαίδευσης (localization) σε ασθενείς με αυχενικό πόνο: μια τυχαιοποιημένη κλινική μελέτη»

Παρακαλώ διαβάστε προσεκτικά τις παρακάτω ερωτήσεις.
Αν δεν είστε βέβαιος ή χρειάζεστε διευκρινίσεις παρακαλώ συζητήστε με την ερευνητική ομάδα.

1. Είστε άνω των 18 και κάτω των 65 ετών ;
2. Έχετε υποβληθεί σε χειρουργείο στην Αυχενική Θωρακική Μοίρα της Σπονδυλικής Στήλης;
3. Έχετε τραυματιστεί στη Αυχενική Θωρακική Μοίρα της Σπονδυλικής Στήλης τους τελευταίους 3 μήνες;
4. Έχετε κάνει συστηματική χρήση κορτικοστεροειδών φαρμάκων;
5. Πάσχετε από αλλεργίες δέρματος/ ευαισθησίες/ δερματικές παθήσεις (δερματίτιδα, έκζεμα);
6. Πάσχετε/ έχετε διαγνωσθεί με Σακχαρώδη Διαβήτη;
7. Πάσχετε από κάποια νευρολογική πάθηση όπως περιφερικής νευροπάθεια, πολλαπλή σκλήρυνση;
8. Σας έχει αναφέρει ο ιατρός ότι πάσχετε από σύνδρομο Σπονδυλοβασικής Ανεπάρκειας;
9. Υποφέρετε από ιλίγγους, νυσταγμό, περιστατικά απώλεια συνείδησης, απώλεια ισορροπίας λόγω ζάλης;
10. Έχετε κάποια ανοιχτή πληγή στην περιοχή του αυχένα/ πλάτης ;
11. Πάσχετε από ριζίτιδα στην αυχενοθωρακική μοίρα της Σπονδυλικής Στήλης;
12. Έχετε διαγνωσθεί με αστάθεια στην αυχενοθωρακική μοίρα της Σπονδυλικής Στήλης;
13. Έχετε διαγνωσθεί με κάποιο είδος κακοήθειας;
14. Πάσχετε από πόνο στην περιοχή του λαιμού κεφαλής που είναι συνεχόμενος (δεν αλλάζει);

Δηλώνω υπεύθυνα ότι διάβασα τις παραπάνω ερωτήσεις και από όσο γνωρίζω οι απαντήσεις μου είναι **ΟΧΙ** σε όλα τα παραπάνω . Εάν απαντήσατε **ΝΑΙ** σε μία ή περισσότερες ερωτήσεις, λυπούμαστε αλλά δε θα συμμετέχετε στην έρευνα.

Συζήτησα με τον ερευνητή άλλα πιθανά προβλήματα υγείας που με αφορούν και έλαβα γνώση.

_____	_____	_____
Όνομα Συμμετέχοντα	Ημερομηνία	Υπογραφή

_____	_____	_____
Όνομα Ερευνητή	Ημερομηνία	Υπογραφή

ΣΤΟΙΧΕΙΑ ΕΠΙΚΟΙΝΩΝΙΑΣ ΕΡΕΥΝΗΤΙΚΗΣ ΟΜΑΔΑΣ

Ελευθερία Θωμαϊδου email: elethom@gmail.com
Δρ. Ευδοκία Μπίλλη email: evdokiabillis@gmail.com

