A Comparative Study between the Short Term Pain Relief Effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in Neck Pain.

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under the supervision of Mr Christopher Fenech

A dissertation presented to the Faculty of Health Sciences in part-fulfilment of the requirements for the Bachelor of Science (Honours) in Physiotherapy, at the University of Malta

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Abstract

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Title: A Comparative Study between the Short Term Pain Relief Effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in Neck Pain.

Objective: The main objective of the study was to identify the superior modality between Transcutaneous Electrical Nerve Stimulation (TENS) and Hot Water Bottle (HWB) interventions, when treating mild to moderate neck pain in 18 to 25 year old students. This was primarily identified on the basis of which modality provided higher immediate and short term pain relief.

Method: The study design was quantitative, comparative, and explanatory. The WILDA Pain Assessment Guide and the Numerical Rating Scale were the main outcome measures, used in the pre-test and post-tests, respectively. A randomised control trial was utilised, whereby participants were allocated a TENS, TENS placebo, HWB, or HWB placebo, intervention through a digital randomiser. Furthermore, a single blind approach minimised bias. Recruitment was on a voluntary basis, provided participants met the study's criteria.

Results: The primary outcome of the data analysis identified that there was no significant difference in TENS and HWB analgesia immediately post-intervention (p=0.891) nor short term post-intervention (p=0.705).

Furthermore, a significant decrease was seen in the mean pain intensity score reduction of TENS (p=0.000) and HWB (0.002) against their respective placebos, immediately post-intervention. Conversely, non-significant scores were obtained by TENS (0.619) and HWB (0.537), at short term.

Keywords: Transcutaneous Electrical Nerve Stimulation OR TENS, Hot Water Bottle OR Superficial Heat, Neck Pain, Pain Relief.

Declaration of Authenticity

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FACULTY/INSTITUTE/CENTRE/SCHOOL Health Sciences

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Dedications

This dissertation is dedicated to my friends, family, and lecturers who have provided me with an abundance of support and motivation throughout these four years as a physiotherapy student.

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List of Abbreviations

HWB	Hot Water Bottle/s
LB	Lateral Bilateral
LBQ	Lower Bottom Quadrant
LUBQ	Left Upper and Bottom Quadrants
LRBQ	Left Right Bottom Quadrant
M	Midline
MHSA	Malta Health Students' Association
NDI	Neck Disability Index
NRS	Numerical Rating Scale
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QTFC	Quebec Task Force Classification
RBQ	Right Bottom Quadrant
RUBQ	Right Upper and Bottom Quadrants
SPSS	Statistical Product and Service Solutions
TENS	Transcutaneous Electrical Nerve stimulation

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1. Introduction

1.1 Significance of the Study

Neck pain is a serious worldwide public health problem. Globally in 2017, there were 288,700,000 active cases, 65,300,000 incident cases, and 28,600,000 lived with disability for multiple years (Safiri et al. 2020). Furthermore, the international presentation of neck pain was seen to be higher in females than in males, while also increasing with age up to 70 to 74 years and then decreasing with older age (Safiri et al. 2020).

Malta was included in a study by Safiri et al. (2020), which analysed neck pain prevalence in 195 countries. The study identified that 4.8% to 5.1% of Maltese individuals had neck pain in 2017. Neck pain is such a concern that it is also influencing life-expectancy, in fact in 2015 it was one of the leading determinants of Malta's disability adjusted life years (*State of Health in the EU Malta Country Health Profile 2017* 2017).

Limited data on the prevalence of neck pain in 18 to 25 year old students in Malta was available. Nonetheless, a study of 684 Thai students aged from 18 to 25 years, reported a 46% onset of neck pain, 33% of which had persistent pain after 1 year (Kanchanomai et al. 2011). Furthermore, a study of 1002 Chinese

students aged 18 years old or older identified a 17% onset of neck pain, and a 45% prevalence in the previous year (Chan et al. 2020).

A plethora of tools are available for the management of neck pain. Transcutaneous Electrical Nerve Stimulation (TENS) and Hot Water Bottle (HWB) were selected with the demographic in mind, as they conform with the following 5 concepts: affordable, practical, compact and portable, accessible, and safe. TENS and HWB are relatively inexpensive products which an average student can afford, while HWB is also a common household item (Jones and Johnson 2009, Jabir et al. 2013). TENS, once set up by a physiotherapist can be used effortlessly, it is also practical as it is battery operated and the electrodes can be attached when experiencing pain (Jones and Johnson 2009). HWB is also a straightforward device, as water heated in a microwave or kettle, together with insulation, are primarily needed for the set up (Jabir et al. 2013). Furthermore, both devices are compact and portable, allowing them to be used effortlessly (Jones and Johnson 2009). HWB is readily available for purchase at most pharmacies, while TENS units are usually less accessible, but can nonetheless also be purchased over the counter (Jones and Johnson 2009, Jabir et al. 2013). In terms of safety, despite HWB having a risk of burns, as previously described it is a common household item and most have a thorough understanding of its use (Jabir et al. 2013). Furthermore, although TENS has its own risk factors there is no known potential for overdose, deeming it also as a safe device (Jones and Johnson 2009). These characteristics allow for non-

pharmaceutical, non-invasive, and effective analgesia for students' neck pain, whether in class or on campus.

1.2 Aim

The aim of the study is to identify the superior modality between TENS and HWB interventions when treating mild to moderate neck pain. This is to be identified primarily on the basis of which modality provides higher immediate and short term pain relief.

The study was conceptualised through multiple independent interventions on students aged between 18 and 25. Self-reported pain intensity was the primary outcome measure for this study and it was quantified through the WILDA Pain Assessment in the pre-test and the Numerical Rating Scale (NRS) in the post-tests. This was used in conjunction with time in the short term post-test, where the duration of analgesia was noted.

1.3 Research Question

Which modality between TENS and HWB provides the highest immediate and short term neck pain relief, in 18 to 25 year old students?

1.4 Objectives

There are several objectives for this study, these being:

- To determine if TENS or HWB provides higher pain relief,
    - A) Immediately post-intervention
    - B) Short term post-intervention
- To determine which modality between TENS and HWB provides the longest pain relief.
- To determine whether TENS and HWB are significantly more effective than placebo,
    - A) Immediately post-intervention
    - B) Short term post-intervention
- To identify trends in participants' personal and non-personal factors.
- To identify trends in the change in mean pain intensity for participants' personal and non-personal factors,
    - A) Immediately post-intervention
    - B) Short term post-intervention

1.5 Hypotheses

This study will be investigating 3 alternative hypotheses where all but one will be disproved, provided that the null hypothesis is refused. The hypotheses are the following:

H0: There is no significant difference between the modalities in terms of reduction in the immediate or short term pain intensities.

H1: Either TENS or HWB is significantly more effective than the alternate modality at reducing the immediate pain intensity, but not the short term pain intensity.

H2: Either TENS or HWB is significantly more effective than the alternate modality at reducing the short term pain intensity, but not the immediate pain intensity.

H3: Either TENS or HWB is significantly more effective than the alternate modality at reducing the immediate and short term pain intensities.

1.6 Conclusion

This chapter introduced the study and its intent to tackle the gap in relevant literature. It also stated the aims, research question, objectives, and the hypotheses of the study.

2. Literature Review

2.1 Introduction

This chapter describes the search strategy and gives an overview of the acquired research regarding the prevalence of neck pain, as well as TENS's and HWB's analgesic effects on an individual and comparative level.

2.2 Search strategy

A search strategy was implemented using the keywords "Transcutaneous Electrical Nerve Stimulation", "Hot Water Bottle", "Neck Pain", and "Pain Relief", taken from the research project's title. Furthermore, synonyms of the above terms were also used, these included "TENS" and "Superficial Heat". These catered for variations in terminology, allowing for the attainment of as many valid results as possible. The above keywords were inputted into electronic databases, namely Google Scholar and HyDi.

The search strategy resulted in limited outcomes, the most pertinent of which were identified using the search engine filters that excluded resources published before 1980. This left a forty year search window. Media articles and low reliability sources were also removed. The use of boolean commands, further to employing the filtering process, allowed the most relevant articles to be selected. 36 articles remained, with varying relevance to the subject of interest. A few

were identified as being very relevant, and these were utilised in the majority of the literature review. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram below illustrates the described literature search strategy (Moher et al. 2009). See Figure 1.0.

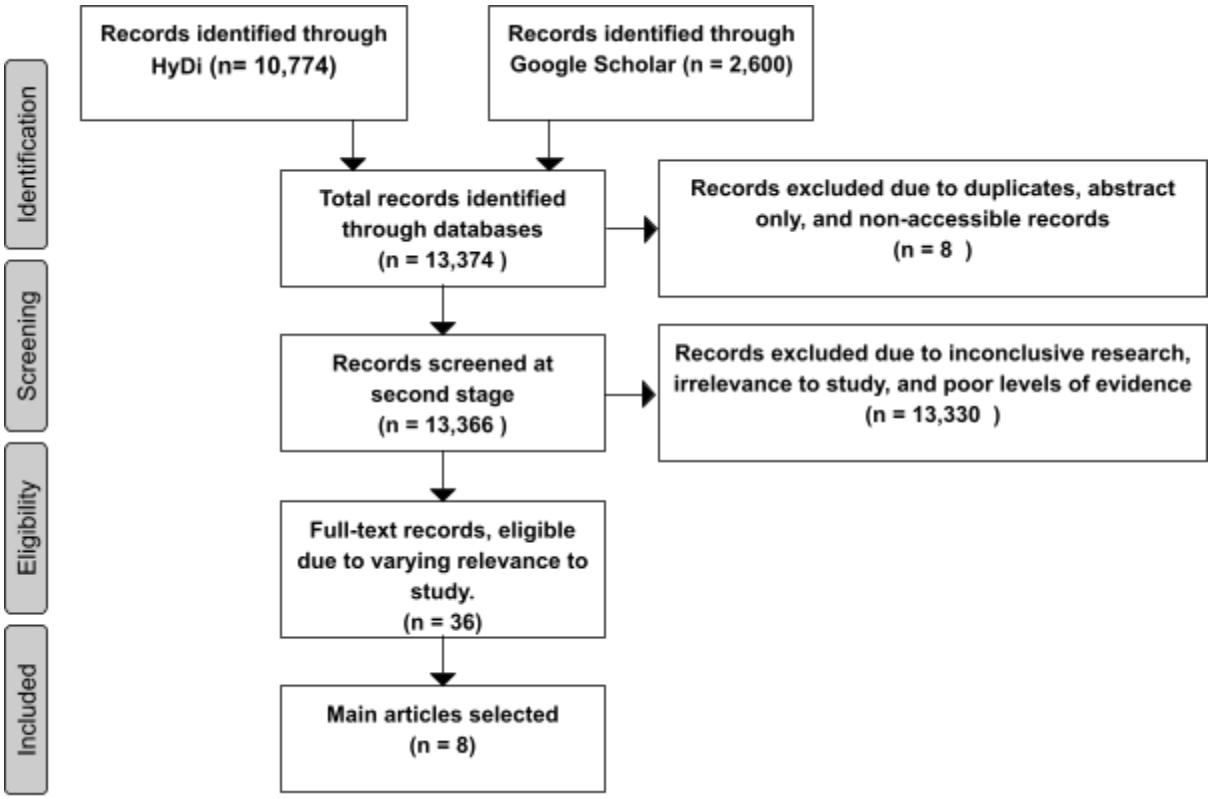

Figure 1.0 PRISMA diagram illustrating the adopted strategy for the literature search.

2.3 The Prevalence of Neck Pain

The prevalence of chronic neck pain has been seen in various studies which featured young adult students. 46% of the 684 students in Kanchanomai et al.

(2011)'s study presented with neck pain, and after a one year follow up 33% of the population reported persistent neck pain. Prolonged poor posture when using computers was identified as the prime contributing factor, while personal discomfort, disability, and decreased quality of life were reported as neck pain resultants (Kanchanomai et al. 2011). Al-Hadidi et al. (2019) and Silva et al. (2009) similarly identified forward flexed posture during prolonged smartphone use to illicit neck pain in students. Additionally, Ayanniyi and Mbada (2010) found that females were more susceptible to neck pain rather than males, to which Chan et al. (2020) and Kanchanomai et al. (2011) concurred.

Chan et al. (2020) performed a similar study where the neck pain of students from various educational backgrounds was analysed. 45% of the 1002 participants reported neck pain in the previous year and 17% were in pain during the time of participation. Neck pain was associated with anxiety, lower back pain, prolonged smartphone use, height, and it also increased with academic year seniority. Kanchanomai et al. (2011) also identified neck pain to increase with age. In Chan et al. (2020)'s study nursing and physiotherapy students had the highest pain intensities.

2.4 TENS and Neck Pain Relief

When investigating the use of TENS, a study by Johnson (2007) identified three TENS variations: intense, acupuncture-like, and conventional. Intense TENS

parameters include a high frequency, high intensity, and a duration of a few minutes. This activates noxious afferent neurons, resulting in a peripheral nerve blockade and hence extrasegmental analgesia. Acupuncture-like TENS is a high-intensity and low-frequency alternative which is applied for fifteen to thirty minutes. It stimulates motor and afferent neurons, causing strong but comfortable muscle contractions and analgesia, respectively. Furthermore, conventional TENS utilises a low-intensity, high-frequency of 50Hz to 100Hz, and a pulse width of 50μs to 200μs. It can be administered whenever in pain as it applies a strong but comfortable segmental paraesthesia, by stimulating non-noxious afferent neurons. A systematic review by Martimbianco et al. (2019) concurred that conventional TENS is to be applied at a high frequency of 50Hz to 130Hz, a low intensity, and a short pulse duration of 50μs to 200μs. It was also stated that this conventional TENS is most commonly used with long-term neck pain cases (Martimbianco et al. 2019).

A systematic overview and meta-analysis by Aker et al. (1996) compared conventional TENS to laser, spray, stretch, exercise, electromagnetic treatment, infrared, traction, and acupuncture in its effectiveness and efficacy when treating neck pain. TENS ranked among the highest, but unfortunately the study stated that at the time there was not enough literature to assess the modalities accurately. Further, Johnson (2007) identified TENS to be an effective and efficient way to treat neck pain. Additionally, a randomised controlled trial by Maayah (2010) concluded that a single intense TENS treatment was effective in

treating mild musculoskeletal disorder related neck pain, as participants' pain threshold levels increased exponentially during, immediately after treatment, and one week post-treatment.

TENS has also demonstrated inconclusive results in its effectiveness against placebo in a systematic review by Martimbianco et al. (2019). Two out of the seven of the featured studies reported that TENS was not significantly more effective than inactive treatment, when attempting to relieve neck pain. Furthermore, a systematic review by Khadilkar et al. (2013) also identified that conventional TENS was not significantly more effective than placebo, as it did not provide a significant reduction in NRS measured intensity post-intervention.

2.5 HWB and Neck Pain Relief

HWB has been identified as a mode of application of superficial heat by Banks and MacKrodt (2005), among heating pads, paraffin wax, and hot water immersion. According to Banks and MacKrodt (2005) HWB's localised heat application influences superficial structures' mechanoreceptors, stimulating afferent neurons and decreasing pain through the pain gate mechanism. Furthermore, analgesia is provided through muscle relaxation, and reducing joint and soft tissue tightness. This modality is only able to provide short-term topical pain relief, but has been identified as a simple and effective modality for pain

self-management (Banks and MacKrodt 2005). Yap (2007) concurred with the above features and benefits of HWB.

When investigating the parameters for HWB application a study by Tepperman and Devlin (1983) stated that they may be applied for 20 to 30 minutes every two to four hours, as needed. Dyson (2006) agreed that HWB and similar heat conduction devices may be used for 20 to 30 minutes over towel covered skin. In a randomised controlled trial by Chaudhuri et al. (2013) HWB were wrapped in towels, and the water temperature was deemed suitable via practitioner perception, where the skin was palpated.

Unfortunately, limited research about the use of HWB specifically for neck pain analgesia was found. Nonetheless, Chaudhuri et al. (2013) used HWB for dysmenorrheic pain and it significantly decreased NRS pain intensity scores, when compared to the control. Furthermore, a randomised control trial by Cramer et al. (2012) tackled neck pain analgesia by using heat packs, which are structurally and functionally similar to HWB (Banks and MacKrodt 2005). The superficial heating modality provided a significant decrease in chronic mechanical neck pain intensity through NRS measurements, when compared to the control group. Further, there was no significant difference in neck disability through the neck disability index (NDI), and quality of life through the SF-36.

2.6 The Comparative Effects of TENS and HWB for Neck Pain Relief

Limited research comparing TENS's and HWB's effectiveness on neck pain relief was found. Nonetheless, Aker et al. (1996)'s systematic review and meta-analysis stated that TENS provides superior outcomes than HWB applications when treating neck pain. In contrast, Chapman (1991) identified that superficial heat and TENS are equally effective at chronic musculoskeletal pain management. Furthermore, a systematic review of eighty three studies by van Middelkoop et al. (2010) was inconclusive when comparing the effectiveness of TENS and HWB treatments for lower back pain management, but it was noted that the incorporated randomised control trials had an insufficient sample size. Cetin et al. (2008) stated that an integrated approach, where TENS followed by superficial heat had a better performance over individual-use interventions, when seeking to decrease knee osteoarthritic pain.

