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

Πρόταση – Εισήγηση Ερευνητικού Προγράμματος

Τμήμα: ΠΜΣ «Επιστήμες της Αποκατάστασης»
Κατεύθυνση: ΦΥΣΙΚΟΘΕΡΑΠΕΙΑ

Κύριοι Ερευνητές: ΕΛΕΥΘΕΡΙΑ ΘΩΜΑΙΔΟΥ, Δρ.ΕΥΔΟΚΙΑ ΜΠΙΛΛΗ, Dr.CRISTOPHER McCARTHY

ΕΡΕΥΝΗΤΙΚΟ ΠΡΟΓΡΑΜΜΑ

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

Σκοπός: Ο σκοπός της έρευνας είναι να διερευνηθεί και να συγκριθεί η αποτελεσματικότητα της Χειροθεραπευτικής Φυσικοθεραπείας και της απτικής αισθητικής επανεκπαίδευσης (localization) στη βελτίωση της έντασης του πόνου και του εύρους κίνησης της αυχενικής μοίρας της σπονδυλικής στήλης σε ασθενείς με αυχενικό πόνο.

Σημασία: Ο πόνος στην Αυχενική μοίρα της Σπονδυλικής στήλης αποτελεί ένα από τα μείζονα προβλήματα υγείας, επηρεάζοντας τη ζωή των ανθρώπων και, σημειώνοντας υψηλά ποσοστά επιπολασμού και εμφάνισης (Fejeret al.,2006; Rahmaniet al.,2013). Έχει αποδειχθεί ότι υπάρχει στενή συσχέτιση μεταξύ της εργονομίας και λειτουργικότητας του αυχένα και της θωρακικής μοίρας της σπονδυλικής στήλης (Julletal., 2008).Από λειτουργικής πλευράς όλης της σπονδυλικής στήλης, η κίνηση στην αυχενική μοίρα περιλαμβάνει και κίνηση στην άνω θωρακική μοίρα (Potterfield& De Rose; Tsang, Szeto& Lee,2013). Πιο ειδικά, υποκινητικότητα στη άνω θωρακική περιοχή μπορεί να οδηγήσει σε πόνο στον αυχένα λόγω αντισταθμιστικών μηχανισμών, ενώ αντιθέτως υπερκινητικότητα στην άνω θωρακική περιοχή επηρεάζει την αυχενική μοίρα (Edomostong & Singer, 1997).
Η χειροθεραπευτική φυσικοθεραπεία εφαρμόζεται για τη θεραπεία του αυχενικού πόνου (Cleland, Glynn Whitman,2007; Suvarnnato ,Puntumetakul& Kaber,2013).Πρόκειται για "τις δια χειρός ειδικές τεχνικές με σκοπό τη θεραπεία" με στόχο την βελτίωση της κινητικότητας και τη μείωση του πόνου (Lederman, 1997:1). Η χειροθεραπευτική φυσικοθεραπεία περιλαμβάνει εξειδικευμένες χειρομαλάξεις, ειδικές τεχνικές κινητοποίησης εστιασμένες στιςαρθρώσεις, οι οποίες συνήθως περιλαμβάνουν παθητικές κυρίως ενδο-αρθρικές κινήσεις (Frenchetal., 2011) . Οι Maitland et al (2015) περιγράφουν τις ειδικές τεχνικές κινητοποίησης στην σπονδυλική στήλη, ως παθητικές