APPENDIX G

ΠΑΝΕΠΙΣΤΗΜΙΟ ΠΑΤΡΩΝ
UNIVERSITY OF PATRAS

REHAB SCIENCES

ΦΟΡΜΑ ΑΞΙΟΛΟΓΗΣΗΣ ΑΣΘΕΝΟΥΣ

 # ΑΡΧΕΙΟ _____ ΗΜΕΡΟΜΗΝΙΑ _____

ΟΜΑΔΑ 1 2

ΟΝΟΜΑΤΕΠΩΝΥΜΟ ΑΣΘΕΝΟΥΣ _____

ΔΙΕΥΘΥΝΣΗ _____

ΣΤΟΙΧΕΙΑ ΕΠΙΚΟΙΝΩΝΙΑΣ ΤΗΛ_____EMAIL_____

1. ΦΥΛΟ _____ ΘΗΛΥ _____ ΑΡΡΕΝ

2. ΗΛΙΚΙΑ_____

3.ΒΑΡΟΣ(KG)_____

4.ΥΨΟΣ (Μ)_____

5.ΔΕΙΚΤΗΣ ΜΑΖΑ ΣΩΜΑΤΟΣ_____

6.ΑΠΑΣΧΟΛΗΣΗ_____

7. ΩΡΕΣ ΕΡΓΑΣΙΑΣ ΗΜΕΡΙΣΙΩΣ_____

8.ΜΕΣΟΣ ΟΡΟΣ ΔΙΑΒΑΣΜΑΤΟΣ/ ΧΡΗΣΗΣ Η/Υ ΗΜΕΡΗΣΙΩΣ _____

9.ΜΟΡΦΩΣΗ __ ΔΗΜΟΤΙΚΟ ___ ΓΥΜΝΑΣΙΟ ____ ΛΥΚΕΙΟ ____ ΤΡΙΤΟΒΑΘΜΙΑ ΕΚΠ

10. ΧΟΜΠΥ/ΔΡΑΣΤΗΡΙΟΤΗΤΑ/ΨΥΧΑΓΩΓΙΑ _____

11. ΟΙΚΟΓΕΝΕΙΑΚΗ ΚΑΤΑΣΤΑΣΗ ____ ΑΓΑΜΟΣ/Η ____ ΕΓΓΑΜΟΣ/Η

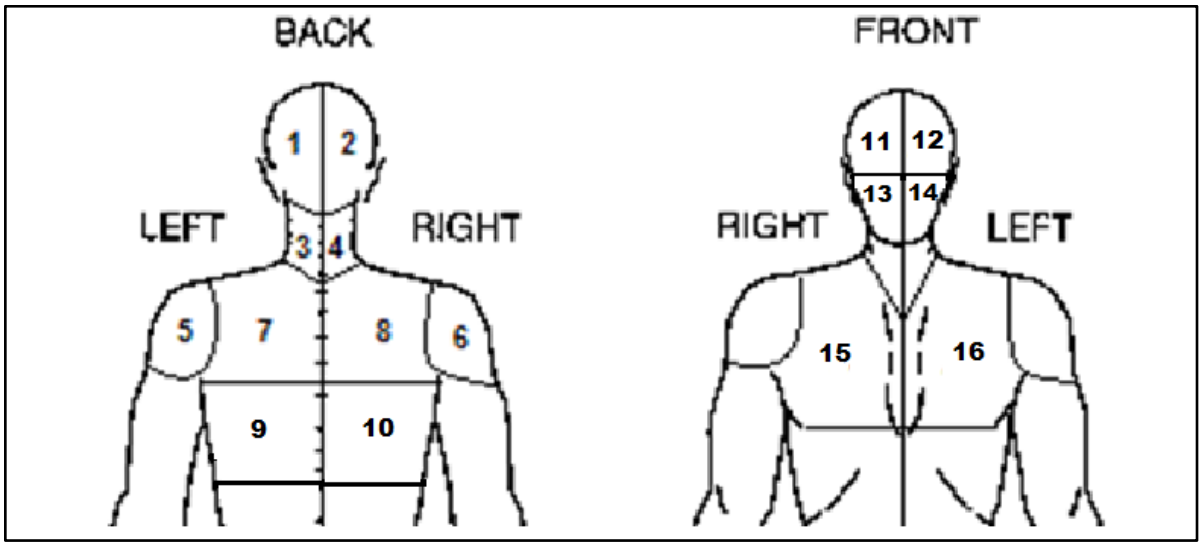
___ ΔΙΑΖΕΥΓΜΈΝΟΣ/Η ___ ΧΗΡΟΣ/Α

12. ΕΧΕΤΕ ΑΚΟΛΟΥΘΗΣΕΙ ΚΑΠΟΙΑ ΜΟΡΦΗ ΘΕΡΑΠΕΙΑΣ ΓΙΑ ΤΟ ΠΡΟΒΛΗΜΑ ΣΑΣ;