2.7 Conclusion

Through the use of PRISMA, limited literature regarding the application of TENS and HWB for neck pain was acquired. The lack of research in this field influenced the quality of studies used and depth of the above review. Furthermore, reference can be made to Table 1.0 for a summary of the main articles used.

Study Title	Author(s)	Design	Sample	Investigation	Conclusion
Therapeutic heat and cold. (2016)	Tepperman, P. and Devlin, M.	Expert Opinion.	Not Applicable.	Not Applicable.	Use of superficial heat modalities such as HWB, may increase metabolism, circulation, inflammation, and promote pain relief.
Myofascial Pain – An Overview. (2007)	Yap, E.	Review Article.	Not Applicable.	Not Applicable.	Superficial heating modalities decrease superficial soft tissue tightness and provide short term pain relief topically.
Transcutaneous electrical nerve stimulation: mechanisms, clinical application and evidence. (2015)	Johnson, M.	Review Article.	Not Applicable.	Not Applicable.	Conventional, acupuncture-like, and intense TENS together with the corresponding parameters were identified.

Transcutaneous electrical nerve stimulation (TENS) for chronic neck pain. (Review) (2019)	Martimbianco, A., Porfírio, G., Pacheco, R., Torloni, M. and Riera, R.	Systematic Review of 7 randomised control trials.	651 participants with mean age ranging from 31.7 to 55.5 years and all participants had neck pain for at least 12 weeks.	2 of the 7 studies compared TENS to sham TENS, the rest compared TENS to other medical and physiotherapeutic interventions.	Conventional TENS can be applied at a high frequency of 50Hz to 130Hz, a low intensity, and a short pulse duration of 50μs to 200μs for neck pain relief. TENS has demonstrated inconclusive results in its effectiveness against placebo.
Can the use of physical modalities for pain control be rationalized by the research evidence? (1991)	Chapman, C.	Systematic Review containing 30 experimental and quasi-experimental studies.	An unspecified number of participants who have musculoskeletal pain.	5 articles about superficial heating agents and 2 articles about TENS, among other modalities.	Superficial heat and TENS are equally effective at chronic musculoskeletal pain management.

A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. (2011)	van Middelkoop, M., Rubinstein, S., Kuijpers, T., Verhagen, A., Ostelo, R., Koes, B. and van Tulder, M.	A systematic review containing 83 randomised controlled trials.	Participants were18 years old or older, who had non-specific chronic lower back pain that persisted for a minimum of 12 weeks.	1 of the articles was about superficial heating techniques and 5 articles were about TENS.	In view of insufficient data, the study was inconclusive when comparing the effectiveness of TENS and HWB treatments for lower back pain management.
Conservative management of mechanical neck pain: systematic overview and meta-analysis. (1996)	Aker, P., Gross, A., Goldsmith, C. and Peloso, P.	Systematic overview and meta-analysis, containing 24 randomised controlled trials.	An unspecified number of participants who have mechanical neck disorders which illicit pain.	3 articles were about superficial heating modalities and 2 were about TENS.	TENS provided superior outcomes to HWB applications when treating neck pain. The study also stated that at the time there was not enough literature to assess the modalities accurately.

Comparing Hot Pack, Short-Wave Diathermy, Ultrasound, and TENS on Isokinetic Strength, Pain, and Functional Status of Women with Osteoarthritic Knees. (2008)	Cetin, N., Aytar, A., Atalay, A. and Akman, M.	A Single-Blind, Randomized, Controlled Trial.	100 patients with bilateral knee osteoarthritis.	Participants were randomised into five groups of 20 patients where interventions included superficial heat applications and TENS, among modalities.	TENS followed by superficial heat had a better performance over individual-use interventions when seeking to decrease knee osteoarthritic pain.

Table 1.0 Summary of main articles used in the study.

3. Method

3.1 Introduction

This chapter describes the methodological approach used in the study, including participant recruitment, research tools' acquisition and application, intervention preparation and actualisation, together with assumed ethical considerations.

3.2 Study Design

The study design was quantitative, comparative, and explanatory, with a pre-test and post-tests to collect data. A randomised control trial was utilised, whereby participants were allocated to receive HWB, TENS, or their placebos, through a digital randomiser. Furthermore, a single blind approach was used to minimise bias in interventions.

3.3 Participant Recruitment

Malta Health Students' Association (MHSA) was contacted as an intermediary. Their AssisThesis programme was utilised with the correlating permission. Ms Kylie Fenech, the correspondent from MHSA set up a post on the AssisThesis programme group, briefing the study and inviting students to participate. Interested students were asked to contact the researcher for the dissemination of the information letter and session planning. The participation of said students was purely voluntary, and based completely on their willingness and availability

to attend, provided that they qualified through the inclusion and exclusion criteria.

A sample size of ninety participants (n=90) was sought. Thirty were to undergo TENS, similarly to HWB, while both TENS and HWB placebo cohorts were to be comprised of fifteen participants each.

3.3.1 Inclusion Criteria

Participants were eligible, provided that they followed the below inclusion criteria.

- Aged between 18 to 25 years
- In possession of active student status
- Currently experiencing neck pain, with a minimum onset of 12 weeks
- Qualified as Grade 1 or 2 on the Quebec Task Force Classification (QTFC)

Students aged 18 to 25 were selected for the purpose of the study. This decision was made in light of various studies which found that teenagers and young adults complained of non-specific neck pain. In fact, Mbada and Ayanniyi (2010) identified neck pain in 18 to 24 year old students. Additionally, in Hanvold et al. (2010)'s study 16 to 22 year old students presented with neck pain, while in Kanchanomai et al. (2011)'s, students with neck pain were 18 to 25 years old.

National Center for Biotechnology Information (2010) determined pain onset of at least 12 week to be chronic. Therefore, a participant pool with a similar pain history was selected, excluding acute pain. It is to note that participants with recurring neck pain who were at the time experiencing a chronic episode, were still accepted to participate. Additionally, participants were not to be accepted if they presented with severe neck pain, as according to Johnson (2007) and Denegar et al. (2011), TENS and HWB modalities are ideal for management of mild to moderate pain. Grade 1 and Grade 2 categories in the QTFC reflect mild and moderate pain and disability, and hence was utilised to classify participants (Seferiadis et al. 2004).

3.3.2 Exclusion Criteria

Participants were excluded from the study if they did not fit in the inclusion criteria. These were then further processed via the exclusion criteria, where health related factors influenced their eligibility.

Individuals with fibromyalgia and shoulder subluxation or dislocation were excluded as adjacent pain could mimic neck pain (Mitchell et al. 2005, Clauw 2009). Spondyloarthropathies including cervical osteoarthritis and cervical spondylolisthesis, together with rheumatoid arthritis, were also excluded from the study as non-specific neck pain was sought.

Individuals experiencing the below health issues were contraindicated to TENS and HWB (Akin 2001, Bazin et al. 2006).

- Metal implants in the area of proximity
- Local dermatological lesions
- Trauma related neck pain
- Cancer in the head, neck, or shoulders
- Surgery within the last 5 months at the head, neck, or shoulders
- Active use of pharmaceutical analgesics
- Impaired skin sensation

Individuals experiencing the below health issues were contraindicated to TENS (Johnson 2012).

- Artificial cardiac pacemaker
- Hearing aid
- Implantable cardioverter defibrillator
- Conducting gel allergy

Individuals experiencing the below health issues were contraindicated to HWB (Akin 2001).

- Peripheral vascular disease
- Deep vein thrombosis
- Implantable cardioverter defibrillator

- Aneurysm

Further, precaution was practiced when applying TENS or HWB to participants with cognitive restrictions, along with epilepsy in TENS (Bazin et al. 2006).

In order to ensure participant safety with the unforeseen, note was taken of any unlisted conditions and seen to accordingly.

3.4 Research Tools

A total of four standardised research tools were used for the purpose of this study. The WILDA Pain Assessment Guide, NDI, and QTFC were used during the pre-test, while the NRS was used in the post-tests.

3.4.1 WILDA Pain Assessment Guide

The WILDA Pain Assessment Guide is a tool used to assess pain. The tool encompasses five dimensions regarding pain; “Words to describe pain”, “Intensity”, “Location”, “Duration”, and “Aggravating and Alleviating Factors”. Its inclusion in the study, together with the NDI, allowed for participant categorisation through the QTFC. The “Intensity” dimension was subsequently used as the pre-test comparative parameter (Fink 2000).

The labelling system as in Figure 2.0 was used to effectively identify the pain "Location". The neck was divided into 4 quadrants, namely the "Left Upper Quadrant", "Right Upper Quadrant", "Left Bottom Quadrant", and the "Right Bottom Quadrant". The location of the presented pain was taken note of depending on the affected quadrant/s. Pain was also seen along the midline and laterally along the neck.

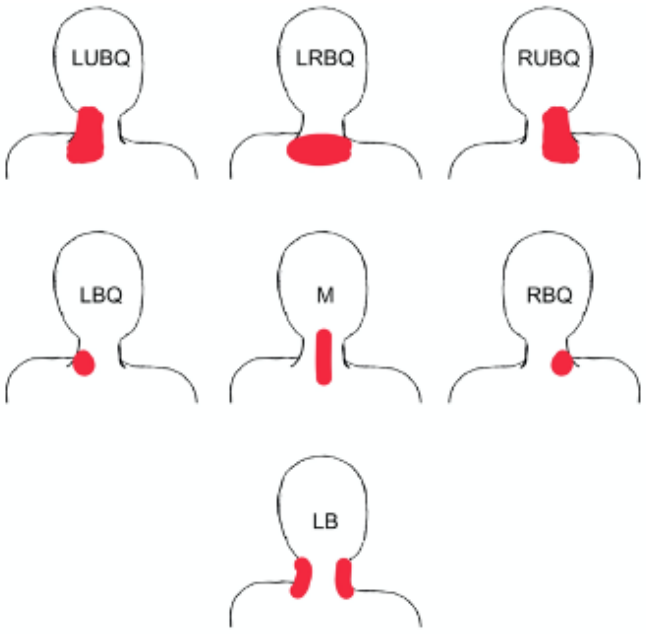

Figure 2.0 Diagram of the neck pain distribution labelling system.

3.4.2 Neck Disability Index (NDI)

The NDI is a one dimensional questionnaire consisting of a ten item scale. It allows for the measure of impact that neck pain related disability imposes on ten aspects of the individual's life, as described by Vernon and Mior (1991). Its

inclusion in the study, together with the WILDA Pain Assessment Guide, allowed for participant categorisation through the QTFC.

3.4.3 Quebec Task Force Classification (QTFC)

The QTFC targets the categorisation of neck pain and related disability in Whiplash Associated Disorders. This tool was repurposed for this study as the desired demographic fit the Grade 1 and Grade 2 description, as described by Pastakia and Kumar (2011). The NDI and WILDA Pain Assessment Guide allowed for said classification to take place.

3.4.4 Numerical Rating Scale (NRS)

The NRS is a unidimensional tool which was used to measure pain intensity. It is a ten point likert scale, where 0 is “No pain” and 10 is the “Worst possible pain”. This tool was used in the post-tests; immediately post-intervention and short term post-intervention. This was also compared with the pain intensity recorded in the WILDA Pain Assessment Guide during the pre-test (Aziato et al. 2015).

3.5 Method

3.5.1 Pre-Intervention

In preparation for the intervention two c-shaped HWB, a kettle, and two TENS units were purchased, for session use. A database with the uncoded data was set up, and all participants were allocated randomised modalities via an online

randomiser. Additionally, Room 9 Electrotherapy Laboratory at the Faculty of Health Sciences at Mater Dei Hospital was booked for the intervention sessions, following permission of use acquisition.

Participants were allocated times and dates based on the parties' availability, while ensuring that there were not more than four participants concurrently. This was limited by the number of intervention devices available, while also seeking to abide by the venue's capacity, particularly during the COVID-19 pandemic. Additionally, participants were contacted one day pre-intervention to remind them about the session, together with asking them to get a towel for HWB insulation, irrelevant of their allocated intervention. Concurrently, the research supervisor was sent a Google Meets link for online supervision.

3.5.2 Intervention

Previous to session initiation, the venue was set up. Apart from the purchased equipment and seating, portable privacy screens were set up to ensure participant privacy and confidentiality. Upon arrival, students were seated and provided with a printed consent form and data management sheet. The consent form and its contents were explained and signatures were acquired. Ethical remarks were also made.

Upon consent provision, eligibility was assessed through the inclusion and exclusion criteria on the data management sheet. If participants were contraindicated to the randomised intervention, they underwent a subsequent randomisation excluding all contraindicated modalities. Provided that they were eligible to participate in at least one intervention option, the participants were assessed via the WILDA Pain Assessment Guide and NDI, and ranked in the QTFC. This was followed by a 20 minute treatment session of TENS, TENS placebo, HWB, or HWB placebo.

3.5.2.1 TENS and TENS Placebo Administration

Initially, the neck was cleaned with soap and water, as a hygienic precaution. The TENS unit was subsequently set at a frequency of 100Hz, with a pulse width of 200μs, and a normal wave type. A two-pole or four-pole approach was taken based on the presenting pain location, a timer was set up, and the amplitude was raised until a participant-reported comfortable sensation was acquired. Additionally, the skin under the electrodes was assessed at instances as a safety precaution. Instructions and information were given according to “Treatment A. Instructions and Information” on the data management sheet (Johnson 2007, Verruch et al. 2019). See Appendix 7.

A similar approach was taken for TENS placebo administration. Nonetheless, the intervention was varied by keeping the amplitude at zero, as by doing so the

device did not operate. Instructions and information were given according to “Treatment C. Instructions and Information” on the data management sheet (Khadilkar et al. 2013). See Appendix 7.

3.5.2.2 HWB and HWB Placebo Administration

Water required for the HWB was heated and poured just before the participants arrival. The participants were then asked for the previously requested towel, in which the HWB were wrapped. Spare towels were also supplied by the researcher and used when further insulation was required. These were discarded after one use. A timer was set up and the skin under the HWB was assessed at instances as a safety precaution. Instructions and information were given according to “Treatment B. Instructions and Information” on the data management sheet (Akin 2001). See Appendix 7.

A similar approach was taken for HWB placebo. Nonetheless, the intervention was varied by pouring room temperature water from the kettle into the HWB. Elimination of the hot water nullified the superficial heating aspect of the treatment. Instructions and information were given according to “Treatment D. Instructions and Information” on the data management sheet (Mohammadpouri et al. 2014). See Appendix 7.

3.5.3 Post-Intervention

Immediately post-intervention the NRS assessment was performed to collect data on the immediate alleviative effect of the modality.

The participants were then provided with the researcher's email address and were taught how to perform a NRS assessment. They were asked to self-report the intensity of the pain during their next painful episode via email. The time of email receipt was taken as the incident time, unless otherwise stated by the participant. This component investigated the short term pain relief effect of the used modality.

3.6 Ethics

Ethical approval was acquired by FREC and UREC previous to data collection, as in the Appendix . It was decided that participants were not to be informed about placebo related deception to limit test influence to both active and prospective participants. Upon dissertation publication, participants would be able to review the study and gain insight on said deception.

When sampling, the researcher ensured confidentiality of the participant and provided information. The application of the pseudo-anonymity, confidentiality, and privacy concepts were explained in relation to the study. Interested participants were provided with an information letter, briefing the aims,

expectations, and session process. These were further explained by word of mouth. Consent forms, previously signed by the research supervisor, were also signed by participants¸ to acquiring eligibility. Participants were informed that their participation was completely voluntary, and that they were entitled to accept, refuse, or stop participation at any time without providing reason or experiencing any negative repercussions. It was affirmed that in such a case any data collected would be erased.

It was sought to protect the participants' privacy when collecting any form of data. This was ensured by treating said data with the utmost confidentiality and abiding by the Maltese Data Protection Act of 2001 and the General Data Protection Regulation. Collected data was exclusively used for the purpose of the study. Only the researcher had access to the uncoded data, while the research supervisor and examiners were only to be granted access in a scenario where verification is required. Print uncoded data was stored in a locked cupboard, while digital data was stored on a password protected computer. Upon study completion all uncoded data was destroyed.

To ensure participant safety, the physiotherapist Luke Musu warranted remedy at no financial cost to the participant. Privacy was ensured through the instalment of portable privacy screens during sessions. The skin was checked during interventions, and participants were advised to notify the researcher if

TENS or TENS placebo were too strong, or if HWB or HWB placebo were too hot. Contraindications and precautions for modalities were assessed and participants were invited to share unlisted health conditions of potential influence to prevent physical, emotional, or psychosocial harm.

3.7 Conclusion

The data acquired through the above method was analysed through the use of IBM Statistical Product and Service Solutions (SPSS), further explained in the next chapter.