ρυθμικές ταλαντώσεις που πραγματοποιούνται στην αρχή, στο μέσο και στο τέλος του παθητικού εύρους κίνησης της άρθρωσης. Έχουν προταθεί 3 μηχανισμοί δράσης της χειροθεραπευτικής φυσικοθεραπείας- μηχανικός, νευροφυσιολογικός, και/ή placebo (Bialosky et al.,2009; Bishop et al.,2011). Αυτό εξηγείται με μία αλυσίδα αντιδράσεων που μεταφέρεται από το μηχανικό ερέθισμα, μέσω του περιφερικού νευρικού συστήματος, στο νωτιάιο μυελό και τελικά σε ανώτερα κέντρα. Επιπλέον, ο Mulligan (1987) εισήγαγε την έννοια των Φυσιολογικών Αποφυσιακών Ολισθήσεων Παρατεινόμενης Πίεσης, Sustained Natural Apophyseal Glides (SNAGs) και αποδείχθηκαν αποτελεσματικές στην αυχενική περιοχή σε πολλά συγγράμματα (Grieve,1991; Boyling & Palastanga,1994, Petty& Moore,1998)

Η απτική αισθητική επανεκπαίδευση, localization σε συγκεκριμένα σημεία , περιλαμβάνεται στις προσεγγίσεις για την Εκπαίδευση της Νευροεπιστήμης του Πόνου. Επιπλέον, τα τελευταία χρόνια γίνεται λόγος για την Εκπαίδευση στην Νευροεπιστήμη του Πόνου (Moseley 2002, Louwet al.,2015; Louwet al.,2016; Puentendura and Flynn,2016), με στόχο την αλλαγή στην αντίληψη του πόνου του ασθενούς (Moseley,2005), τη μείωση του πόνου και της ανικανότητας (Louwet al.,2011) εκπαιδεύοντας τον στις νευροφυσιολογικές και νευροβιολογικούς μηχανισμούς του πόνου. Η απτική αισθητική επανεκπαιδευση, χωρίς κίνηση, θεωρείται ότι «οξύνει» και «επανεστιαζει» την αντιπροσώπευση του ανθρωπαρίου στο φλοιό του εγκεφάλου, βελτιώνοντας την κίνηση και μειώνοντας τα επίπεδα του πόνου (Moseley 2008 ; Louw et al.,2011). Ειδικότερα, το ανθρώπινο σώμα φυσιολογικά αποτυπώνεται στο εγκεφαλικό φλοιό με ένα δίκτυο νευρώνων. Η πιο γνωστή περιοχή του εγκεφάλου είναι η πρωτογενής σωματοαισθητική περιοχή (Flor,200, Stavrinou ,2007). Έχει αναφερθεί ότι οι ασθενείς που πάσχουν από πόνο ,εμφανίζουν τροποποιημένες απεικονίσεις σε σύγκριση με υγιείς (Flor et al.,1997;Moseley et al.,2008) ενώ έχει βρεθεί συσχέτιση μεταξύ του σχήματος, μεγέθους της παραπάνω περιοχής με τον πόνο και την ανικανότητα (Flor et al.,1997; Lloyd et al.,2008). Βάσει αυτών των νευροπλαστικών αλλαγών που συμβαίνουν , η φυσικοθεραπεία στοχεύει στην ενίσχυση των προσαγωγών αισθητικών ερεθισμάτων , μέσω απτικής επανεκπαίδευσης προς το Κεντρικό Νευρικό Σύστημα, ώστε να ομαλοποιήσει τις τροποποιήσεις στο φλοιό (Flor et al.,2001; Moseley et al.,2008). Έως σήμερα, η απτική οξύτητα και η φλοιϊκή αναδιοργάνωση έχει μελετηθεί σε περιορισμένο αριθμό παθολογιών (Catley et al.,2014) ενώ έχει αποδειχθεί ότι η αισθητική επανεκπαίδευση έχει θετική επίδραση στη μείωση του πόνου(Flor et al.,2001).

Από όσο γνωρίζουμε, η σύγκριση της αποτελεσματικότητας της χειροθεραπευτικής φυσικοθεραπείας και της Απτικής Αισθητικής Επανεκπαίδευσης δεν έχει έως τώρα διερευνηθεί σε ασθενείς με πόνο στον αυχένα

Διάρκεια: 6 μήνες

Title: Manual Therapy vs localization (tactile sensory training) in patients with neck pain: a randomized clinical trial

Aim : The primary aim of the research is to investigate and compare the effects of manual therapy versus localization by tactile stimulus on pain intensity and mobility of the neck.