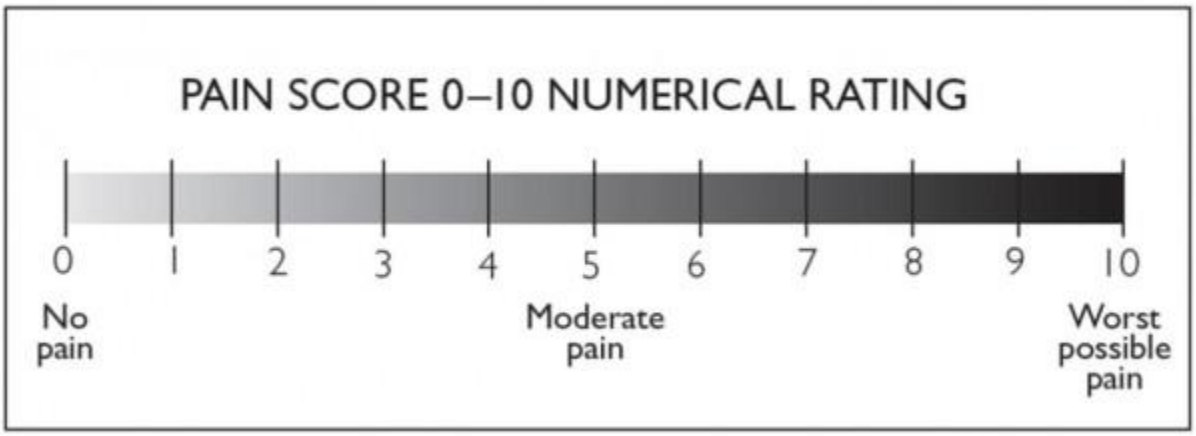
____ ΝΑΙ _____ ΟΧΙ ΑΝ ΝΑΙ ΠΕΡΙΓΡΑΨΤΕ ΤΗΝ ΘΕΡΑΠΕΙΑ _____

1.ΠΑΡΟΝΤΑ ΣΥΜΠΤΩΜΑΤΑ

1.1 ΠΕΡΙΟΧΗ ΠΟΝΟΥ. Σημειώστε τις περιοχές πόνου, τοπικού ή/και ανακλώμενου (περιοχές με μούδιασμα να σημειωθούν με τελείες)



1.2 ΕΝΤΑΣΗ ΠΟΝΟΥ



	ΠΡΙΝ ΤΗΝ ΠΑΡΕΜΒΑΣΗ	ΜΕΤΑ ΤΗΝ ΠΑΡΕΜΒΑΣΗ
Μέση κατάσταση πόνου τώρα		
Στα καλύτερα μου		
Στα χειρότερά μου		

1.3 ΑΛΛΑ ΣΥΜΠΤΩΜΑΤΑ

___ ΖΑΛΗ __ ΙΛΙΓΓΟΣ __ ΥΠΑΙΣΘΗΣΙΕΣ __ ΜΟΥΔΙΑΣΜΑ ___ΜΥΡΜΗΓΚΙΑΣΜΑ ____ ΑΔΥΝΑΜΙΑ
ΑΝ ΝΑΙ, ΠΟΥ ΕΝΤΟΠΙΖΟΝΤΑΙ_____

1.4 ΠΕΡΙΓΡΑΦΗ ΠΟΝΟΥ (περιγράψτε την ποιότητα του πόνου σας (κυκλώστε)

- Μουντός/ Έντονος/ Επιφανειακός/ Εν τω βάθει/οξύς/ Διάχυτος/ Εντοπισμένος/ Αλλο_____
- Συνεχής /Διακοπτόμενος

1.5 24ΩΡΗ ΣΥΜΠΕΡΙΦΟΡΑ ΠΟΝΟΥ. Πότε αισθάνεστε το σοβαρότερο πόνο; (κυκλώστε)