4. Results

4.1 Introduction

This chapter gives an overview of the data collected and the statistical interpretation of said data through SPSS. The main areas covered are the distribution of participants' personal and non-personal factors, change in pain intensity post-intervention, and the participants' change in pain intensity in relation to their personal and non-personal factors.

4.2 Participants and Distributions

Through liaison with the intermediary 63 participants who were deemed eligible for the study were recruited. The initial goal was to attain 90 participants, however in view of certain limitations only 70% of the desired number was obtained.

Several trends have been identified; these can be classified to personal and non-personal factors. Personal factors were provided by participants and include: gender, age category, and educational institution of attendance, while non-personal factors include the: pain location, pre-intervention pain duration, pain chronicity, QTFC classification, and intervention type.

4.2.1 Gender Distribution

The distribution of participants' gender was investigated. Although the number of participants was limited, it was seen that the female gender was predominant. 71.4% of the participants were in fact female and the remaining 28.6% were male. See Figure 3.0.

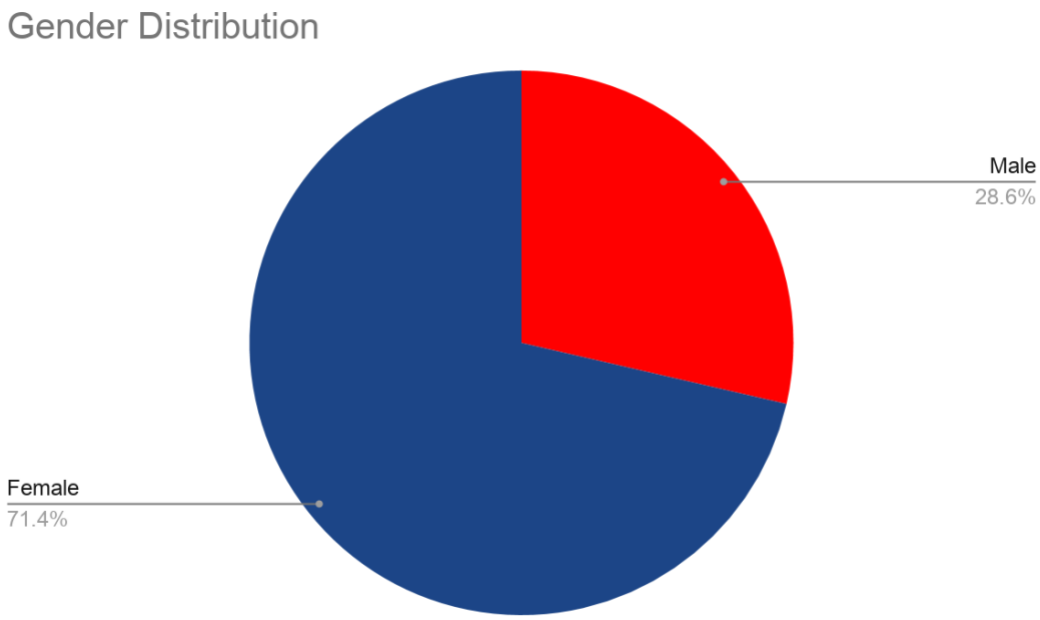

Figure 3.0 Pie chart illustrating gender distribution.

4.2.2 Age Categories Distribution

The distribution of participants' age was investigated. Students aged from 18 to 25 years were being taken into consideration for the purpose of the study. The participants were grouped based on the number of participants with a similar

age, to ensure representative and significant sample sizes. The 18-20 year old category encompassed the highest number of participants, followed closely by the 21-22 year olds, and the 23-25 year old category. See Table 2.0 and Figure 4.0.

Age Category	Percentage Participant Representation
18-20 Years Old	39.7%
21-22 Years Old	38.1%
23-25 Years Old	22.2%

Table 2.0 Tabulation of age category distribution.

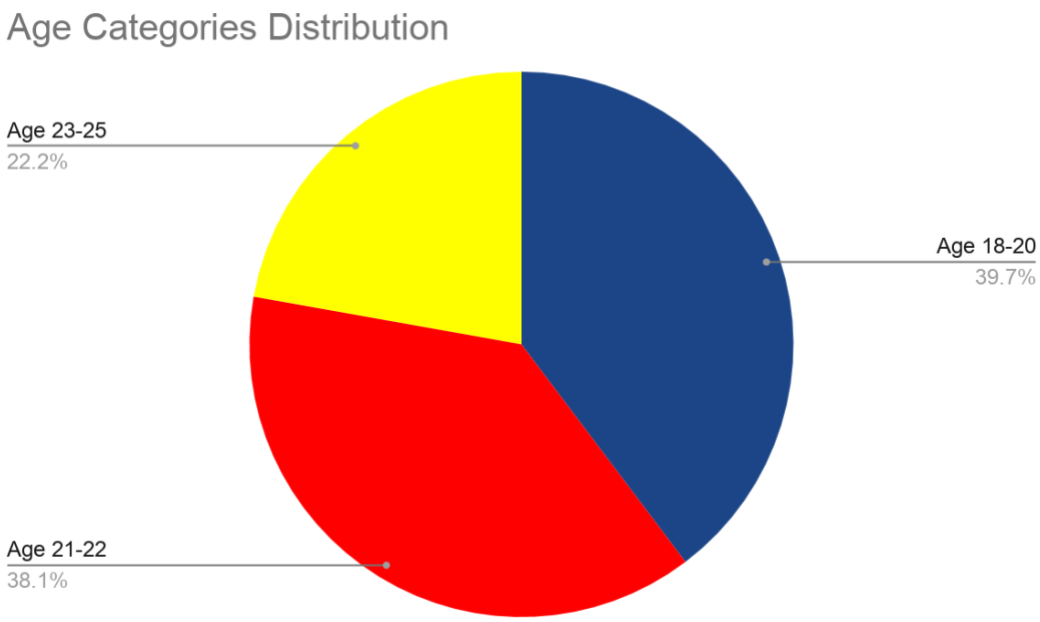

Figure 4.0 Pie chart illustrating age group distribution.

4.2.3 Educational Institution of Attendance Distribution

The distribution of the participants' educational institution of attendance was investigated. It is to note that the opportunity for students out of the University of Malta to participate was limited due to the intermediary selection. In fact, 95.2% of the participants were students at the University of Malta, while 4.8% presented from other institutions. See Figure 5.0.

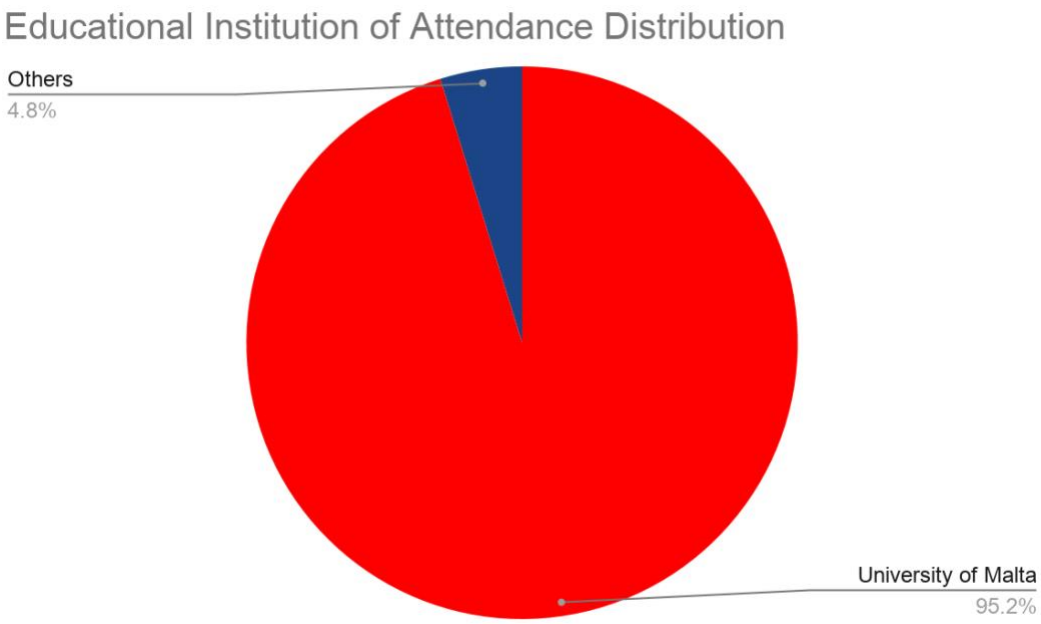

Figure 5.0 Pie chart illustrating educational institute of attendance distribution.

4.2.4 Pain Location Distribution

The distribution of the neck pain location was investigated. The most common neck pain area was the left and right bottom quadrant (LRBQ), followed by the lateral bilateral (LB) and midline (M) pain, the right bottom quadrant (RBQ), and the left upper and bottom quadrants (LUBQ). The lower bottom neck quadrant (LBQ), and right upper and bottom quadrants (RUBQ) had the lowest presentation, together with the Others category. This encompassed pain at the lateral right, lateral left, and right and left upper and bottom quadrants, and were classified as so since they were composed of 1, 2, and 1 participants respectively. Grouping ensured comparable and significant sample sizes. See Table 3.0 and Figure 6.0.

Pain Location	Percentage Participant Representation
LRBQ	34.9%
LB	14.4%
M	14.4%
RBQ	9.5%
LUBQ	7.9%
LBQ	6.3%
RUBQ	6.3%
Other	6.3%

Table 3.0 Tabulation of pain location distribution.

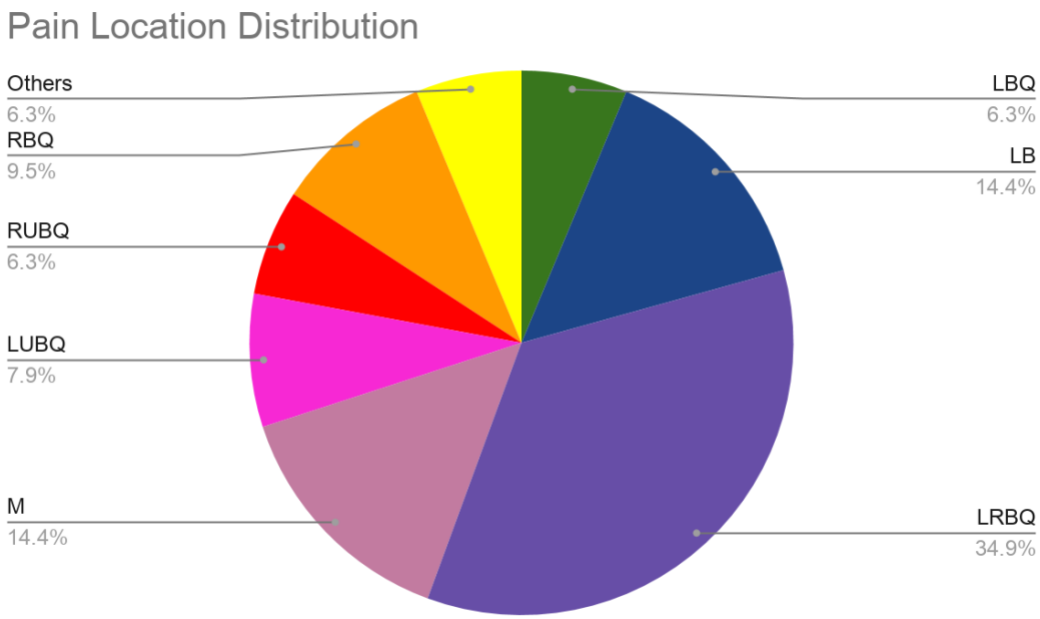

Figure 6.0 Pie chart illustrating pain location distribution.

4.2.5 Pain Duration Distribution

The distribution of neck pain onset duration pre-intervention was investigated. Participants with a minimum of a 12 week onset were exclusively accepted to participate. They were also grouped based on their onset duration, ensuring relevant and significant sample sizes. The 0-1 year old pain category encompassed the highest number of participants, followed by pain older than 4 years, the 2-4 years category, and finally 1-2 year old pain. See Table 4.0 and Figure 7.0.

Pain Duration	Percentage Participant Representation
0-1 year	33.3%
1-2 years	17.5%
2-4 years	23.8%
More than 4 years	25.4%

Table 4.0 Tabulation of pain duration distribution.

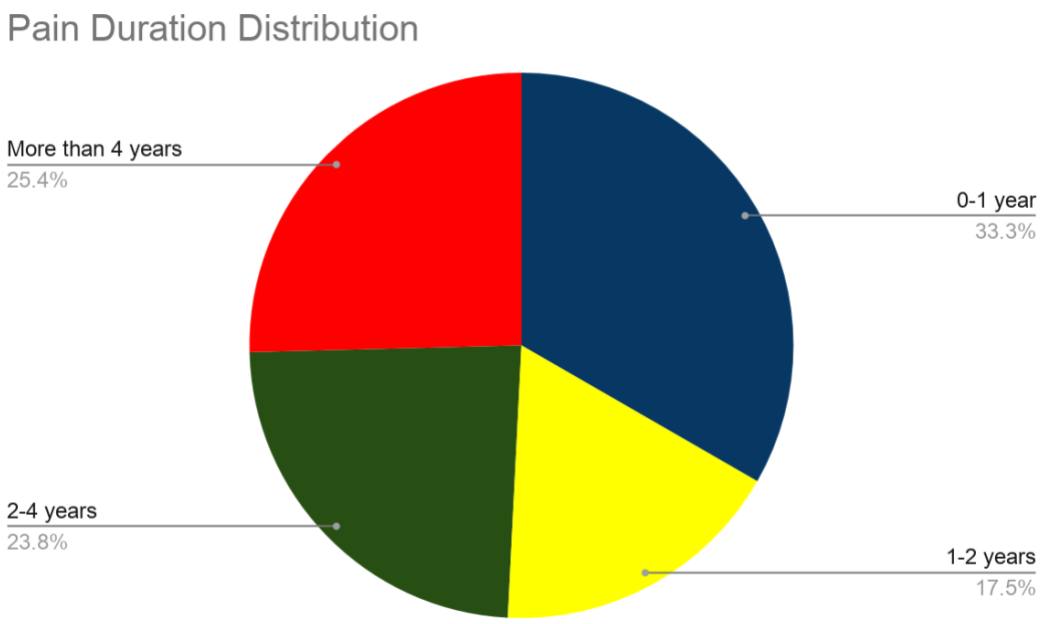

Figure 7.0 Pie chart illustrating pain duration distribution.

4.2.6 Pain Chronicity Distribution

The distribution of neck pain chronicity was investigated. Participants with chronic neck pain were to be accepted for the purpose of the study. 81.0% of the participants had recurring neck pain and were in a chronic episode, while those with constant chronic pain had a weighting of 19.0%. See Figure 8.0.

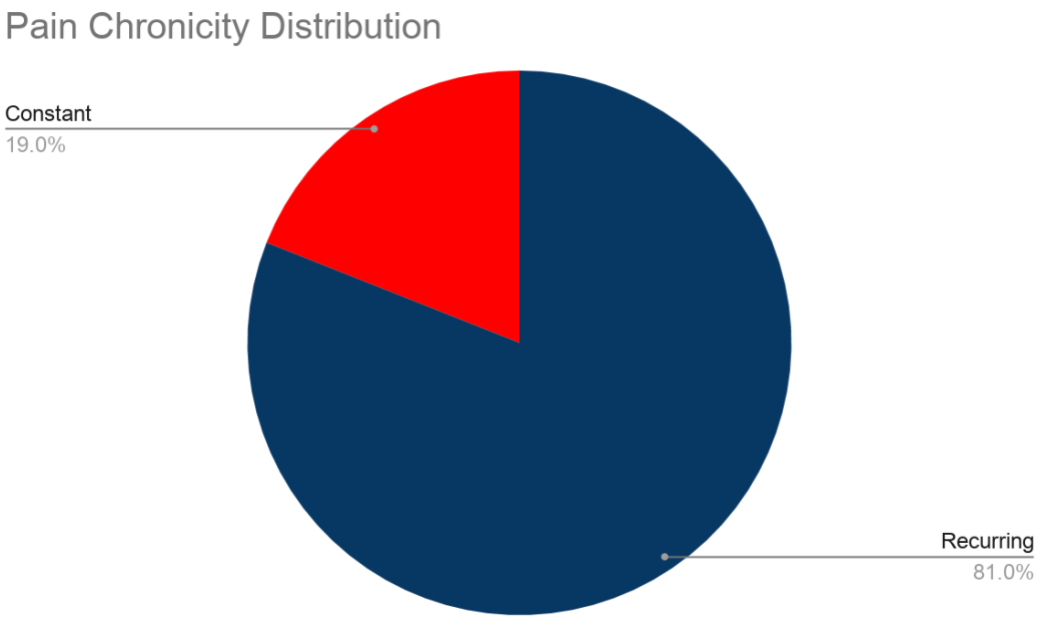

Figure 8.0 Pie chart illustrating pain chronicity distribution.