Hypotheses :

Null hypotheses

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

Hypotheses

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

Rationale: Neck pain is one of the major public health problems, which has a great impact on people's lives, with high prevalence and occurrence rates (Fejer et al.,2006; Rahmani et al.,2013).
A relationship between the cervical and the thoracic spine has been described as interrelated and ergonomically-related (Jull, Oleary&Folla ,2008) .From functional viewpoint, since the movement of the cervical spine includes the movement of the upper thoracic (1st thoracic T1 to 4th thoracic T4 (Potterfield& De Rose; Tsang, Szeto & Lee,2013),hypomobility of the upper thoracic can lead to pain in the Cx because of compensation, whereas hypermobility of the upper Tx can induce dysfunction of the Cx(Edomostong& Singer, 1997).

Physiotherapists are using methods such as manual therapy to manage neck pain (Cleland, Glynn Whitman,2007; Suvarnnato ,Puntumetakul& Kaber,2013).Manual therapy is defined as ''the use of hands-on techniques with therapeutic intent'' (Lederman, 1997:1). Manual therapy is used by physiotherapists to treat musculoskeletal pain and disability and utilizes physical treatments that include massage therapy, joint mobilization and manipulation techniques (French et al., 2011). Maitland et al (2005) describe spinal mobilizations as passive rhythmical oscillations performed at the beginning, within, or at the limit of joint range. It is suggested that the mechanisms of manual therapy involve a mix of three mechanisms- biomechanical , neurophysiological and/or placebo effects (Bialosky et al.,2009; Bishop et al.,2011). This can be explained by the creation of a cluster of the above effects through the peripheral nervous system, spinal cord and higher centers. Furthermore, Mulligan firstly introduced in 1987 the Sustained Natural Apophyseal Glides, whereas an increasing number of clinical texts provide its effectiveness on neck pain ((Grieve,1991; Boyling& Palastanga,1994, Petty & Moore,1998). In addition it is believed that the delivery of manual therapy, which is classically considered to be a "bottom-up" or a "hand-on" approach, could

also reorganise and sharpen the homunculus and improve the mobility so that “top-down” effects in manual therapy could be similar to the localization (Puentedura and Flynn, 2016).

Localization which involves tactile sensory training without physical movement is thought to “sharpen” or “refocus” the homoculus’ representation on the cortex of the brain and thus improve the movement and decrease the levels of pain (Moseley 2008 ; Louw et al.,2011)The last decades, greater attention has been reported in hands-off approaches, known as pain neuroscience education PNE (Moseley 2002, Louw et al.,2015; Louw et al.,2016; Puentenduraand Flynn,2016) aiming to change patients’ cognition (Moosley,2015), pain relief and decrease dysfunction (Louw et al.,2011) by educating them about neurophysiological and neurobiological processes of pain . More specific, the body of a person is normally represented in the cortex of the brain by a network of neurons (Flor,2000; Stavrinou,2007) The most famous area of the brain representation is the primary somatosensory area (S1) (Flor,200, Stavrinou ,2007). It has been reported that patients suffering from pain display different representation compared to healthy individuals (Flor et al.,1997;Moseley et al.,2008) and a correlation between shape and size of the above area with pain and disability was found (Flor et al.,1997; Lloyd et al.,2008). Based on these neuroplastic changes, physiotherapy has focused on techniques to enhance sensory afferent stimuli to the Central Nervous System and aiming to normilise these altered cortical representations. Various strategies have been studied to induce patients develop an increased acuity of their altered body mapping, including two point discrimination, graphaesthesia (Moseley, 2007 ;Moseley ,2008). To date only limited pathological conditions have been investigated in terms of tactile acuity and cortical reorganization (Catley et al .,2014), whilst the positive effects of the sensory training have already been suggested (Flor et al.,2001)

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

Duration : 6 months

Συνεργασία με:

ΠΕΡΙΛΗΠΤΙΚΗ ΠΕΡΙΓΡΑΦΗ ΕΡΕΥΝΗΤΙΚΟΥ ΠΡΟΓΡΑΜΜΑΤΟΣ

ΜΕΘΟΔΟΛΟΓΙΑ

Participants

Volunteer adults suffering from neck pain will be invited to participate in the study. Recruitment will be performed via social media and local newspaper adverts (i.e.posters will be displayed on notice boards on TEI of Western Greece Campus as well as on the TEI's social media page with details and information related to the study i.e. appendix).Additionally, the project supervisor will sent an email to T.E.I of Western Greece staff and students, inviting individuals to participate in the study. All those who will express interest, will receive an email in response with attached information.

Prior to participation the study informed consent will take place and all participants will be able to ask questions before their written consent. In addition, ethical approval will be provided by TEI's Ethical Committee, and according to the ethical standards of the Declaration of Helsinki.The researcher will give explanation of the procedure and participants will be reminded at this point that they are free to withdraw from the study at any point.The participants will be asked to sign two copies of the consent form (appendix) one for themselves to keep and one for the researchers to retain in the TEI's file. Participants will also be reminded that the data gathered/analysed will be confidential, thus maintaining patient's anonymity.

Patients will be excluded if they can not read or understand spoken /written Greek, are under the age 18 and over 65, have undergone spinal surgery in the area of focus, have any skin condition preventing them from receiving tactile stimuli, have any contraindications to manual therapy (vertebral arteries insufficiency, spinal instability, steroid medication use, malignancy), present any symptoms related to neurological conditions altering sensation (i.e peripheral neuropathy, multiple sclerosis,diabetes), have diagnosis of radiculopathy with high irritability.Patients will have to present with neck pain for at least 1 week.

Table :Inclusion and Exclusion Criteria	
Inclusion Criteria ● Participants must be between the ages of 18-65, including both males and females ● Participants able to understand spoken and written Greek	**Exclusion Criteria** ● Trauma/surgery to the CxTx in past ● Skin allergies/ irritation/dermatological conditions (dermatitis, eczema) ● Neurological disorders such as altered

● Participants must be able to give informed consent ● Participants should suffer from neck pain for at least 1 week ● No previous adverse effects to manual therapy	sensation , peripheral neuropathy, multiple sclerosis ● Vertebral arteries insufficiency ● Steroid medication use ● Spinal instability ● High irritability ● Radiculopathy. ● Malignant neoplasm ● Those who answered YES to any of the questions in the health screening questionnaire, suggesting having contraindication on treatment.

Sample

There is no previous research available to suggest the minimum number of subjectsrequired for adequate statistical power to detect a treatment effect. Due to time restriction and volunteer availability, aiming for a sample of more than 20 participants.

Participants will be randomly allocated into two groups, the manual therapy group, with mobilizations and the tactile sensory stimulation group, using GraphPad QuickCalcs Software (2015) in a private room in the Physiotherapy lab.

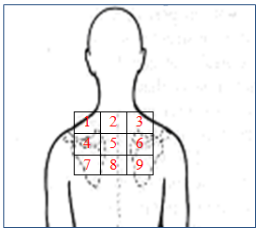
Manual Therapy Group

With the subject lying supine on an adjustable plinth the researcher will palpate and mark the C6, C7,T1,T2,T3,T4 vertebral segments in an n attempt to enhance reliability and validity of palpation (REF) levels will be cross checked with the second researcher. The therapist will apply AP mobilization in C7, Grade III for 1 minute, at a frequency of 2 HZ (metronome).Then the patient will be in sitting position. .The therapist will locate the T1-T2 level and then T3-T4 and will place her hand unilaterally. Then the participant will actively rotate to the right for 30 seconds and to the left for 30 seconds while the therapist will guide the glide during the movement, thus performing a SNAG in rotation The force will be applied parallel to the facet plane (Exelby,2002).SNAG technique was chosen, as it is suggested for painful movement dysfunctions and in contrast to other manual therapy techniques is performed with the spine under normal load bearing conditions. Further it includes active and passive elements of physiological movements with accessory glides, within the available range of movement and it is under patient's control.