ΜΕ ΞΥΠΝΑΕΙ ΤΗ ΝΥΧΤΑ/ ΔΥΣΚΟΛΙΑ ΝΑ ΚΟΙΜΗΘΩ/ΧΕΙΡΟΤΕΡΟΣ ΤΙΣ ΠΡΩΙΝΕΣ ΩΡΕΣ/ ΧΕΙΡΟΤΕΡΟΣ ΤΙΣ ΒΡΑΔΙΝΕΣ ΩΡΕΣ/
ΑΛΛΟ_____

1.6 ΣΥΧΝΟΤΗΤΑ ΠΟΝΟΥ

ΣΠΑΝΙΑ/ ΚΑΠΟΙΕΣ ΜΕΡΕΣ/ ΤΙΣ ΠΕΡΙΣΣΟΤΕΡΕΣ ΜΕΡΕΣ/ ΚΑΘΕ ΜΕΡΑ

1.7 ΔΙΑΡΚΕΙΑ . Πόση ώρα διαρκούν τα συμπτώματα;

(πχ μερικά λεπτά, μερικές ώρες)

_____

1.8 ΧΡΟΝΙΟΤΗΤΑ ΠΟΝΟΥ. Πριν πόσο καιρό ξεκίνησαν τα συμπτώματα;

1 εβδομάδα - 1 μήνα/ 1 μήνα - 3 μήνες / 6 μήνες / 1 χρόνο / Άλλο _____

1.9 ΔΡΑΣΤΗΡΙΟΤΗΤΕΣ ΠΟΥ ΚΥΡΙΩΣ ΕΝΟΧΛΕΙ Ή ΕΙΝΑΙ ΑΙΣΘΗΤΗ Η ΑΥΞΗΣΗ ΤΟΥ ΠΟΝΟΥ.

Σε όρθια θέση (στατική)/ Σε όρθια θέση με κίνηση (δυναμική)/ Καθιστή θέση χαλαρή (π.χ. Διάβασμα, Εργασία στον υπολογιστή)/ Κάποια συγκεκριμένη κίνηση (π.χ. Στροφή αριστερά) _____

2. ΙΑΤΡΙΚΟ ΙΣΤΟΡΙΚΟ

2.1 ΣΗΜΕΙΟΛΟΓΙΑ ΣΟΒΑΡΗΣ ΠΑΘΟΛΟΓΙΑΣ (RED FLAGS)

□ Δυσαρθρία □ Διπλωπία □ Λιποθυμίες □ Δυσφαγία □ Αταξία □ Ναυτία □ Νυσταγμός

2. 2 ΠΡΟΗΓΟΥΜΕΝΟΣ ΤΡΑΥΜΑΤΙΣΜΟΣ ΑΥΧΕΝΑ

□ ΝΑΙ □ ΟΧΙ Περιγραφή (π.χ. κάκωση δίκην μαστιγίου): _____

2. 3 ΠΡΟΗΓΟΥΜΕΝΟ ΧΕΙΡΟΥΡΓΕΙΟ

□ ΝΑΙ □ ΟΧΙ Περιγραφή: _____

2.4 ΣΥΝΟΣΗΡΟΤΗΤΑ

Ιστορικό εγκεφαλικού επεισοδίου: □ ΝΑΙ □ ΟΧΙ

- Νευρολογικές ασθένειες (π.χ. Σκλήρυνση κατά πλάκας): □ ΝΑΙ □ ΟΧΙ Περιγραφή:

_____

- Αρτηριακή Πίεση :□ Υπέρταση (Ρυθμιζόμενη: □ ΝΑΙ □ ΟΧΙ) □ Υπόταση (Ρυθμιζόμενη: □ ΝΑΙ □ ΟΧΙ) □ Φυσιολογική

2.5 ΦΑΡΜΑΚΕΥΤΙΚΗ ΑΓΩΓΗ

Αντιφλεγμονώδη: □ ΝΑΙ □ ΟΧΙ
Αναλγητικά: □ ΝΑΙ □ ΟΧΙ
Κορτικοστεροειδή (Κορτιζόνη): □ ΝΑΙ □ ΟΧΙ