4.2.7 QTFC Classification Distribution

The distribution of participants' classification in the QTFC was investigated. Those who were classified within Grade 1 or 2 of the QTFC were allowed to participate. 25.0% of the participants were classified within Grade 1, while the remaining 75% were Grade 2 participants. See Figure 9.0.

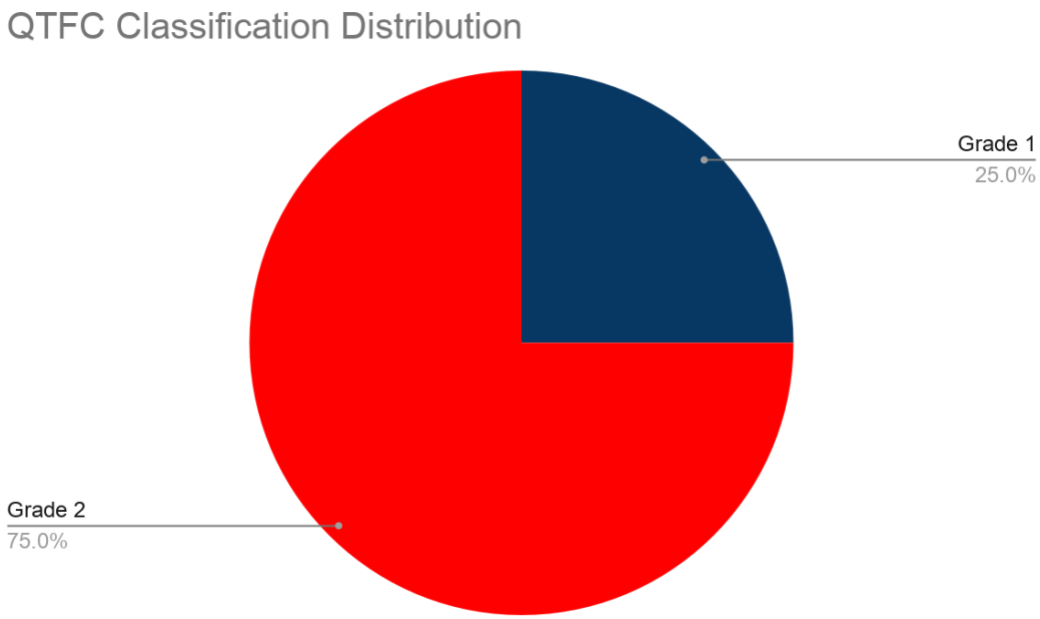

Figure 9.0 Pie chart illustrating QTFC classification distribution.

4.2.8 Intervention Type Distribution

The distribution of participants among the randomly assigned interventions was investigated. The four interventions were TENS, TENS placebo, HWB, and HWB placebo. The participant quota was not reached, but despite this the randomisation allowed for the desired quasi 2:1 ratio between the treatment and placebo groups. See Table 5.0 and Figure 10.0.

Intervention Type	Percentage Participant Representation
TENS Treatment	33.3%
HWB Treatment	34.9%
TENS Placebo	15.9%
HWB Placebo	15.9%

Table 5.0 Tabulation of intervention type distribution.

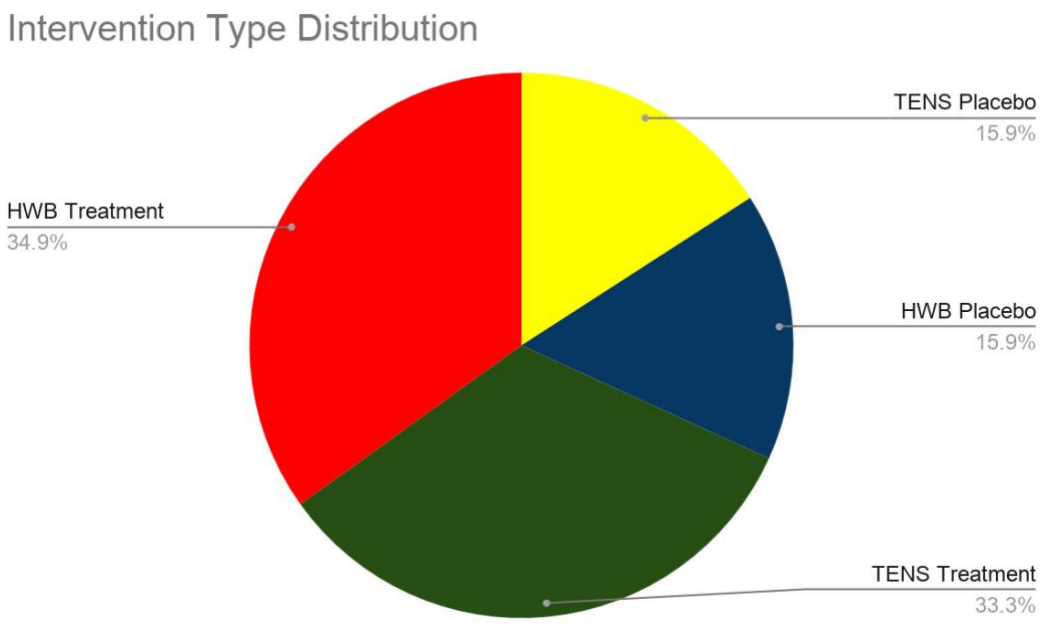

Figure 10.0 Pie chart illustrating intervention type distribution.

4.3 Pain Intensity Data Interpretation

The dependent variable in the study was pain intensity. Its outcomes with regards to the two modalities used and their placebo counterparts was understood through the use of SPSS calculations.

4.3.1 Pain Intensity Data Distribution

The initial step was to identify the data's distribution; whether the pain intensity values were normal or skewed. This was accomplished through the use of the Kolmogorov-Smirnov and Shapiro-Wilk Tests. Their null hypothesis specifies that pain intensity distribution is normal and accepted if the p-value exceeds the 0.05 level of significance. Furthermore, the tests' alternative hypothesis specifies that pain intensity distribution is skewed and accepted if the p-value is less than the 0.05 criteria.

The Kolmogorov-Smirnov and Shapiro-Wilk Test's values for pain intensity were lower than the 0.05 level of significance, therefore the pain intensity distribution violates the normality assumption pre-intervention ($p=0.016$ and $p=0.040$ respectively), immediately post-intervention ($p=0.005$ and $p=0.024$, respectively), and short-term post intervention ($p=0.002$ and $p=0.023$, respectively). The pain intensity distribution was skewed to the right, therefore it can be confirmed that most participants presented with a higher pain intensity. See Table 6.0.

Tests of Normality

	Kolmogorov-Smirnov			Shapiro-Wilk		
	Statistic	df	P-value	Statistic	df	P-value
Pre-intervention pain intensity	.157	39	.016	.941	39	.040
Immediate post-intervention pain intensity	.174	39	.005	.934	39	.024
Short term post-intervention pain intensity	.183	39	.002	.933	39	.023

Table 6.0 Tabulation of pain intensity data distribution

4.3.2 Pain Intensity Data Temporal Comparison

The difference in mean pain intensity between the three instance readings was calculated through the Wilcoxon Signed Ranks Test. This was used to compare the mean difference between two time points: pre-intervention pain intensity against immediate post-intervention pain intensity, pre-intervention pain intensity against short term post-intervention pain intensity, and immediate post-intervention pain intensity against short term post-intervention pain intensity. The test's null hypothesis specifies that the mean pain intensity changes slightly between the two points in time, and is accepted if the p-value exceeds the 0.05 level of significance. The test's alternative hypothesis specifies that the mean pain score varies significantly between the two time points and is accepted if the p-value is less than the 0.05 criteria.

There was a significant decrease (p=0.000) in the mean pain intensity between the pre-intervention and immediate post-intervention pain intensities. This means that the modalities used, generally decreased pain intensity immediately post-intervention. However, there was a significant increase (p= 0.000) in the mean score between the immediate and short term post-intervention pain intensities, meaning that pain intensity increased a while after the intervention. Overall, there was a marginal decrease in the mean pain score between the pre-intervention and the short term post-intervention pain intensities, but it was not significant (p=0.124), exceeding the 0.05 criteria. In summary, the mean pain intensity significantly decreased from the pre-intervention value immediately after the intervention, but then increased by time, although not reaching the pre-intervention intensity. See Table 7.0.

Wilcoxon Signed Ranks Test

	Mean Score	Sample Size	Std. Deviation	P-value
Pre-intervention pain intensity	4.29	63	1.818	0.000
Immediate post-intervention pain intensity	2.60	63	1.871	
Immediate post-intervention pain intensity	2.59	39	1.697	0.000
Short term post-intervention pain intensity	3.64	39	1.724	
Pre-intervention pain intensity	4.00	39	1.504	0.124
Short term post-intervention pain intensity	3.64	39	1.724	

Table 7.0 Tabulation of pain intensity data temporal comparison.

The discrepancy in sample size in Table 7.0 is also noteworthy. Unfortunately, only 61.9% of the total participants reported the short term post-intervention pain intensity due to unspecified reasons. This ultimately influenced sample representation.

4.3.3 The Immediate and Short Term Effects of TENS and TENS Placebo

The clinical effectiveness and significance of TENS was calculated by comparing the difference in mean pain intensity of TENS and TENS placebo. This was done for the difference between the pre-intervention and immediately post-intervention, as well as the pre-intervention and short term post-intervention time intervals. Both calculations were performed through the non-parametric Kruskal Wallis Test. The test's null hypothesis states that the decrease in the mean pain scores varies marginally between the treatment and placebo groups, and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the decrease in the mean pain scores varies significantly between the groups, and is accepted if the p-value is less than the 0.05 criteria.

There was a significant decrease (p=0.000) in the reduction in mean pain intensity scores of TENS against TENS placebo immediately post-intervention. Therefore, TENS set at described parameters can be identified as clinically significant at reducing neck pain immediately post-intervention. In contrast, there

was not a significant decrease (p=0.619) in the mean pain intensity scores of TENS against TENS placebo short term post-intervention. Hence, one can conclude that the analgesic effect was not transferable to the short term post-intervention mean duration. See Table 8.0.

Kruskal Wallis Test

	Modality	Sample Size	Mean Score	Std. Deviation	P-value
Reduction in mean pain intensity immediately post-intervention	TENS	21	2.38	1.532	.000
	TENS Placebo	10	-.10	.316	
Reduction in mean pain intensity short term post-intervention	TENS	11	.55	2.252	0.619
	TENS Placebo	21	-.10	.316	

Table 8.0 Tabulation of the immediate and short term effects of TENS and TENS placebo.

4.3.4 Immediate and Short Term Effects of HWB and HWB Placebo

The clinical effectiveness and significance of HWB was calculated by comparing the difference in mean pain intensity of HWB and HWB placebo. This was done for the difference between the pre-intervention and immediately post-intervention, as well as the pre-intervention and short term post-intervention time intervals. Both calculations were performed through the previously utilised non-parametric Kruskal Wallis Test.

There was a significant decrease (p=0.002) in the reduction in mean pain intensity scores of HWB against HWB placebo immediately post-intervention. Therefore, HWB set at described parameters can be identified as clinically significant at reducing neck pain immediately post-intervention. In contrast, there was not a significant decrease (p=0.537) in the mean pain intensity scores of HWB against HWB placebo short term post-intervention. Hence, one can conclude that the analgesic effect was not transferable to the short term post-intervention mean duration. See Table 9.0.

Kruskal Wallis Test

	Modality	Sample Size	Mean Score	Std. Deviation	P-value
Reduction in mean pain intensity immediately post-intervention	HWB	22	2.41	1.992	.002
	HWB Placebo	10	.40	.843	
Reduction in mean pain intensity short term post-intervention	HWB	12	.67	1.557	0.537
	HWB Placebo	6	.17	.408	

Table 9.0 Tabulation of the immediate and short term effects of HWB and HWB placebo.

4.3.5 Immediate and Short Term Effects of TENS and HWB

The clinical effectiveness and significance of TENS and HWB was calculated by comparing the difference in their mean pain intensity. This was done for the difference between the pre-intervention and immediately post-intervention, as well as the pre-intervention and short term post-intervention time intervals. Both

calculations were performed through the previously utilised non-parametric Kruskal Wallis Test.

HWB application provided a slightly higher decrease in pain intensity immediately post-intervention. Nonetheless, there was no significant difference (p=0.891) in the reduction of mean pain intensity scores of TENS against HWB immediately post-intervention. Therefore, TENS and HWB set at described parameters can be identified as equally effective in reducing neck pain immediately post-intervention. Similarly, HWB provided a slightly higher decrease in pain intensity short term post-intervention. Despite this, there was no significant difference (p=0.705) in the mean pain intensity scores of TENS against HWB short term post-intervention. This led to the conclusion that TENS and HWB are equally effective at reducing neck pain at set parameters, short term post-intervention. See Table 10.0.

Kruskal Wallis Test

	Modality	Sample Size	Mean Score	Std. Deviation	P-value
Reduction in mean pain intensity immediately post-intervention	TENS	21	2.38	1.532	.891
	HWB	22	2.41	1.992	
Reduction in mean pain intensity short term post-intervention	TENS	11	.55	2.252	.705
	HWB	12	.67	1.557	

Table 10.0 Tabulation of the immediate and short term effects of TENS and HWB.

4.3.6 Gender and Change in Pain Intensity

The reduction in mean pain intensity immediately and at short term post-intervention was compared against the gender categories, through the non-parametric Kruskal Wallis Test. The pain reduction between the genders was clinically significant (p=0.006) immediately post-intervention with males experiencing the largest improvement. The same trend was observed in the short-term post intervention but this change was not significant (p=0.633). See Table 11.0.

Kruskal Wallis Test

	Gender	Sample Size	Mean Score	Std. Deviation	P-value
Reduction in mean pain intensity immediately post-intervention	Male	18	2.72	1.965	0.006
	Female	45	1.27	1.615	
Reduction in mean pain intensity short term post-intervention	Male	11	.82	2.136	0.633
	Female	28	.18	1.124	

Table 11.0 Tabulation of the change in pain intensity with gender.

4.3.7 Age Groups and Change in Pain Intensity

The reduction in mean pain intensity immediately and at short term post-intervention was compared against the age groups, through the non-parametric Kruskal Wallis Test. The pain reduction between the age groups was not clinically significant immediately post-intervention (p=0.518) nor at the short-

term post intervention (p=0.886). Nonetheless, for both intervals 23 to 25 year olds experienced the greatest improvement, followed by 18 to 20 year olds, and 21 to 22 year olds. See Table 12.0.

Kruskal Wallis Test

	Age Group	Sample Size	Mean Score	Std. Deviation	P-value
Reduction in mean pain intensity immediately post-intervention	18-20 years	24	1.67	1.404	0.518
	21-22 years	25	1.36	1.578	
	23-25 years	14	2.29	2.701	
Reduction in mean pain intensity short term post-intervention	18-20 years	14	.36	1.082	0.886
	21-22 years	16	.19	1.109	
	23-25 years	9	.67	2.449	

Table 12.0 Tabulation of the change in pain intensity with age categories.

4.3.8 Pain Location and Change in Pain Intensity

The reduction in mean pain intensity immediately and at short term post-intervention was compared against the inherent pain locations, through the non-parametric Kruskal Wallis Test. The pain reduction between the pain locations immediately post-intervention was clinically significant (p=0.007), with those having midline pain experiencing the largest improvement. In contrast, at short term post-intervention the pain reduction between the pain locations was not clinically significant (p=0.717), with those having a LUBQ presentation experiencing the best improvement. See Table 13.0.

Kruskal Wallis Test

	Pain Location	Sample Size	Mean Score	Std. Deviation	P-value
Reduction in mean pain intensity immediately post-intervention	LBQ	4	3.25	.957	0.007
	LB	9	1.78	1.922	
	LRBQ	22	1.45	1.595	
	M	9	3.44	2.007	
	LUBQ	5	.40	.548	
	RUBQ	4	.50	1.000	
	RBQ	6	.33	1.633	
	Other	4	2.00	1.633	
Reduction in mean pain intensity short term post-intervention	LBQ	2	.00	2.828	0.717
	LB	8	.88	1.246	
	LRBQ	15	.13	.834	
	M	6	.83	2.787	
	LUBQ	2	1.00	1.414	
	RUBQ	4	-.25	.500	
	RBQ	2	-.50	2.121	

Table 13.0 Tabulation of the change in pain intensity with pain location.

4.3.9 Pain Duration and Change in Pain Intensity

The reduction in mean pain intensity immediately and at short term post-intervention was compared against the pain onset duration, through the non-parametric Kruskal Wallis Test. The pain reduction between the duration categories was clinically significant immediately post-intervention (p=0.023) and at the short-term post intervention (p=0.035). The highest pain reduction immediately post-intervention was seen in participants who had neck pain for 2 to 4 years, closely followed by those who had neck pain for more than 4 years. Alternatively in the short term, those with a neck pain onset longer than 4 years experienced the best improvement. See Table 14.0.