Localization Tactile sensory training group

For the localization group to the cervicothoracic area a paper with a 9 block grip on a body chart will be designed(appendix).Participants will be asked to sit in normal relaxed position shirtless. At first, the staff will teach participants, viewing the body chart, which grid will be touched by a stylus(pen) in order to familiarize them with the procedure. Then, whilst the staff will touch randomly one of the 9 grids on the lower cervical- upper thoracic spine, the participant will be requested to answer which

number is being touched, and give continuous verbal feedback. If the patient successfully identifies the grid, the next area will be tested. In case of incorrect response, the same grid will be touched, and then the therapist will identify the correct stimulated grid. The areas will be stimulated will depend on a random number generator (1-9).The size of the 9 block grid will be designed based on the minimal two point discrimination in the neck area. The localization training will be performed for 3 minutes, in order to be in accordance with the first group.



The therapist throughout this study will be the project supervisor, expert in Manual therapy with more than 20 years of clinical experience and the assessor will be the postgraduate student who will collect the data before and after the intervention , record the findings based on the outcome measures suggested in this study.

Equipment

Standard Plinth
Grid x9
China graph pencil
Bubble goniometer
Manual held electronic Algometer
Stopwatch
Stylus Pen

Blinding

Blinding will be possible, due to the researcher and therapist will independently collect and analyse the data. The information of which intervention has been performed to participants, will be concealed from the researcher. On the other hand, participants' blindness is not feasible but we will ensure that the participants will not be informed about the hypotheses of the research and the expected outcome.

Pilot study

A pilot study, using healthy subjects incorporating the series of intervention and measurement relevant to the study will be completed a week prior to the data collection to standardize the timings, logistics of the procedure, use of equipment and patient comfort. Leon et al. (2011) found that pilot studies are necessary in the planning and design of a larger trial. Also, pilot studies reduce measurement error and confirm that the treatment dose is appropriate (Thabane et al., 2010) and provides the opportunities to make amendments in the methodology of the main study so as to

enhance the outcome. With regards to the measurements , during the pilot study the most reliable method of assessement will be investigated and ensured in the main study.

Outcome Measures pre and post intervention

Pain (Pain Pressure Threshold) using algometer
Pain scales (VAS, NPS)
Range of motion for the cervical spine (goniometer)
Function (Neck Disability Index)

Data Collection

Data collection will be conducted in the Physiotherapy lab of TEI of Western Greece. Electronic data will be stored on a password protected computer known only by the researcher , with respect and will be kept confidential whilst anonymity of participants will be protected.

Data Analysis

Statistical testing will be carried out using the IBM Statistical Package for Social Science (SPSS)Software (version 24?) Chicago ,IL)
Descriptive data will be reported as mean, range and standard deviations. For the normality test, A Shapiro Wilk test will be conducted to determine if the data is normally distributed.Then, the normative data will be tested for statistical significance. Statistical significance will be accepted at $p<.05$ (in line with the other studies with similar nature).

Declaration of Interest

The researcher reports no conflicts of interest

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ΒΙΒΛΙΟΓΡΑΦΙΑ

ΠΡΟΣΠΙΚΟ ΕΡΕΥΝΑΣ			
α/α		Θέση στο Ίδρυμα	Απασχόληση %
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3	……	……	……
4	…….	…….	……
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ο ΕΠΙΒΛΕΠΩΝ ΔΙΔΑΣΚΩΝ

ο/Η ΜΕΤΑΠΤΥΧΙΑΚΟΣ/Η ΦΟΙΤΗΤΗΣ/ΤΡΙΑ: ΕΛΕΥΘΕΡΙΑ ΣΤ. ΘΩΜΑΪΔΟΥ

Έγκριση επιτροπής Δεοντολογίας Και Ηθικής