APPENDIX H

ΠΑΝΕΠΙΣΤΗΜΙΟ ΠΑΤΡΩΝ
UNIVERSITY OF PATRAS

REHAB SCIENCES

ΦΟΡΜΑ ΑΞΙΟΛΟΓΗΣΗΣ ΑΣΘΕΝΟΥΣ

ΚΩΔΙΚΟΣ ΑΣΘΕΝΟΥΣ _____ΟΝΟΜΑΤΕΠΩΝΥΜΟ_____

ΑΞΙΟΛΟΓΗΣΗ ΕΥΡΟΥΣ ΚΙΝΗΣΗΣ ΑΥΧΕΝΑ

	ΠΡΙΝ ΤΗΝ ΠΑΡΕΜΒΑΣΗ			ΜΕΤΑ ΤΗΝ ΠΑΡΕΜΒΑΣΗ		
ΔΕ ΣΤΡΟΦΗ						
ΑΡ ΣΤΡΟΦΗ						
ΔΕ ΠΛΑΓΙΑ ΚΑΜΨΗ						
ΑΡ ΠΛΑΓΙΑ ΚΑΜΨΗ						
ΚΑΜΨΗ						
ΕΚΤΑΣΗ						

ΑΞΙΟΛΟΓΗΣΗ ΠΟΝΟΥ

ΣΗΜΕΙΟ	ΠΡΙΝ ΤΗΝ ΠΑΡΕΜΒΑΣΗ	ΜΕΤΑ ΤΗΝ ΠΑΡΕΜΒΑΣΗ
ΚΕΝΤΡΙΚΟ (ΝΟΥΜΕΡΟ 5)		
ΔΕ (ΝΟΥΜΕΡΟ 6)		
ΑΡ (ΝΟΥΜΕΡΟ 4)		

APPENDIX I

ΚΛΙΜΑΚΑ HAD

Έχω άγχος ή νιώθω σαστισμένος:

- Τις περισσότερες φορές …….. ☐
- Αρκετές φορές …… ☐
- Περιστασιακά ……. ☐
- Καθόλου ……. ☐

Αισθάνομαι με "πεσμένη" διάθεση:

- Σχεδόν διαρκώς ……. ☐
- Πολύ συχνά ……... ☐
- Κάποιες φορές ……... ☐
- Καθόλου …… ☐

Εξακολουθώ να απολαμβάνω πράγματα που συνήθως με ευχαριστούσαν:

- Σίγουρα το ίδιο……. ☐
- Όχι τόσο πολύ…….. ☐
- Μόνο κάποιες φορές…… ☐
- Σχεδόν καθόλου……... ☐

Νιώθω ένα αίσθημα σφιξίματος στο στομάχι:

- Καθόλου…… ☐
- Περιστασιακά…… ☐
- Αρκετά συχνά…… ☐
- Πολύ συχνά…….. ☐

Αισθάνομαι ένα άσχημο προαίσθημα σαν κάτι το «κακό» πρόκειται να συμβεί:

- Πολύ συγκεκριμένα και έντονα……. ☐
- Ναι αλλά όχι τόσο έντονα……. ☐
- Ελάχιστα αλλά δεν με απασχολεί……. ☐
- Καθόλου…… ☐

Έχασα το ενδιαφέρον για την εμφάνιση μου:

- Σίγουρα…….. ☐
- Δεν φροντίζω τον εαυτό μου όπως θα έπρεπε.. ☐
- Πιθανόν δεν τον φροντίζω αρκετά……. ☐
- Τον φροντίζω όπως πάντοτε…….. ☐

Μπορώ να γελάω και εξακολουθώ να διακρίνω την αστεία πλευρά των γεγονότων

- Τόσο όσο μπορούσα…… ☐
- Όχι και τόσο πολύ τώρα…….. ☐
- Σίγουρα όχι τόσο πολύ τώρα…….. ☐
- Καθόλου……. ☐

Νιώθω υπερκινητικός σαν να έπρεπε διαρκώς να κάνω κάτι:

- Πραγματικά πολύ…….. ☐
- Αρκετά…….. ☐
- Όχι πολύ…… ☐
- Καθόλου…… ☐

Ανησυχητικές σκέψεις περνούν από το μυαλό μου:

- Το περισσότερο καιρό…….. ☐
- Αρκετό καιρό…… ☐
- Από καιρό σε καιρό αλλά όχι πολύ συχνά ☐
- Μόνο περιστασιακά……. ☐

Ανυπομονώ να απολαύσω κάποια πράγματα:

- Όπως έκανα πάντα…… ☐
- Μάλλον λιγότερο από ότι συνήθως…. ☐
- Σίγουρα λιγότερο από ότι συνήθως…. ☐
- Σχεδόν καθόλου……... ☐

Αισθάνομαι χαρούμενος –η

- Καθόλου…… ☐
- Όχι συχνά…….. ☐
- Κάποιες φορές…….. ☐

Αισθάνομαι ξαφνικά αισθήματα πανικού:

- Πραγματικά πολύ συχνά…….. ☐
- Αρκετά συχνά ……. ☐
- Όχι πολύ συχνά…… ☐

Το περισσότερο καιρό……. ☐

Καθόλου…….. ☐

Μπορώ να κάθομαι ήσυχος και να χαλαρώνω

Πάντα…… ☐
Συνήθως…… ☐
Όχι συχνά……. ☐
Καθόλου…… ☐

Μπορώ να απολαύσω ένα καλό βιβλίο, ένα ραδιοφωνικό ή τηλεοπτικό πρόγραμμα:

Συχνά.....…… ☐
Μερικές φορές ……. ☐
Όχι συχνά……. ☐
Πολύ σπάνια…… ☐

Δείκτης Ανικανότητας του Αυχένα

*Όνομα ασθενούς:*_____ *#Αρχείο*_____ *Ημερομηνία:*_____

Παρακαλούμε διαβάστε τις οδηγίες:

*Αυτό το ερωτηματολόγιο έχει σχεδιαστεί προκειμένου να δώσει στον ιατρό πληροφόρηση αναφορικά με τον τρόπο που ο πόνος στον αυχένα σας έχει επηρεάσει την ικανότητά σας να διαχειρίζεστε την καθημερινή σας ζωή. Παρακαλώ απαντήστε σε κάθε ερώτηση και σημειδέψτε σε κάθε μία μόνο **ΕΝΑ** κουτί που σας ταιριάζει. Αντιλαμβανόμαστε ότι μπορεί να θεωρήσετε ότι δύο από τις απαντήσεις σε κάποια ερώτηση μπορεί να σας αφορούν, όμως παρακαλούμε απλώς **σημειδέψτε το κουτί που καλύτερα περιγράφει το πρόβλημά σας.***

ΜΕΡΟΣ 1- ΕΝΤΑΣΗ ΠΟΝΟΥ

☐Δεν έχω καθόλου πόνο στον αυχένα αυτή τη στιγμή.
☐Ο πόνος στον αυχένα είναι πολύ ήπιος αυτή τη στιγμή.
☐Ο πόνος στον αυχένα είναι μέτριος αυτή τη στιγμή.
☐Ο πόνος στον αυχένα είναι αρκετά σοβαρός αυτή τη στιγμή.
☐Ο πόνος στον αυχένα είναι πολύ σοβαρός αυτή τη στιγμή.
☐Ο πόνος στον αυχένα αυτή τη στιγμή είναι ότι χειρότερο έχω φανταστεί.

ΜΕΡΟΣ 2- ΠΡΟΣΩΠΙΚΗ ΦΡΟΝΤΙΔΑ (Πλύσιμο, ντύσιμο κ.λπ.)

☐Μπορώ να φροντίσω τον εαυτό μου φυσιολογικά χωρίς να προκαλώ περισσότερο πόνο στον αυχένα.
☐Μπορώ να φροντίσω τον εαυτό μου φυσιολογικά αλλά προκαλώ περισσότερο πόνο στον αυχένα.
☐Είναι επώδυνο να φροντίσω τον εαυτό μου και είμαι αργός/ή και προσεκτικός/ή.
☐Χρειάζομαι κάποια βοήθεια αλλά μπορώ να ανταποκριθώ στο μεγαλύτερο μέρος της προσωπικής μου φροντίδας.
☐Χρειάζομαι βοήθεια καθημερινά στα περισσότερα θέματα που αφορούν την προσωπική μου φροντίδα.
☐Δεν μπορώ να ντυθώ, πλένομαι με δυσκολία και παραμένω στο κρεβάτι.