Kruskal Wallis Test

	Pain Duration	Sample Size	Mean Score	Std. Deviation	P-value
Reduction in mean pain intensity immediately post-intervention	0-1 year	21	.95	1.627	0.023
	1-2 years	11	1.18	1.601	
	2-4 years	15	2.40	1.724	
	More than 4 years	16	2.31	1.991	
Reduction in mean pain intensity short term post-intervention	0-1 year	10	-.10	.994	0.035
	1-2 years	8	-.50	.926	
	2-4 years	9	.22	1.302	
	More than 4 years	12	1.42	1.730	

Table 14.0 Tabulation of the change in pain intensity with pain duration.

4.3.10 QTFC Classification and Change in Pain Intensity

The reduction in mean pain intensity immediately and at short term post-intervention was compared against the participants' QTFC classification, through the non-parametric Kruskal Wallis Test. The pain reduction between the two grades immediately post-intervention was significant (p=0.025), with those at Grade 1 pain experiencing the largest improvement. In contrast, even though Grade 1 participants experienced higher improvement at short term, the pain reduction between the grades was not clinically significant (p=0.658). See table 15.0.

Kruskal Wallis Test

	QTFC Grade	Sample size	Mean Score	Std. Deviation	P-value
Reduction in mean pain intensity immediately post-intervention	1	16	2.44	1.590	0.025
	2	47	1.43	1.850	
Reduction in mean pain intensity short term post-intervention	1	11	.45	1.864	0.658
	2	28	.32	1.335	

Table 15.0 Tabulation of the change in pain intensity with QTFC classification.

4.4 Mean Short Term Analgesia Duration

The short term analgesic duration post-intervention was to be reported by the participants themselves, but unfortunately only 61.9% of the participants answered. Nonetheless, the duration for TENS interventions averaged to 33.7 hours, while that of TENS placebo was 0.1 hours. Additionally, the average short term analgesic duration for HWB interventions was 93.8 hours, while that of HWB placebo was 0.2 hours. Therefore, TENS provided analgesia for 35.9% of the duration HWB did.

4.5 Conclusion

The use of various statistical tools allowed for the results' analysis and consecutively their appropriate presentation as a figure and/or table. The obtained outcomes are discussed in the following chapter.

5. Discussion

5.1 Introduction

This chapter gives insight on the study's position within the pool of relevant literature and allows for the identification of potential hypotheses with regards to the outcomes.

5.2 Neck Pain Prevalence

The prevalence of neck pain in gender, age, and pain location presentation for the demographic is discussed below. It is to note that further factors were included in the results section, but were omitted due to limited literature and/or outcomes from the study's side, to allow for an adequate discussion.

5.2.1 Gender Prevalence

71.4% of the participants in the study were females experiencing neck pain. Ayanniyi and Mbada (2010), Chan et al. (2020), and Kanchanomai et al. (2011) featured students with a similar demographic to the study and their results were in correspondence, as they identified females to be the most susceptible to neck pain.

It can be hypothesised that the value acquired was due to the fact that females were more comfortable participating in the study, as women are usually more

likely to seek medical care for pain management (Raghavendra 2016). The physical difference between males and females may have also contributed to the discrepancy. Breast and adipose tissue are more developed in females, thus increasing their risk for neck pain, particularly upon physical exertion or when not wearing appropriate support (Mason et al. 1999, Rogliani et al. 2009).

5.2.2 Age Prevalence

Age and neck pain prevalence demonstrated a positive correlation in the study. Chan et al. (2020), and Kanchanomai et al. (2011) similarly identified an increase in neck pain with age.

It has been identified that the accumulative influence of students' study programmes increased their susceptibility to neck pain (Chan et al. 2020). Curriculum related tasks including prolonged computer use and repeated heavy lifting, such as in patient transfers, contributed to the risk for neck pain. The upkeep of such tasks is expected to further the pain (Chan et al. 2020).

5.2.3 Neck Pain Location Presentation Prevalence

Silva et al. (2009) identified prolonged neck forward flexion related neck pain to be located primarily on both sides of the neck, followed by midline, right sided, and left sided. The study's findings were not in congruence, as midline pain was

the most common location among the above listed locations, followed by right sided, and left sided pain. Furthermore, bilateral pain presentation was classified under “Others” due to its minimal predominance.

Forward head posture increases the compressive forces on the posterior aspects of the cervical apophyseal and vertebral joints, causes changes in connective tissue length and strength, and shortens the posterior neck muscles, ultimately resulting in neck pain (Silva et al. 2009). Therefore, it can be possibly implied that many students spend a long amount of time with a forward head posture, in neck extension, eliciting midline pain. Unilateral pain follows a similar pattern, but it also incorporates prolonged lateral flexion and/or rotation (Silva et al. 2009). This ties into the previous section as computer use for an extended amount of time is often linked with a forward head posture. It would be interesting to investigate if the participants’ neck pain location is linked to their usual computer setup; whether it is in front of them or at the side (Silva et al. 2009, Chan et al. 2020).

5.3 TENS Clinical Significance against Placebo

The study identified that conventional TENS set at a frequency of 100Hz, with a pulse width of 200μs, a normal wave type, and a comfortable amplitude for 20 minutes, significantly decreased the reduction in mean pain intensity immediately post-intervention when compared to TENS placebo. This was not

the case in the short term post-intervention as TENS did not provide significant segmental paraesthesia through non-noxious afferent neuron stimulation (Johnson 2007). Nonetheless, due to a difference in participant quantity, the statements' reliability is decreased. A systematic review by Martimbianco et al. (2019) was inconclusive when determining the short term effects of TENS's pain relief. Furthermore, Khadilkar et al. (2013) identified TENS not to be clinically effective against placebo when decreasing pain intensity, in contrast to Johnson (2007) who identified TENS to be effective and efficient at treating neck pain.

Apart from the use of current, or its absence, 2 differential factors between the two interventions were identified; the time at which the short term duration data was collected, and the participants' comfort and belief with regards to said modality. The duration of neck pain re-perception was not reported by a number of participants, ultimately influencing the short term results. Standardisation or close monitoring of participants' neck pain in future research might contribute to improved results. Furthermore, participants' comfort and belief with regards to said modality might influence the result. If participants, for example, were not familiar with the device and were afraid of the electrical component, negative outcomes are to be expected with TENS use (Leibowitz et al. 2019). The above factors could improve insight on the significance of the analgesic short term effects of TENS.

5.4 HWB Clinical Significance against Placebo

The study identified that a 20 minute application of HWB significantly decreased the reduction in mean pain intensity immediately post-intervention when compared to HWB placebo. In contrast, HWB did not significantly stimulate superficial mechanoreceptors and hence, did not stimulate afferent neurons to decrease pain through the pain gate mechanism, short term post-intervention. Nonetheless, due to a difference in participant quantity, the statements' reliability is decreased. In light of the limited literature availability regarding HWB applications for neck pain, studies by Chaudhuri et al. (2013) and Cramer et al. (2012) were used as a comparison. The first, used HWB for dysmenorrheic pain and it was significantly more effective than placebo. The latter used heat packs, which are structurally and functionally similar to HWB, for neck pain and obtained similar results. The available literature and the study's findings had varied views, particularly in the short term post intervention.

Apart from the use of heat, or its absence, 2 differential factors between the two interventions were identified. These were similar to those of TENS and its placebo; the time at which the short term duration data was collected, and the participants' comfort and belief with regards to said modality. The above factors could improve insight on the significance of the analgesic short term effects of HWB (Leibowitz et al. 2019).

5.5 HWB and TENS Pain Relief Effectiveness

The study did not identify a significant difference in TENS's and HWB's effectiveness towards decreasing neck pain immediately and short term post-intervention. Limited research comparing TENS's and HWB's effectiveness particularly for neck pain relief was found. Nevertheless, TENS was identified as superior to HWB when treating neck pain in Aker et al. (1996)'s systematic review and meta-analysis, while Chapman (1991) found them to be equally effective at chronic musculoskeletal pain management. Furthermore, van Middelkoop et al. (2010) had inconclusive results when comparing the modalities for lower back pain, and Cetin et al. (2008) stated that optimal results were achieved through an integrated approach, where TENS is followed by superficial heat in single use interventions for knee osteoarthritic pain.

Similarly to the available literature, this study did not determine one modality which is superior to the other. Firstly, as mentioned above, participants' previous experiences may have played a role (Leibowitz et al. 2019). Furthermore, both interventions have different effectiveness patterns, whereby the HWB cools down by time as heat dissipates to the body and to the environment (Hawkes et al. 2013). Meanwhile with TENS, based on participant reported sensation, the amplitude can be adjusted to optimise treatment intensity, in contrast to the degenerative intensity of HWB (Pantaleão et al. 2011). The final factor that should be considered is that the heat from the HWB may be positively influencing other issues in the area, such as decreased circulation and muscle

stiffness, gaining ulterior benefits to analgesia (Cramer et al. 2012). In contrast, this concept does not apply to TENS at set parameters (Johnson 2007).

5.6 Modalities' Influence on Participants' Gender and Age

The analgesic effect of the modalities on various personal and non-personal factors were investigated in the study. Unfortunately, only gender and age could be discussed due to limited outcomes from the study's side and/or literature to allow for an adequate discussion.

The study identified that males generally experienced a significant improvement immediately post-intervention, but this was insignificant short term post-intervention. In contrast, Lund et al. (2005)'s study featuring students with a similar age to the dissertation's, identified females to have a superior physiological response to TENS, rather than men.

Denegar et al. (2011) found that females were more likely to report improvements in pain following superficial heat for knee osteoarthritic pain. Additionally, Fillingim et al. (2009) identified that females have a higher sensitivity to pain, therefore although initially more females presented with pain, after treatment, the decrease in pain was also perceived as lower. These are possible reasons why such results have been obtained.

In the study no age group experienced a significant improvement immediately or short term post-intervention. Unfortunately, limited literature with a similar demographic or findings was identified, but Simon et al. (2015) found that older adults and younger individuals both experienced a similar decrease in pain intensity when treating chronic lower back pain with TENS.

Yezierski (2012) identified a positive relationship between pain sensitivity and age, therefore in older participants pain ratings are expected to be lower post-intervention. 20 young adults, 20 middle aged adults, and 20 older adults, with a mean age bracket of approximately 33 years participated in Yezierski (2012)'s study. In contrast, the study had an age bracket of 8 years, possibly leading to the difference in outcomes.

5.7 Conclusion

The above section aimed at providing an in-depth understanding of the research's results by linking it to pertinent literature. The existing research was also utilised to identify possible reasons to why such results were obtained.

6. Conclusion

6.1 Introduction

This chapter concludes the study by answering the research question and approving of a hypothesis. It also identifies the benefits of the study, describes the limitations and improvements, together with highlighting the needs and opportunities for future research.

6.2 Overview

The study's intent was to identify which, between TENS and HWB, would be ideal for the management of neck pain. It was identified that the affordable, practical, compact, portable, accessible, and safe devices allowed for significant immediate pain relief ($p=0.000$ and $p=0.002$, respectively), but no significant difference was seen between the two modalities ($p=0.891$). Meanwhile, limited evidence was available for the TENS's and HWB's short term analgesia ($p=0.619$ and $p=0.537$, respectively), and there was no significant difference between the two modalities ($p=0.705$). Therefore, to answer the research question, a superior modality between TENS and HWB could not be identified through this study. This also allows for the approval of a hypothesis from the three alternative hypotheses and the null hypothesis. The null hypothesis H0 "There is no significant difference between the modalities in terms of reduction in the immediate or short term pain intensities." was accepted, since the change in neck pain intensity immediately and short term post-intervention was not significantly different between TENS and HWB.

Furthermore, the non-pharmaceutical intervention provides a safe alternative with minimal side effects (Jones and Johnson 2009, Jabir et al. 2013). It also empowers users by providing the opportunity to self manage neck pain, giving them control over the unpleasant sensation. On a national level, the use of such devices can limit Malta's neck pain prevalence and disability adjusted life years, while positively influencing life-expectancy (*State of Health in the EU Malta Country Health Profile 2017* 2017, Safiri et al. 2020).

6.3 Benefits

The study provides a basis for the utilisation of TENS and HWB modalities; whereby it is suggested that the individual may use any modality for neck pain relief, unless contraindicated, as their immediate and short term effects are similar. The use of affordable, practical, compact and portable, accessible, and safe devices allow for non-invasive self pain management for students aged between 18 to 25 years old, whether in class or on campus.

Additionally, a better understanding of: the prevalence of neck pain in students, the immediate and short term analgesic effects of both TENS and HWB interventions, and the modalities' interaction with students' personal and non-personal factors, was gained through this study.

Furthermore, from an ethical point of view, participants who were deceived and unknowingly received placebo will gain clarity once the dissertation is published. Upon reading the dissertation, they can view the documentation regarding the placebo groups utilised, hence avoiding false ideations of TENS and HWB.

The study also provides an opportunity for further research, as in subtitle 6.5.

6.4 Limitations and Improvements

The discrepancy in the quantity of participants in the immediate and short term post-intervention groups limited the reliability of the short-term results. There are a myriad of potential reasons for which participants did not respond in the short term, including forgetfulness, decreased interest in study, and a prolonged analgesic effect which exceeded the data collection termination date. Monetary or otherwise incentives might have encouraged participants to complete the intervention fully.

Secondly, the fact that the duration for short term pain relief was not standardised may have contributed to the above limitation. An opt-in and opt-out system at set time intervals could have provided a better idea of the modalities' analgesic effects, eliminating potential forgetfulness related non-submission of

the analgesic duration. Furthermore, the non-standardised approach prevented further discussion of the results obtained.

Additionally, the intermediary selection limited the educational institution of attendance variety, which could have been an interesting factor to take into consideration. The utilisation of a multi-educational institute intermediary could have allowed for a better comparison among students from different institutes, as well as potentially allowing for quota achievement.

Restricted time and human resources have also negatively influenced quota achievement and the discrepancy in the quantity of participants between the immediate and short term post-intervention groups. Concurrently, the availability of insufficient and inadequate academic resources has also contributed to the use of some low relevance studies, together with limiting an in depth analysis of clinical findings.

Furthermore, the participants could have been asked for their active field of study, allowing for the identification of neck pain prevalence trends in different disciplines, if any.

6.5 Further Research

A large scale study with a satisfactory follow up could allow for a better understanding of the short term pain relief effects of TENS and HWB on chronic neck pain in 18 to 25 year old students. It might also be worthwhile to investigate the analgesic effect of TENS and HWB in different locations and demographics.

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List of Appendices

Appendix 1. Research Ethics & Data Protection (REDP) Form

UNIQUE FORM ID: 4674_25032020_Malcolm Camilleri

Ticked one or more self-assessment issues. Submitting to FREC for review.

L-Università ta' Malta

ETHICS & DATA PROTECTION

PART 1: APPLICANT AND PROJECT DETAILS

1. Name and surname: Malcolm Camilleri
Email Address: malcolm.camilleri.17@um.edu.mt
2. Applicant status: UM student
3. Faculty: Health Sciences
4. Department: Department of Physiotherapy

If applicable

5. Principal supervisor's name: Christopher Fenech
6. Co-supervisor's name:
7. Study-unit code: Bachelor of Science (Honours) in Physiotherapy - PHT4200
8. Student number: 387599M

9. Title of research project: A Comparative Study between the Short-term Pain Relief Effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in Neck Pain.
10. Research question/statement & method: Research question: When comparing Transcutaneous Electrical Nerve Stimulation to Hot Water Bottles, which modality can be identified as superior on the bases of immediate pain relief, and duration until pain is re-perceived?

Method: Participants who meet the inclusion and exclusion criteria will be assessed through the Neck Disability Index and WILDA Pain Assessment. These assessments will aid in the understanding of the participants' neck disability and pain, respectively. These will allow for the grading of such individuals through the Quebec Task Force Classification. Participants at Grade I and Grade II will be considered, as both Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles are ideal for mild to moderate neck pain. A digital randomiser will be used to prevent bias when selecting a treatment modality. Nonetheless, in the presence of contraindication to a specific modality an alternative treatment will then be provided. Transcutaneous Electrical Nerve Stimulation will be applied at a frequency of 100Hz, with a pulse width of 200µs, with a comfortable amplitude, and a normal wave type for 20 minutes. Alternatively, a Hot Water Bottle will be filled with hot water and be complemented with towels, allowing for a comfortably warm application. A twenty-minute application on the area of pain will be administered. Immediately after treatment a Numerical Rating Scale will be used to assess the participant's pain. The participant will then be dismissed from the venue. One will be asked to self-report though the applicant's University's email address, when neck pain is felt again.This will be done by performing a previously demonstrated Numerical Rating Scale. The results pre-treatment and post-treatment will then be tabulated and compared to each other through a visual aid. The above will be performed by the applicant, and overseen by the supervisor.

11. Collection of primary data from human participants?

UNIQUE FORM ID: 4674_25032020_Malcolm Camilleri

Ticked one or more self-assessment issues. Submitting to FREC for review.

Yes/Unsure (PLEASE ANSWER NEXT QUESTION)

12. If applicable, explain: 12a. The gatekeeper will open communications with thirty participants per modality, in addition to thirty participants for the control. In the control, fifteen will receive placebo Transcutaneous Electrical Nerve Stimulation with no dose, and fifteen will receive placebo Hot Water Bottle treatment with room temperature water instead of hot water. Therefore, a total of ninety participants will be involved in this study. These participants, aged between eighteen and twenty-five, must be students with neck pain caused by a maintained poor neck position, lasting or recurring for more than three months.

12b. "AssisThesis", a programme launched by Malta Health Students' Association (MHSA) will be used to reach students. Upon ethical clearance MHSA will be recontacted to announce a request for student volunteers. These potential participants will be put in contact with the applicant. Additionally, the University of Malta's Registrar has agreed to communicate the request for participants to all students at the University. Further communication with regards to date and time of the meeting will be at the discretion of the applicant, and the participants' preferred communication platform will meditate it.

12c. Apart from the criteria mentioned in the method (Question 10) the participants will be asked to dress in clothing that appropriately exposes the neck so that treatment can be applied, prior to the session. Information regarding gender, age, educational background, and medical history will be asked in the assessment. During the treatment the patients will be asked to lie in prone while receiving passive treatment, and will be asked to alert the applicant if complications arise.

12d. The participants will be expected to attend one session, which will take approximately thirty minutes; broken down into twenty minutes of treatment, and ten minutes of pre-treatment assessment and post-treatment assessment.

12e. The session will be free of charge, and no ulterior inducements/rewards/compensations will be provided.

12f. No direct benefit for the participants.

PART 2: SELF-ASSESSMENT

Human Participants

1. Risk of harm to participants: Yes or Unsure
2. Physical intervention:
3. Vulnerable participants:
4. Identifiable participants:
5. Special Categories of Personal Data (SCPD): Yes or Unsure
6. Human tissue/samples:
7. Withheld info assent/consent: Yes or Unsure
8. Opt-out consent/assent:
9. Deception in data generation: Yes or Unsure
10. Incidental findings:

UNIQUE FORM ID: 4674_25032020_Malcolm Camilleri
Ticked one or more self-assessment issues. Submitting to FREC for review.

Unpublished secondary data

11. Was the data collected from human participants?
12. Was the data collected from animals?
13. Is written permission from the data controller still to be obtained?

Animals

14. Live animals out of habitat:
15. Live animals, risk of harm:
16. Dead animals, illegal:

General considerations

17. Cooperating institution:
18. Risk to researcher/s:
19. Risk to environment:
20. Commercial sensitivity Yes or Unsure
21. Other potential risks:

Self-assessment outcome: Ticked one or more self-assessment issues. Submitting to FREC for review.

PART 3: DETAILED ASSESSMENT

1. Risk of harm to participants: i. Transcutaneous Electrical Nerve Stimulation and Hot Water Bottle treatments may pose the risk of burns, while the conductive gel used in Transcutaneous Electrical Nerve Stimulation treatment could cause an allergic reaction. In the case that either occurs, harm can not only occur physically, but may also effect one's psychosocial wellbeing.

ii. The risk of burns is unavoidable as this is a product of each modality being used. The non-use of the conductive gel will increase the risk of burns significantly, therefore it must be used in Transcutaneous Electrical Nerve Stimulation applications. Nonetheless, in the scenario that a burn takes place, cool water will be applied to the part, and if this does not suffice Luke Musu, a physiotherapist who has ensured free treatment for the purpose of this study, will be contacted.

iii. In the assessment, the patient will be asked questions regarding treatment, precautions, and contraindications so to minimise risk. In Hot Water Bottle applications, towels will be used to prevent direct heat exposure, and the skin under the Hot Water Bottle will be checked for redness, adjusting the number of towels accordingly. Prior to Transcutaneous Electrical Nerve Stimulation application the participant will be asked whether he/she is allergic to the conducting gel to prevent an allergic reaction. During treatment, the electrode is to be lifted periodically to check for skin redness or irritation, and the volume of gel present. In the scenario that any complications arise Luke Musu, a physiotherapist who has ensured free treatment for the purpose of this study, will be contacted.

UNIQUE FORM ID: 4674_25032020_Malcolm Camilleri

Ticked one or more self-assessment issues. Submitting to FREC for review.

2. Physical intervention on participants:
3. Vulnerable participants:
4. Identifiable participants:
5. Special Categories of Personal Data (sensitive personal data): Information regarding the participants' gender, age, educational background, medical history, and health status will be asked for so to determine whether they are suitable candidates for the study, and for later use in the data analysis.

Therefore, information regarding: race and ethnic origin, political opinions, religious and philosophical beliefs, trade union memberships, sex life or sexual orientation, genetic information, or biometric data that may uniquely identify a natural person will not be asked of the participant.

There will be no means that will allow the identification of the participant through the requested data, and vice versa. Participants' names will only be written on consent forms, and these similarly to other hard-copy material, will be kept in a locked cupboard by the applicant. Unless the supervisor and examiner need access for verification, only the applicant will have access to the uncoded data.
6. Collection of human tissue/samples:
7. Withholding information at consent/assent: i.The information letter will not inform the participants of the presence of control groups, therefore all participants will be expecting treatment.

ii.This information will not be disclosed to maintain the integrity of the treatment outcomes, and the validity of the placebo.

iii. The participants will not be given the above information at any time during the research.
8. Opt-out consent/assent:
9. Deception in data generation: i.During data collection, the participants receiving placebo Hot Water Bottle treatment will not be told that the water in the hot water bottle is at room temperature. Similarly, participants receiving placebo Transcutaneous Electrical Nerve Stimulation treatment will not be told that there is no dose.

ii.The presence of a control through placebo is essential so to identify whether the pain relief is due to the treatment applications, or other variables.Therefore, the placebo together with the deception it brings along with it are essential to validate each modality.

iii. The information might be important to the participants in the placebo cohorts, as the session may develop a false idea that the treatment does not work, when in fact they had not received any. Nonetheless, after finishing my dissertation the information will be available publicly and one can inform himself/herself regarding the matter. In contrast, the information would not be as important to participants in the treatment cohorts.

iv. The explanation for either modalities will be the same as its placebo counterpart, and if the application is queried the set up will be adjusted slightly so to try deceive him/her.
10. Incidental findings:
11. Unpublished secondary data - human participants :
12. Unpublished secondary data - animals:
13. Unpublished secondary data - no written permission from data controller:
14. Lasting harm to animals out of natural habitat:

UNIQUE FORM ID: 4674_25032020_Malcolm Camilleri

Ticked one or more self-assessment issues. Submitting to FREC for review.

15. Risk of harm to live animals :
16. Use of non legal animals/tissue:
17. Permission from cooperating institution:
18. Risk to researcher/team:
19. Risk of harm to environment:
20. Commercial sensitivity: i. WILDA Pain Assessment - A pain assessment that will be used to get qualitative and quantitative data with regards to the participants' neck pain.
ii. Access has been give to the applicant from the author Prof Regina Fink

i. Neck Disability Index - A neck disability assessment that will be used to classify the level of disability experienced by participants due to neck pain.
ii. The author Dr Howard Vernon confirmed that the study is free for any unfunded research, and it was accessed through ePROVIDE as suggested.

i. Quebec Task Force Classification - A classification system which takes into consideration neck pain and disability, used to classify participants.
ii. The article Pastakia, K. and Kumar, S., 2011. Acute whiplash associated disorders (WAD). Open Access Emergency Medicine, 3, pp.29-32. is open access.

i. Numerical Rating Scale - A pain assessment that measures the intensity of the participants' neck pain.
ii. The article Aziato, L., Dedey, F., Marfo, K., Asamani, J. and Clegg-Lamptey, J., 2015. Validation of three pain scales among adult postoperative patients in Ghana. BMC Nursing, 14(42), pp.1-9. is open access.
21. Other issues
    - 21a. Dual use and/or misuse:
    - 21b. Conflict of Interest:
    - 21c. Dual role:
    - 21d. Use research tools:
    - 21e. Collaboration/data/material collection in low/lower-middle income country:
    - 21f. Import/export of records/data/materials/specimens:
    - 21g. Harvest of data from social media:
    - 21h. Other considerations:

PART 4: SUBMISSION

1. Which FREC are you submitting to? : Health Sciences
2. Attachments: Information and recruitment letter*, Consent forms (adult participants)*, Data collection tools (interview questions, questionnaire etc.), Data Management Plan, Letter granting institutional approval for access to participants, Other (please specify in remarks below)
3. Cover note for FREC :
4. Declarations: I hereby confirm having read the University of Malta Research Code of Practice and the University of Malta Research Ethics Review Procedures., I hereby confirm that the answers to the questions above reflect the contents of the research proposal and that the information provided above is truthful., I hereby give consent to the University Research Ethics Committee to process my personal data for the purpose of evaluating my request, audit and other matters related to this application. I understand that I have a right of access to my personal data and to obtain the rectification, erasure or restriction of

UNIQUE FORM ID: 4674_25032020_Malcolm Camilleri

Ticked one or more self-assessment issues. Submitting to FREC for review.

processing in accordance with data protection law and in particular the General Data Protection Regulation (EU 2016/679, repealing Directive 95/46/EC) and national legislation that implements and further specifies the relevant provisions of said Regulation.

5. Applicant Signature: MALCOLM CAMILLERI
6. Date of submission: 25032020
7. If applicable data collection start date:
8. E-mail address (Applicant): malcolm.camilleri.17@um.edu.mt
9. E-mail address (Principal supervisor): cfene03@um.edu.mt
10. Conclude: Proceed to Submission

Appendix 2. Participants' Information Sheet - English Version

Participants` Information Sheet

Dear Participant,

My name is Malcolm Camilleri and I am currently reading for a Bachelor of Science (Honours) in Physiotherapy at the University of Malta. As part of my course requirements I am conducting a research study entitled," A comparative study between the short-term pain relief effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in neck pain". The aim of this study is to compare the alleviative effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles on neck pain caused by endured poor neck position in students. Although precautions will be taken, there will still be the risk of burns and an allergic reaction due to the conduction gel used in the Transcutaneous Electrical Nerve Stimulation application. Therefore, in the event that you experience such injuries or are distressed due to participation in this study, the physiotherapist Luke Musu will remedy and treat accordingly at no financial cost. Furthermore, only data relevant to the research will be asked for and the data collected shall be used solely for the purpose of this study.

You are being invited to participate in a study which will identify which compact modality could provide students more effective pain relief when it comes to pain self-management. If you agree to participate, you will meet the researcher once, at Room 9 Electrotherapy Laboratory, at the Faculty of Health Sciences, Mater Dei Hospital for approximately 30 minutes, at a date, and time suitable for you.

During the visit I, as the researcher will:

- Ask you questions such as your gender, age, educational background, and medical history.
- Apply Transcutaneous Electrical Nerve Stimulation or Hot Water Bottle treatment.
- Measure the change in neck pain before and after treatment through a Numerical Rating Scale, as well as measure the duration until neck pain is reperceived.

You are not obliged to participate in this study or to answer all the questions and you may withdraw from the study at any time without giving a reason. Furthermore, withdrawal from the study will not have any negative repercussions on you and any data collected will be erased. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in any publications, reports or presentations arising from this research. All data collected will be pseudonymised meaning that the data will be assigned codes and that this data will be stored securely and separately from any codes and personal data. Uncoded data will only be available in hard copy and will be stored in a locked cupboard until results are published. This data may only be accessed by the researcher. The academic supervisor and the examiners will have access to coded data only, unless the need for verification arises. Any material in hard-copy form will be placed in a locked cupboard and kept until results are published.

There is no direct benefit related to volunteering for this dissertation. Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning you to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

Thank you for your time and consideration. Should you want to participate, or have any questions or concerns do not hesitate to contact me 79290404 or by e-mail malcolm.camilleri.17@um.edu.mt or my supervisor Christopher Fenech on christopher.fenech@gov.mt or 22761824

Yours Sincerely,

Malcolm Camilleri

Researcher

Christopher Fenech

Research Supervisor

Appendix 3. Participants' Information Sheet - Maltese Version

Formula ta' Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jien Malcolm Camilleri , fil-preżent qed nistudja biex ikolli grad fil-Baċċellerat tax-Xjenza (bl-Unuri) fil-Fiżjoterapija. Bħala parti mir-rekwiżiti tal-kors, qed nagħmel riċerka bit-titlu, "A comparative study between the short-term pain relief effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in neck pain". L-għan ta' dan l-istudju hu li ninvestiga l-effett ta' Transcutaneous Electrical Nerve Stimulation u Hot Water Bottles b'enfasi fuq kemm itaffu l-uġieħ fl-għonq, ikkawżat minn pożizzjoni ħazina tal-għonq li giet miżmuma għal ħin twil f'demografika studenteska. Minkejja li prekawzjonijiet se jittieħdu, dan it-trattament iġib miegħu r-riskju ta' ħruq u reazzjoni alleġika għall-ġel konduttiv użat fit-trattament tal-Transcutaneous Electrical Nerve Stimulation. F'każ li tħoss li l-istudju ħoloqlok diffikultà u, il-fiżjoterapist Luke Musu se jkun qed jipprovdi trattament u servizz ta' għajnuna mingħajr ħlas. Kull informazzjoni mitluba, kif ukoll miġbura ħa tintuża biss għall-għan ta' dan l-istudju.

Bħala parteċipant/a inti se tintalab tieħu sehem f'dan l-istudju sabiex ninvestigaw liema modalita' tista' jipprovdi l-aħjar serħan mill-uġieħ, b'rigward speċjali għat-terapija li wieħed jista' jamministra b'mod indipendenti fuqu nnifsu. Jekk taċċetta li tieħu sehem inti tintalab sabiex tiltaqa' darba mar-riċerkatur Malcolm Camilleri, ġewwa Kamra 9, Electrotherapy Laboratory, fil-Fakulta tal-Health Sciences, fl-isptar Mater Dei, f'data u ħin li jkun konvenjenti għalik. Din il-laqgħa se tieħu madwar 30 minuta.

Waqt din il-laqgħa jien ħa:

- Nistaqsi xi mistoqsijiet dwarek, bħal sess, l-età tiegħek, informazzjoni dwar l-edukazzjoni u xi mistoqsijiet dwar is-saħħa tiegħek.
- Napplika trattament ta' Transcutaneous Electrical Nerve Stimulation jew Hot Water Bottle.
- Inkejjel il-bidla fl-uġieħ qabel u wara it-trattament bl-użu ta' Numerical Rating Scale, kif ukoll inkejjel kemm idum biex jerġa jinħass l-uġieħ.

M'intix obbligat/a li twieġeb il-mistoqsijiet kollha u tista' twaqqaf l-istudju fi xħin trid mingħajr ma tagħti l-ebda raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqek u l-informazzjoni li tinġabar mingħandek titħassar. Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek u kull informazzjoni personali miġbura mhumiex se jiġu żvelati mkien fit-teżi, ir-rapporti, il-preżentazzjonijiet u/jew il-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Kull tagħrif miġbur se jiġi psewdonomizzat, jiġifieri id-data kollha se tkun protetta permezz ta' sistema ta' kodiċi u miżmuma separatament mill-informazzjoni personali. Informazzjoni personali se tkun stampata u se tinżamm f'kexxun misakkar sakemm joħroġ ir-riżultat. Ir-Riċerkatur biss ser ikollu aċċess għall-informazzjoni miġbura. Is-Superviżur akkademiku u l-

eżaminaturi se jkollhom biss aċċess għal data kodifikata, sakemm ma jkunx hemm bżonn ta' verfikazzjon. Barra minn hekk, il-materjal stampat se jinqafel f'post sigur u se tinżamm f'kexxun misakkar sakemm joħroġ ir-riżultat.

Dan l-istudju ma fieħ l-ebda benefiċċju dirett għall-parteċipant. Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma jkun hemm konsegwenzi fil-konfront tiegħek. Se tingħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex tkun tista' taċċessahom fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-data li tikkonċerna lilek. L-informazzjoni personali kollha se titħassar hekk kif jintemm dan l-istudju ta' riċerka u jkunu ppubblikati r-riżultati miksuba.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li ktun tixtieq tipparteċipa, jew jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq 79290404 jew tibgħatli email fuq malcolm.camilleri.17@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżur Christopher Fenech fuq 22761824 jew billi tibgħat email fuq christopher.fenech@gov.mt

Dejjem tiegħek,

Malcolm Camilleri
Ir-Riċerkatur

Christopher Fenech
Is-Superviżur tar-Riċerka

Appendix 4. Participants' Consent Form - English Version

Participants` Consent Form

A comparative study between the short-term pain relief effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in neck pain.