ΜΕΡΟΣ 3- ΑΡΣΗ ΒΑΡΟΥΣ

☐Μπορώ να σηκώσω μεγάλα βάρη χωρίς περισσότερο πόνο στον αυχένα.
☐Μπορώ να σηκώσω μεγάλα βάρη αλλά αυτό προκαλεί περισσότερο πόνο στον αυχένα.
☐Ο πόνος στον αυχένα με εμποδίζει να σηκώσω μεγάλα βάρη από το πάτωμα, αλλά μπορώ να τα καταφέρω εάν είναι κατάλληλα τοποθετημένα, π.χ. πάνω σε ένα τραπέζι.
☐Ο πόνος στον αυχένα με εμποδίζει να σηκώσω μεγάλα βάρη από το πάτωμα, αλλά μπορώ να σηκώσω ελαφριά και μέτρια βάρη εάν είναι κατάλληλα τοποθετημένα.
☐Μπορώ να σηκώσω πολύ ελαφριά βάρη.
☐Δεν μπορώ να σηκώσω ή να μεταφέρω οτιδήποτε.

ΜΕΡΟΣ 4- ΔΙΑΒΑΣΜΑ

☐Μπορώ να διαβάσω όσο θέλω, χωρίς πόνο στον αυχένα μου.
☐Μπορώ να διαβάσω όσο θέλω, με λίγο πόνο στον αυχένα μου.
☐Μπορώ να διαβάσω όσο θέλω, με μέτριο πόνο στον αυχένα μου.
☐Δεν μπορώ να διαβάσω όσο θέλω, εξαιτίας μέτριου πόνου στον αυχένα μου.
☐Μετά βίας μπορώ να διαβάσω εξαιτίας δυνατού πόνου στον αυχένα μου.
☐Δεν μπορώ να διαβάσω καθόλου.

ΜΕΡΟΣ 5- ΠΟΝΟΚΕΦΑΛΟΙ

☐Δεν έχω καθόλου πονοκεφάλους.
☐Έχω ήπιους πονοκεφάλους που εμφανίζονται σπάνια.
☐Έχω μέτριους πονοκεφάλους που εμφανίζονται σπάνια.
☐Έχω μέτριους πονοκεφάλους που εμφανίζονται συχνά.
☐Έχω ισχυρούς πονοκεφάλους που εμφανίζονται συχνά.
☐Έχω πονοκεφάλους σχεδόν πάντα.

ΜΕΡΟΣ 6- ΣΥΓΚΕΝΤΡΩΣΗ
☐Μπορώ να συγκεντρωθώ πλήρως όταν το θελήσω, χωρίς καμία δυσκολία.
☐Μπορώ να συγκεντρωθώ πλήρως όταν το θελήσω, με μικρή δυσκολία.
☐Έχω μέτριο βαθμό δυσκολίας στο να συγκεντρωθώ όταν το θελήσω.
☐Έχω αρκετή δυσκολία στο να συγκεντρωθώ όταν το θελήσω.
☐Έχω πολύ μεγάλη δυσκολία στο να συγκεντρωθώ όταν το θελήσω.
☐Δεν μπορώ να συγκεντρωθώ καθόλου.

ΜΕΡΟΣ 7- ΕΡΓΑΣΙΑ
☐Μπορώ να εργαστώ όσο θέλω.
☐Μπορώ να κάνω τη συνηθισμένη εργασία μου, αλλά όχι κάτι περισσότερο.
☐Μπορώ να κάνω το μεγαλύτερο μέρος από τη συνηθισμένη εργασία μου, αλλά όχι κάτι περισσότερο.
☐Δεν μπορώ να κάνω τη συνηθισμένη εργασία μου.
☐Μετά βίας μπορώ να εργαστώ.
☐Δεν μπορώ να εργαστώ καθόλου.