I, the undersigned, give my consent to take part in the study conducted by Malcolm Camilleri. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in a study, in which the researcher will ask questions and perform a test to identify which modality between Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles offers superior alleviative effects on neck pain caused by endured poor neck position in students
3. I am aware that the meeting will take approximately 30minutes. I understand that the meeting is to be conducted at Room 9 Electrotherapy Laboratory, at the Faculty of Health Sciences, Mater Dei Hospital and at a time that is convenient for me.
4. I am aware that the data collected will be coded and that this data will be stored securely and separately from any codes and personal data.
5. I am aware that the researcher is the only person who has access to this data. The academic supervisor and examiners will have access to coded data only, unless verification is required.
6. I am also aware that the any material in hard-copy form will be placed in a locked cupboard and kept until results are published.
7. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research. Uncoded data will only be available in hard copy, and will therefore be stored in a locked cupboard and kept until results are published.
8. I also understand that I am free to accept, refuse or stop participation at any time without giving any reason. This will have no negative repercussions on myself and that any data collected form me will be erased.
9. I also understand that my contribution will serve to the identify which of the two modalities offers superior pain relief, allowing students to manage their own neck pain when necessary.
10. Both, Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles may pose the risk of burns, while in Transcutaneous Electrical Nerve Stimulation conductive gel allergies could also be of risk. Therefore, if I experience distress or an injury as a result of participation in this study, the physiotherapist Luke Musu will remedy and treat accordingly, at no financial cost.

11. I understand that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
12. I also understand that once the study is completed and results are published the data will be retained in anonymous form. Any personal details will be destroyed.
13. I will be provided with a copy of the information letter and consent form for future reference.
14. I am aware that there is no direct benefit to participating in this dissertation.
15. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Thank you for your time and consideration. Should you want to participate, or have any questions or concerns do not hesitate to contact me 79290404 or by e-mail malcolm.camilleri.17@um.edu.mt or my supervisor Christopher Fenech on christopher.fenech@gov.mt or 22761824

Participant: _____

Signature: _____

Date: _____

Malcolm Camilleri

Researcher

Christopher Fenech

Research Supervisor

Appendix 5. Participants' Consent Form - Maltese Version

Formula ta' Kunsens tal-Parteċipanti

A comparative study between the short-term pain relief effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in neck pain.

Jien, hawn taħt iffirmat/a, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi minn Malcolm Camilleri. L-għan ta' dan id-dokument hu li jiġu speċifikati t-termini tal-parteċipazjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li se nkun qed nipparteċipa fi studju, fejn ir-Riċerkatur ħa jinvestiga l-effett ta' Transcutaneous Electrical Nerve Stimulation u Hot Water Bottles b'enfasi fuq kif itaffu l-uġieħ fl-għonq, ikkawżat minn pożizzjoni ħazina tal-għonq li giet miżmuma għal ħin twil f'demografika studenteska.
3. Naf li l-istudju se jieħu madwar 30 minuta. Nifhem, li l-laqgħa se ssir ġewwa Kamra 9, Electrotherapy Laboratory, fil-Fakulta tal-Health Sciences, fl-isptar Mater Dei, u ħin konvenjenti għalija.
4. Naf ukoll li se ssir kodifikazzjoni tad-data u din se tinżamm separatament mill-informazzjoni personali.
5. Naf ukoll li r-Riċerkatur hu l-uniku persuna li se jkollu aċċess għal din l-informazzjoni. Is-Superviżur akkademiku u l-eżaminaturi se jkollhom aċċess għal data kkodifikata biss, sakemm ma jkunx hemm bżonn ta' verifikazzjoni.
6. Barra minn hekk, naf li l-materjal stampat se jitqiegħed f'post sikur u se jinżamm sakemm joħorġu r-riżultati, dan jinkludi informazzjoni personali li se tkun stampata.
7. Naf li l-identità tiegħi u l-informazzjoni personali mhuma se jinkixfu mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u/jew fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha.
8. Nifhem ukoll li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni f'kull ħin bla ma nagħti raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqi. Nifhem ukoll li la darba nirtira minn dan l-istudju, l-informazzjoni miġbura titħassar.
9. Nifhem ukoll li l-kontribuzzjoni tiegħi ser isservi biex tidentifika liema modalita' toffri l-aħjar serħan mill-uġieħ, b'rigward speċjali għat-terapija li wieħed jista' jamministra b'mod indipendenti fuqu nnifsu.
10. It-trattamenti tat-Transcutaneous Electrical Nerve Stimulation u Hot Water Bottles, joffru ir-riskju ta' ħruq, filwaqt li il-gel użat f'Transcutaneous Electrical Nerve Stimulation jista' jikkawza xi allerġiji. F'każ li tħoss li l-istudju ħoloqlok diffikultà u, il-fiżjoterapist Luke Musu se jkun qed jipprovdi trattament u servizz ta' għajnuna mingħajr ħlas.
11. Nifhem ukoll, li skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika nitlob sabiex titħassar id-data li tikkonċernani.

12. Naf ukoll li meta jintemm l-istudju u r-riżultati jkunu ppubblikati, l-informazzjoni personali miġbura titħassar.
13. Fl-aħħar nett, naf ukoll li se ningħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex inkun nista' naċċessahom fil-futur.
14. Jien naf li m'hemm l-ebda benefiċċju dirett relatat mal-parteċipazzjoni tiegħi f'dan l-istudju.
15. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formula. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li ktun tixtieq tipparteċipa, jew jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq 79290404 jew tibgħatli email fuq malcolm.camilleri.17@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżur Christopher Fenech fuq 22761824 jew billi tibgħat email fuq christopher.fenech@gov.mt

Parteċipant:_____

Firma:_____

Data:_____

Firma: _____

Data: _____

Isem ir-Riċerkatur: Malcolm Camilleri

Firma: _____

Data: _____

Isem is-Superviżur tar-riċerka: Christopher Fenech

Appendix 6. Emergency Contact Evidence

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>

Re: [EXTERNAL] - Dissertation Participant Safeguard
2 messages

Musu Luke at Rehabilitation Services-Health <luke.musu@gov.mt> 27 April 2020 at 19:41

To: Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>
Cc: "chrisfenech@gmail.com" <chrisfenech@gmail.com>

Dear Malcolm,

Further to your email I can confirm that It will not be a problem to review and treat any patients who may have any adverse effects to the treatment provided.

Should you need me to see any patients just advise beforehand and I will see them at the earliest availability I have.

Kind regards

Luke Musu`
Physiotherapist
Health-Rehabilitation Services
Primary Healthcare

e luke.musu@gov.mt

MI
ST LUKE'S HOSPITA

From: Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>
Sent: 27 April 2020 19:33:57
To: Musu Luke at Rehabilitation Services-Health
Cc: hrisfenech@gmail.com
Subject: [EXTERNAL] - Dissertation Participant Safeguard

Dear Mr Musu,

Good afternoon, I hope this email finds you well.

I am a third year BSc. (Hons) Physiotherapy student at the University of Malta, and am currently in the process of writing my ethics form for my dissertation "A comparative study between the short-term pain relief effects of Transcutaneous electrical nerve stimulation and Hot Water Bottles in neck pain".

In the scenario that any injury or distress arises during the sessions, I would like to have a safeguard for the participants. Would it be possible for you to offer your services to cover such scenarios free of charge?

Best regards,
Malcolm Camilleri

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt> 27 April 2020 at 20:39
To: Musu Luke at Rehabilitation Services-Health <luke.musu@gov.mt>
Cc: "chrisfenech@gmail.com" <chrisfenech@gmail.com>

Dear Mr Musu,

Your acknowledgement and contribution to my studies are highly appreciated.
Thanks and have a great evening!

Best wishes,
Malcolm Camilleri
[Quoted text hidden]

Appendix 7. Data Management Sheet

Data Management Sheet

A comparative study between the short-term pain relief effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in neck pain.

Participant Code:

Inclusion Criteria

Participant Age:
Participant Sex:
Student at:
Neck pain for ≥ 12weeks:

Exclusion Criteria

1. If any of the below conditions are present, participant is contraindicated to Transcutaneous Electrical Nerve Stimulation and Hot Water Bottle treatment.

Condition	**Tick if applicable**		**Tick if applicable**
Fibromyalgia		Shoulder Subluxation	
Trauma Related Neck Pain		Cancer in the Head, Neck or Shoulders	
Using pharmaceutical analgesics		Surgery within the last 5 months at Head, Neck or Shoulders	
Impaired skin sensation		Rheumatoid Arthritis	
Local dermatological lesions		Cervical Spondylolisthesis	
Metal implants in the area of proximity		Cervical Osteoarthritis	
Other:			

2. If any of the below conditions are present, participant is contraindicated to Transcutaneous Electrical Nerve Stimulation treatment.

Condition	**Tick if applicable**		**Tick if applicable**
Artificial cardiac pacemaker		Hearing aid	
Implantable cardioverter defibrillator		Conducting Gel Allergy	
Other:			

3. If any of the below conditions are present, participant is contraindicated to and Hot Water Bottle treatment.

Condition	**Tick if applicable**		**Tick if applicable**
Peripheral Vascular Disease		Deep Vein Thrombosis	
Implantable cardioverter defibrillator		Aneurysm	
Other:			

4. If any of the below conditions are present, precaution is to be used when applying Transcutaneous Electrical Nerve Stimulation or Hot Water Bottle.

Condition	**Tick if applicable**		**Tick if applicable**
Cognitive Restrictions		Epilepsy (exclusively for Transcutaneous Electrical Nerve Stimulation)	
Other:			

WILDA Assessment

Required Information	**Participant Answer**
Words to describe pain	
Pain intensity now, if 0 is no pain and 10 is the worst pain imaginable	
Pain intensity in the past 24 hours, if 0 is no pain and 10 is the worst pain imaginable	
Pain location	
Pain duration	
Pain constant or recurring	
Aggravating Factors	
Alleviating Factors	
Any other symptoms	

UNIVERSITY of COLORADO HEALTH

Pain Assessment Guide

Tell Me About Your Pain

W Words to describe pain (discomfort)

Somatic	*Visceral*	*Neuropathic*
aching	crampy	numb
dull	gnawing	burning
throbbing	deep	radiating
sharp	squeezing	shooting
stabbing	pressure	electrical
sore	stretching	tingling
penetrating	bloated	pins & needles

Pain in Other Languages

Japanese - itami	Spanish - dolor	Croatian-Bosnian - bol
Chinese - tong	French - douleur	Arabic - ألم
Vietnamese - dau	Russian - bolno	Ethiopian - amonyal

I Intensity (0-10)

If 0 is no pain and 10 is the worst pain possible, what is your pain now?
....at rest? .....with movement? ...
In the last 24 hours what was your least pain? ...worst? ... average?
What is your comfort-function goal?

L Location

Where is your pain?

D Duration

Is the pain constant? ...intermittent? .....both types?

A Aggravating and Alleviating Factors

What makes the pain worse? ...better?

How does the pain affect:

activity	energy	relationships	appetite
function	sleep	mood	

Are you experiencing medication side effects?

nausea/vomiting	drowsiness	itching	urinary retention
sleepiness	constipation	confusion	dizziness

Things to Check

vital signs, response to past medication/treatment, substance abuse history
use of nonpharmacologic techniques, chronic pain history

Neck Disability Index Assessment

Neck Disability Index

THIS QUESTIONNAIRE IS DESIGNED TO HELP US BETTER UNDERSTAND HOW YOUR **NECK PAIN** AFFECTS YOUR ABILITY TO MANAGE EVERYDAY -LIFE ACTIVITIES. PLEASE MARK IN EACH SECTION THE **ONE BOX** THAT APPLIES TO YOU.
ALTHOUGH YOU MAY CONSIDER THAT TWO OF THE STATEMENTS IN ANY ONE SECTION RELATE TO YOU, PLEASE MARK THE BOX THAT **MOST CLOSELY** DESCRIBES YOUR PRESENT -DAY SITUATION.

SECTION 1 - PAIN INTENSITY

- ❑ I have no neck pain at the moment.
- ❑ The pain is very mild at the moment.
- ❑ The pain is moderate at the moment.
- ❑ The pain is fairly severe at the moment.
- ❑ The pain is very severe at the moment.
- ❑ The pain is the worst imaginable at the moment.

SECTION 2 - PERSONAL CARE

- ❑ I can look after myself normally without causing extra neck pain.
- ❑ I can look after myself normally, but it causes extra neck pain.
- ❑ It is painful to look after myself, and I am slow and careful.
- ❑ I need some help but manage most of my personal care.
- ❑ I need help every day in most aspects of self -care.
- ❑ I do not get dressed. I wash with difficulty and stay in bed.

SECTION 3 – LIFTING

- ❑ I can lift heavy weights without causing extra neck pain.
- ❑ I can lift heavy weights, but it gives me extra neck pain.
- ❑ Neck pain prevents me from lifting heavy weights off the floor but I can manage if items are conveniently positioned, ie. on a table.
- ❑ Neck pain prevents me from lifting heavy weights, but I can manage light weights if they are conveniently positioned.
- ❑ I can lift only very light weights.
- ❑ I cannot lift or carry anything at all.

SECTION 4 – READING

- ❑ I can read as much as I want with no neck pain.
- ❑ I can read as much as I want with slight neck pain.
- ❑ I can read as much as I want with moderate neck pain.
- ❑ I can't read as much as I want because of moderate neck pain.
- ❑ I can't read as much as I want because of severe neck pain.
- ❑ I can't read at all.

SECTION 5 – HEADACHES

- ❑ I have no headaches at all.
- ❑ I have slight headaches that come infrequently.
- ❑ I have moderate headaches that come infrequently.
- ❑ I have moderate headaches that come frequently.
- ❑ I have severe headaches that come frequently.
- ❑ I have headaches almost all the time.

SECTION 6 – CONCENTRATION

- ❑ I can concentrate fully without difficulty.
- ❑ I can concentrate fully with slight difficulty.
- ❑ I have a fair degree of difficulty concentrating.
- ❑ I have a lot of difficulty concentrating.
- ❑ I have a great deal of difficulty concentrating.
- ❑ I can't concentrate at all.

SECTION 7 – WORK

- ❑ I can do as much work as I want.
- ❑ I can only do my usual work, but no more.
- ❑ I can do most of my usual work, but no more.
- ❑ I can't do my usual work.
- ❑ I can hardly do any work at all.
- ❑ I can't do any work at all.

SECTION 8 – DRIVING

- ❑ I can drive my car without neck pain.
- ❑ I can drive my car with only slight neck pain.
- ❑ I can drive as long as I want with moderate neck pain.
- ❑ I can't drive as long as I want because of moderate neck pain.
- ❑ I can hardly drive at all because of severe neck pain.
- ❑ I can't drive my car at all because of neck pain.

SECTION 9 – SLEEPING

- ❑ I have no trouble sleeping.
- ❑ My sleep is slightly disturbed for less than 1 hour.
- ❑ My sleep is mildly disturbed for up to 1-2 hours.
- ❑ My sleep is moderately disturbed for up to 2-3 hours.
- ❑ My sleep is greatly disturbed for up to 3-5 hours.
- ❑ My sleep is completely disturbed for up to 5-7 hours.

SECTION 10 – RECREATION

- ❑ I am able to engage in all my recreational activities with no neck pain at all.
- ❑ I am able to engage in all my recreational activities with some neck pain.
- ❑ I am able to engage in most, but not all of my recreational activities because of pain in my neck.
- ❑ I am able to engage in only a few of my recreational activities because of neck pain.
- ❑ I can hardly do recreational activities due to neck pain.
- ❑ I can't do any recreational activities due to neck pain.

CODE _____ DATE _____

SCORE _____ [50]

Score	Disability Level	Disability Level According to Score
0-4	No Disability	
5-15	Mild Disability	
15-24	Moderate Disability	
25-34	Severe Disability	
>34	Complete Disability	

The Quebec Task Force Classification

Grade	Description	Participant Status
Grade 0	No complaints about the neck. No physical sign(s).	
Grade I	Neck complaint of pain, stiffness or tenderness only. No physical sign(s).	
Grade II	Neck complaint AND musculoskeletal sign(s). Musculoskeletal signs include decreased range of motion and point tenderness.	
Grade II	Neck complaint AND neurological sign(s). Neurological signs include decreased range of motion and point tenderness.	
Grade IV	Neck complaint AND fracture or dislocation.	

Grade 0: No complaints about the neck. No physical sign(s).

Grade I: Neck complaint of pain, stiffness or tenderness only. No physical sign(s).

Grade II: Neck complaint AND musculoskeletal sign(s). Musculoskeletal signs include decreased range of motion and point tenderness.

Grade III: Neck complaint AND neurological sign(s). Neurological signs include decreased range of motion and point tenderness.

Grade IV: Neck complaint AND fracture or dislocation.

Randomiser Mediated Intervention Selection

Intervention Options	Tick the Randomised Intervention	Proceed to Section
Transcutaneous Electrical Nerve Stimulation Treatment		Treatment A.
Hot Water Bottles Treatment		Treatment B.
Transcutaneous Electrical Nerve Stimulation Placebo		Treatment C.
Hot Water Bottle Placebo		Treatment D.

Treatment A. Instructions and Information

1. Would you be comfortable receiving a Transcutaneous Electrical Nerve Stimulation application, as per the information letter?
2. The application features two pairs of electrodes which produce currents. These will be set up in a manner so as to allow the currents to cross over the painful area, producing local pain relief. The parameters to be used are, a frequency of 100Hz, a pulse width of 200μs, a comfortable amplitude, a normal wave type, and a duration of 20 minutes, do you consent to this application?
3. Could you expose your neck as much as possible, within your comfortability?
4. Can you lie down in prone on the plinth, please?
5. I will be setting up the Transcutaneous Electrical Nerve Stimulation application, during this time feel free to make yourself comfortable and relax.
6. I am placing the electrodes on you neck, they should feel cool and wet due to the conducting gel.
7. I am increasing the amplitude, kindly tell me when the it feels is comfortable so that I will stop increasing it.
8. I will be leaving the application on for 20 minutes, but I will come check the skin under the electrodes at instances to check for signs of burns. Kindly inform me if the amplitude becomes too low or too high so that I can adjust it accordingly.
9. The 20 minutes have passed, and the treatment is done.
10. Feel free to get off the plinth and cover you neck again so that we can proceed to the Numerical Rating Scale Assessment.

Treatment B. Instructions and Information

1. Would you be comfortable receiving a Hot Water Bottle application, as per the information letter?
2. The application features a Hot Water Bottle, or two if necessary. It will be filled with hot water and be complemented with towels to prevent burns. A twenty-minute comfortably warm application on the area of pain would be administered, if you consent.
3. Could you expose your neck as much as possible, within your comfortability?
4. Can you lie down in prone on the plinth, please?
5. I will be setting up the Hot Water Bottle application, during this time feel free to make yourself comfortable and relax.
6. I am placing the towels and Hot Water Bottle on you neck.
7. I will come check the skin under the Hot Water Bottle at instances to check for signs of burns, but if you feel that the application is very hot or not warm enough kindly notify me so to adjust the towels.
8. The 20 minutes have passed, and the treatment is done.
9. Feel free to get off the plinth and cover you neck again so that we can proceed to the Numerical Rating Scale Assessment.

Treatment C. Instructions and Information

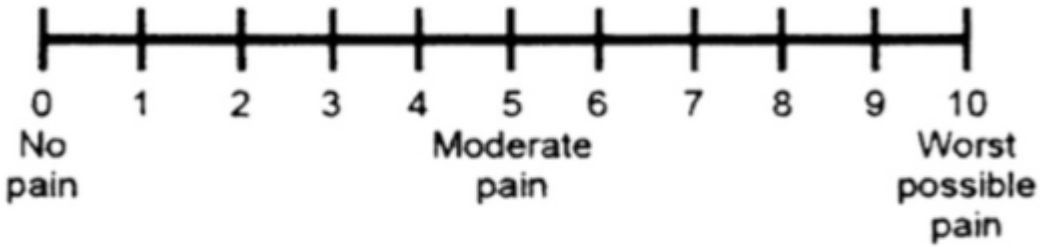
1. Would you be comfortable receiving a Transcutaneous Electrical Nerve Stimulation application, as per the information letter?
2. The application features two pairs of electrodes which produce currents. These will be set up in a manner so as to allow the currents to cross over the painful area, producing local pain relief. The parameters to be used are, a frequency of 100Hz, a pulse width of 200μs, a comfortable amplitude, a normal wave type, and a duration of 20 minutes, do you consent to this application?
3. Could you expose your neck as much as possible, within your comfortability?
4. Can you lie down in prone on the plinth, please?
5. I will be setting up the Transcutaneous Electrical Nerve Stimulation application, during this time feel free to make yourself comfortable and relax.
6. I am placing the electrodes on you neck, they should feel cool and wet due to the conducting gel.
7. I am increasing the amplitude to a comfortable level.
8. I will be leaving the application on for 20 minutes, but I will come check the skin under the electrodes at instances to check for signs of burns. Kindly inform me if the amplitude becomes too low or too high so that I can adjust it accordingly.
9. The 20 minutes have passed, and the treatment is done.
10. Feel free to get off the plinth and cover you neck again so that we can proceed to the Numerical Rating Scale Assessment.

Treatment D. Instructions and Information

1. Would you be comfortable receiving a Hot Water Bottle application, as per the information letter?
2. The application features a Hot Water Bottle, or more if necessary. It will be filled with hot water and be complemented with towels to avoid burns. A twenty-minute comfortably warm application on the area of pain would be administered, if you consent.
3. Could you expose your neck as much as possible, within your comfortability?
4. Can you lie down in prone on the plinth, please?
5. I will be setting up the Hot Water Bottle application, during this time feel free to make yourself comfortable and relax.
6. I am placing the towels and Hot Water Bottle on you neck.
7. I will come check the skin under the Hot Water Bottle at instances to check for signs of burns, but if you feel that the application is very hot or not warm enough kindly notify me so to adjust the towels.
8. The 20 minutes have passed, and the treatment is done.
9. Feel free to get off the plinth and cover you neck again so that we can proceed to the Numerical Rating Scale Assessment.

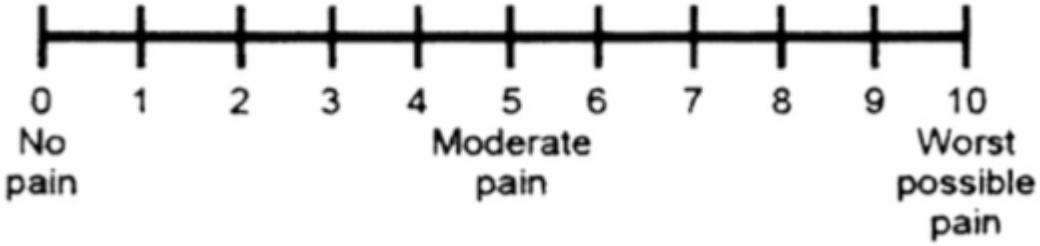
Immediate Numerical Rating Scale Assessment

- Immediately after the application, the participant will be asked to rate the neck pain immediately after treatment, providing a number between 0 and 10, where 0 is equivalent to no pain and 10 is the worst possible pain.
- The value provided will be taken note of.



Second Numerical Rating Scale Assessment

- Before the participant is dismissed from Room 9, Electrotherapy Laboratory, at the Faculty of Health Sciences, Mater Dei Hospital, the applicant's University of Malta email address will be provided.
- The participant will be asked to perform a Numerical Rating Scale Assessment on one's self, when pain is reperceived.
- A number between 0 and 10, where 0 is equivalent to no pain and 10 is the worst possible pain is to be sent on the provided email address.



Pain Relief Duration

Time of treatment termination:
Time of email receival:
Pain relief duration:

Appendix 8. Approval from Registrar Office at the University of Malta

L-Università ta' Malta

Office of the Registrar
University of Malta
Msida MSD 2080, Malta

Tel: +356 2340 2385/6
registrar@um.edu.mt

www.um.edu.mt

16 March 2020

Malcolm Camilleri (387599M)
30 Amiga
Triq Richard Taylor
Iklin IKL 1431

Dear Mr Camilleri

I refer to your request for permission to recruit University of Malta students to participate in your study.

The Office of the Registrar finds no objection to your request, subject to the approval of the Faculty Research Ethics Committee.

Yours sincerely

V. Grech

Veronica Grech
Registrar

Appendix 9. Permission to use Neck Disability Index

SPECIAL TERMS

These User License Agreement Special Terms ("Special Terms") are issued between Mapi Research Trust ("MRT") and Malcolm Camilleri ("User").

These Special Terms are in addition to any and all previous Special Terms under the User License Agreement General Terms.

These Special Terms include the terms and conditions of the User License Agreement General Terms, which are hereby incorporated by this reference as though the same was set forth in its entirety and shall be effective as of the Special Terms Effective Date set forth herein.

All capitalized terms which are not defined herein shall have the same meanings as set forth in the User License Agreement General Terms.

These Special Terms, including all attachments and the User License Agreement General Terms contain the entire understanding of the Parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. If the terms and conditions of these Special Terms or any attachment conflict with the terms and conditions of the User License Agreement General Terms, the terms and conditions of the User License Agreement General Terms will control, unless these Special Terms specifically acknowledge the conflict and expressly states that the conflicting term or provision found in these Special Terms control for these Special Terms only. These Special Terms may be modified only by written agreement signed by the Parties.

1. **User information**

User name	Malcolm Camilleri
Category of User	Student
User address	University of Malta Msida Campus, Msida, MSD 2080, Malta University Msida MSD2080 Malta Malta
User VAT number	
User email	malcolm.camilleri.17@um.edu.mt
User phone	79290404
Billing Address	University of Malta Msida Campus, Msida, MSD 2080, Malta University Msida MSD2080 Malta Malta

2. **General information**

Effective Date	Date of acceptance of these Special Terms by the User
Expiration Date ("Term")	Upon completion of the Stated Purpose
Name of User's contact in charge of the request	Malcolm Camilleri

3. **Identification of the COA**

Name of the COA	NDI - Neck Disability Index
Author	Vernon H Mior S
Copyright Holder	
Copyright notice	NDI © Dr Howard Vernon, 1991. All Rights Reserved
Bibliographic reference	Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. J Manipulative Physiol Ther. 1991 Sep;14(7):409-15. Erratum in: J Manipulative Physiol Ther 1992 Jan;15(1) (PubMed abstract)
Modules/versions needed	NDI

4. **Context of use of the COA**

The User undertakes to use the COA solely in the context of the Stated Purpose as defined hereafter.

4.1 Stated Purpose

Other project

Title	A Comparative Study between the Short-term Pain Relief Effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in Neck Pain.
Disease or condition	Chronic Neck Pain
Planned Term*	Start: 02/2020; End: 06/2021
Description (including format or media)	Will be used in adjunct to Neck Pain Scales to measure the improvement in neck pain and disability

4.2 Country and languages

MRT grants the License to use the COA on the following countries and in the languages indicated in the table below:

Version/Module	**Language**
NDI	English

The User understands that the countries indicated above are provided for information purposes. The User may use the COA in other countries than the ones indicated above.

5. **Specific requirements for the COA**

- The Copyright Holder of the COA has granted ICON LS exclusive rights to translate the COA in the context of commercial

studies or any project funded by for-profit entities. ICON LS is the only organization authorized to perform linguistic validation/translation work on the COA.

- In case the User wants to use an e-Version of the COA, the User shall send the Screenshots of the original version of the COA to MRT or ICON LS for review and approval. The Screenshots review may incur additional fees.

- In case the User wants to use an e-Version of the COA, ICON LS shall update (if needed) and populate the COA translations into the User's or IT Company's system and the User shall send the Screenshots of the translations of the COA to ICON LS for approval. The update (if needed), population of translations and the Screenshots review may incur additional fees.

Appendix 10. Permission to use WILDA Approach to Pain Assessment

L-Università ta' Malta

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>

Permission to use WILDA Approach to Pain Assessment

3 messages

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt> 26 April 2020 at 21:27

To: regina.fink@ucdenver.edu

Dear Prof Fink,

I hope this email finds you well.
I am a third year physiotherapy student studying at the University of Malta, currently I am working on my dissertation entitled "A Comparative Study between the Short-term Pain Relief Effects of Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles in Neck Pain." As part of my neck pain assessment I would like to use the WILDA approach to pain assessment, as in your publication "Pain assessment: the cornerstone to optimal pain management". Therefore, I am sending this email to ask for permission to use it in my studies. Recognition of your work would be made reference to, with particular emphasis to the acknowledgement section of my dissertation.

Best regards,
Malcolm Camilleri

Fink, Regina <REGINA.FINK@cuanschutz.edu> 27 April 2020 at 16:46

To: Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>

Malcolm--
Thank you for your email. I hope you are well.
You have my permission to use the one side of the WILDA card provided you acknowledge The University of Colorado Health (as printed) and my newest email address: regina.fink@cuanschutz.edu.
The other side which has the 0-10 scale and the Faces scale revised will require a separate permission from the International Association for the Study of Pain. Here is their website for additional information:
http://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1519

Best of luck. I am attaching the most recent version of our pdf. Let me know if you have any questions.
Regina

Note: my email address has changed

Regina M. Fink, PhD, APRN, AOCN, CHPN, FAAN
Professor | Department of Medicine
Co-Director Interprofessional MSPC & Palliative Care Certificate Programs
University of Colorado Anschutz Medical Campus
12631 E. 17th Avenue, AO1 - Room 8410, Box B-180
Aurora, CO 80045

regina.fink@cuanschutz.edu
www.cuanschutz.edu/MSPC
303.724.9192 work
303.886.8655 cell

From: Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>
Sent: Sunday, April 26, 2020 1:27 PM
To: Fink, Regina <REGINA.FINK@CUANSCHUTZ.EDU>
Subject: Permission to use WILDA Approach to Pain Assessment

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Wilda RFink.pdf
157K

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt> 27 April 2020 at 17:08
To: "Fink, Regina" <REGINA.FINK@cuanschutz.edu>
Bcc: Christopher Fenech <chrisfenech@gmail.com>

Dear Prof Fink,

Your acknowledgment and contribution to my study is highly appreciated.
Thank you, and have a great day!

Best regards,
Malcolm Camilleri

Appendix 11. Permission to participate in MHSA's AssisThesis Programme

L-Università ta' Malta

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>

AssisThesis
4 messages

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt> 3 March 2020 at 16:43
To: healthofficer.mhsa@gmail.com

Dear Ms Fenech,

Good afternoon, I hope this email finds you well.
I am a third year BSc. (Hons) Physiotherapy student at the University of Malta and am currently in the process of writing my ethics form for my dissertation "A comparative study between the short-term pain relief effects of Transcutaneous electrical nerve stimulation and Hot Water Bottles in neck pain".

This study will involve a student demographic aged between 18 and 25, therefore I would like to request your help in the recruitment of student participants. If you would be willing to help promote my dissertation through your AssisThesis programme and other means possible, I will forward the full information with regards to my study. Thank you for your time and consideration.

Best regards,
Malcolm Camilleri

Kylie Fenech <healthofficer.mhsa@gmail.com> 5 March 2020 at 08:38
To: Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>

Dear Mr Camilleri,

Thank you for your email.

Following discussions within the executive board, MHSA would like to welcome you to our AssisThesis programme!

Would you be able to send me more details regarding your requirements for the student demographic you wish to assemble, a short explanation of what will be done during your research so I can pass on the information to any students that are interested in participating as well as when said research will take place?

I look forward to hearing from you.

Kind regards,

Appendix 12. Permission to use venue

L-Università ta' Malta

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>

Request: Venue for dissertation

3 messages

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt> 3 March 2020 at 16:29

To: anthea.zammit@um.edu.mt, stephen.lungaro-mifsud@um.edu.mt

Dear all,

Good afternoon, I hope this email finds you well.
I am a third year BSc. (Hons) Physiotherapy student at the University of Malta, and am currently in the process of writing my ethics form for my dissertation "A comparative study between the short-term pain relief effects of Transcutaneous electrical nerve stimulation and Hot Water Bottles in neck pain".

As the title implies, I will be using Transcutaneous Electrical Nerve Stimulation and Hot Water Bottles as treatment. Therefore, I would like to request the use of the Electrotherapy Laboratory at the Faculty of Health Sciences as a venue for the study. The venue is being requested as it is adapted for such procedures as it was the venue used to learn the above modalities as first year students. I am aware that lectures occur at the venue, therefore I will be mindful to use it accordingly. Thank you for your time and consideration.

Best regards,
Malcolm Camileri

Stephen Lungaro-Mifsud <stephen.lungaro-mifsud@um.edu.mt> 4 March 2020 at 09:40
To: Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt>
Cc: Anthea Zammit <anthea.zammit@um.edu.mt>, Christopher Fenech <chrisfenech@gmail.com>

Dear Macolm
Thank you for your email. Your dissertation study sounds interesting.
You may use the Electrotherapy Lab for your study during free slots in the timetable. Please liaise with Anthea on this.
A clarification: Are you going to use the Faculty equipment for your study? If yes, please describe how they are going to be used? Given their delicate nature and size, TENS machines must not leave the premises.
Best regards
Stephen

Stephen Lungaro-Mifsud PhD(UK), MMAP
Head - Department of Physiotherapy
Deputy Dean - Faculty of Health Sciences, Office 10
University of Malta
Msida, Malta
Tel: (+356) 23401161, Mob: (+356)99498468
Skype: slungaro1; Twitter: @slun1 @uompt; Facebook: uom.physiotherapy

[Quoted text hidden]

Malcolm Camilleri <malcolm.camilleri.17@um.edu.mt> 4 March 2020 at 17:25
To: Stephen Lungaro-Mifsud <stephen.lungaro-mifsud@um.edu.mt>

Cc: Anthea Zammit <anthea.zammit@um.edu.mt>, Christopher Fenech <chrisfenech@gmail.com>

Dear Dr Stephen Lungaro-Mifsud,

Thank you for granting me permission to use the Electrotherapy Laboratory for my study, will liaise with Anthea as instructed.
Additionally, I appreciate your offer to use the Faculty's equipment, but I will be purchasing and using my own TENS machines and hot water bottles.

Best regards,
Malcolm Camilleri
[Quoted text hidden]