ΜΕΡΟΣ 8- ΟΔΗΓΗΣΗ
☐Μπορώ να οδηγήσω το αυτοκίνητό μου χωρίς καθόλου πόνο στον αυχένα.
☐Μπορώ να οδηγήσω το αυτοκίνητό μου όσο θελήσω, με ελαφρύ πόνο στον αυχένα μου.
☐Μπορώ να οδηγήσω το αυτοκίνητό μου όσο θελήσω, με μέτριο πόνο στον αυχένα μου.
☐Δεν μπορώ να οδηγήσω το αυτοκίνητό μου όσο θελήσω, εξαιτίας μέτριου πόνου στον αυχένα μου.
☐Μετά βίας μπορώ να οδηγήσω, εξαιτίας δυνατού πόνου στον αυχένα μου.
☐Δεν μπορώ να οδηγήσω το αυτοκίνητό μου καθόλου.

ΜΕΡΟΣ 9- ΥΠΝΟΣ
☐Δεν έχω πρόβλημα με τον ύπνο.
☐Ο ύπνος μου είναι ελαφρά διαταραγμένος (λιγότερο από 1 ώρα άυπνος/η).
☐Ο ύπνος μου είναι ήπια διαταραγμένος (1-2 ώρες άυπνος/η).
☐Ο ύπνος μου είναι μέτρια διαταραγμένος (2-3 ώρες άυπνος/η).
☐Ο ύπνος μου είναι πολύ διαταραγμένος (3-5 ώρες άυπνος/η).
☐Ο ύπνος μου είναι εντελώς διαταραγμένος (5-7 ώρες άυπνος/η).

ΜΕΡΟΣ 10- ΨΥΧΑΓΩΓΙΑ
☐Μπορώ να ασχοληθώ με όλες τις ψυχαγωγικές μου δραστηριότητες, χωρίς καθόλου πόνο στον αυχένα.
☐Μπορώ να ασχοληθώ με όλες τις ψυχαγωγικές μου δραστηριότητες, με κάποιο πόνο στον αυχένα.
☐Μπορώ να ασχοληθώ με τις περισσότερες αλλά όχι με όλες τις ψυχαγωγικές μου δραστηριότητες, εξαιτίας πόνου στον αυχένα μου.
☐Μπορώ να ασχοληθώ με λίγες από τις συνήθεις ψυχαγωγικές μου δραστηριότητες, εξαιτίας πόνου στον αυχένα μου.
☐Μετά βίας συμμετέχω σε ψυχαγωγικές δραστηριότητες, εξαιτίας πόνου στον αυχένα μου.
☐Δεν μπορώ καθόλου να συμμετέχω σε ψυχαγωγικές δραστηριότητες.

Για τη μετάφραση, προσαρμογή και στάθμιση του ερωτηματολογίου στην ελληνική γλώσσα έχει δοθεί άδεια στην Κλινική Κοινωνικής και Οικογενειακής Ιατρικής του τμήματος Ιατρικής, Πανεπιστημίου Κρήτης. Υπεύθυνοι είναι οι: *Χρήστος Λιουής, Αναπλ. Καθ. Κοιν. & Οικ. Ιατρ. Παν. Κρήτης.* και *Μαριάννα Τρούλη, Φυσ/τρια, Μετ. Φοιτ. στη Δ.Υ. & Δ.Υ.Υ.*

APPENDIX K

ΕΓΧΕΙΡΙΔΙΟ ΠΑΡΑΚΟΛΟΥΘΗΣΗΣ ΑΣΘΕΝΗ

Κωδικός …….

1. Global rating scale of change (global perceived effect). Σε σχέση με 6 μήνες πριν, πώς θα βαθμολογούσατε την αλλαγή στην κατάστασή σας στην παρακάτω κλίμακα:

    1 – πλήρη ανάρρωση /βελτίωση

    2 – πολύ βελτιωμένη

    3 – ελαφρώς βελτιωμένη

    4 – καμία αλλαγή

    5 – λίγο χειρότερα

    6 – αρκετά χειρότερα

    7 – Χειρότερα από ποτέ