A study to evaluate the efficiency of trans-perineal trigger point dry needling combined with manual therapy as a treatment for chronic pelvic pain compared with treatment by manual therapy only: An open-label clinical trial.

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Study Protocol

Aim

The presence of myofascial trigger points (MTrPs) or tender points in the pelvic floor muscles (PFM) can attribute to myofascial pelvic pain (MFPP). MFPP is considered to be a cause for chronic pelvic pain (CPP) symptoms including dyspareunia. This study will evaluate the efficiency of including trans-perineal trigger point dry needling (TrDN) with manual therapy to target MTrPs in the PFM compared to manual therapy alone.

The primary objective is to evaluate the number of treatments required within the allocated ten treatment sessions to effect improvement in pain in the treatment groups.

Preface

The aetiology of CPP can originate from urological, gynaecological, gastrointestinal, pelvic neural and pelvic musculoskeletal systems (1,2,3). Non-cyclical CPP does not present exclusively with symptoms of dyspareunia, dyschezia or dysuria. It can present with additional symptoms such as suprapubic and lower abdominal pain, and painful pelvic musculatures (2). The pain can worsen after pelvic floor related activities such as coitus or voiding (4). Furthermore, non-cyclical CPP can also present with worsening of dysmenorrhea symptoms due to hormonal changes, giving a mixed cyclical presentation without the presence of an underlying gynaecological pathology (1).

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Due to overlapping symptoms found in cyclical-CPP and non-cyclical CPP and the potential presence of an underlying pathology, a multi-disciplinary approach to diagnosis and management is crucial (1,5). Only 60% of laparoscopic investigations yield a definite diagnosis (6). An inconclusive diagnosis with no evident pathology should suggest myofascial pelvic pain (MFPP) as a probable cause (7). MFPP is caused by the presence of MTrPs in the pelvic muscles, and its presence in PFM can be the primary mediator for non-cyclical CPP (7,8).

Preface to treatments for MFPP

Manual therapy

Empirically, trigger point release (TPR) or myofascial tender point release (MFR) and massage have been standard treatments for MTrPs in myofascial pain syndromes (MPS) (9). Manual therapy for CPP symptoms such as Interstitial cystitis/ Painful Bladder Syndrome (IC/PBS), vulvodynia and dyspareunia have been proved useful (10-14). These studies reviewed manual techniques used externally for abdominal and pelvic muscles as well as intra-vaginal and intra-rectal procedures for the PFM. These procedures varied from TPR, global therapeutic massage (GTM), distension of shortened muscles and ligaments either manually or with a therapeutic glass wand (TW).

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Trigger point dry needling

Trigger point dry needling (TrDN) is a minimally invasive treatment, where an acupuncture needle is inserted directly into the muscle to target the underlying MTrPs, to change the biochemical milieu and reduce neuromuscular pain and dysfunction (15). It is also considered as an intra-muscular technique to increase the range of movement (ROM) of the muscles due to the direct intramuscular stretch effect with the insertion of a needle (16).

Literature review on treatment sessions required to assess improvement with manual therapy

Five randomised clinical trials (RCT) analysed manual therapy with treatment-based interventions (12,13,14,17,18) and had a clinically significant resolution of pain and dyspareunia at follow-up but required ten to twelve treatments for the duration of six months.

The number of treatments required for improvement in pain was analysed in only one RCT (17). This study (17) compared the outcomes of Levator Ani trigger point injection (LTPI) of local anaesthesia to manual therapy for pelvic floor pain. The treatment duration for improvement in the physiotherapy group (n= 17) was over 7.3 weeks with resolution seen in 35% of the group compared to 81% achieving pain resolution in 4.4 weeks in the injection group (n= 12). This study found that with increased manual treatments, the pain with intercourse domain on the Female Sexual Function Index (FSFI) questionnaire for the

physiotherapy group showed more significant improvement (p=0.02), from a baseline of 1.74 to 4.14 compared to the injection group's statistics of 2.80 to 3.60 (17). This indicates that treatment techniques that restore length in the muscles rather than therapies targeting pain alone would be more efficacious.

The RCT (12) comparing myofascial release of the PFM with global therapeutic massage for PBS suffering participants; found that 59% (n= 38) in the physiotherapy group showed a marked improvement with ten treatments compared to only 26% (n=40) in the GTM group (p=0.0012).

One of the first cohort studies (10) to evaluate the benefits of intra-vaginal TPR of muscles for PBS and overactive bladder syndrome achieved 83% marked improvement with 24 sessions.

A pilot RCT (14) (n=9) reviewed the efficacy of self-release of tender points using a therapeutic wand and found twice the improvement in bladder pain when myofascial self-release of the PFM was continued and extended as a home exercise program for six weeks after the cessation of six weeks of physiotherapy treatments.

Heyman et al. (13) compared stretching of the PFM (n=22) to counselling for dyspareunia. This is the only study that showed an improvement in the pelvic pain scores for the distention group (p<0.001) with fewer sessions of four to six treatments.

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

These studies (10,12,14,17) showed the relevance of manual therapy for PFM but required over ten sessions for the observed improvement. The stand-alone efficiency of manual treatments for pelvic floor pain and tightness is unclear as some studies have investigated the outcome of physiotherapy alongside medical or psychological interventions and required eight sessions extending from eight to 24 weeks to show significant improvement (18-20).

Literature review on treatment sessions required with dry needling

In a physiotherapy practice, TrDN is used in conjunction with manual therapy, stretching and exercises. There is evidence that TrDN is an effective treatment to target MTrPs causing MPS (21-24). A systematic review (24) on low back pain (LBP), showed that TrDN when combined with physiotherapy treatments, had a more significant effect in pain improvement with a lower visual analogue scale (VAS) of 1.04cms score than the treatments alone. The treatment duration for the four intervention-based studies varied from 20 days to nine weeks.

The review (22) on TrDN for upper-body MPS analysed one study comparing TrDN combined with shoulder rehabilitation. A more significant decrease in pain was noted for the TrDN group with a minimal clinically important difference (MCID) of 1.81cms on the VAS when TrDN was administered four times every five to seven days.

In a meta-analysis (23), the study that included TrDN with stretches showed a significant increase in the ROM of the muscles (p=0.043) compared to stretches alone. The treatment duration was three weeks.

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

An RCT (25) that reviewed stretches combined with TrDN for chronic non-specific neck pain found 58% (n=65) in the combined intervention group required only two treatments from the allocated four to report resolution of symptoms.

A study (26) on temporomandibular dysfunction (TMD) found that the deep TrDN technique for MTrPs (n=36) had a lasting effect for up to six months post-treatment and showed a significant improvement in pain and increased ROM of the jaw after just one treatment for three weeks ($p<0.01$).

Research Hypotheses

Null hypothesis: The inclusion of trans-perineal TrDN to manual therapy will not influence the number of treatments required to achieve a clinically meaningful reduction in pain within the allocated ten sessions. It will not affect the outcomes for the pain variables and dyspareunia across the categories of treatments.

Research hypothesis: The inclusion of trans-perineal TrDN to manual therapy will influence the number of treatments required to achieve a clinically meaningful reduction in pain within the allocated ten sessions along with a variation in outcomes across the variables evaluated.

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Method

This open label non-randomised clinical trial will compare two interventions pre-and post-treatment. This trial will be analysed by intention to treat. The ethical approval was obtained from the Clinical Research Ethics Committee of the Cork Teaching Hospitals in March 2016.

The trial is conducted at the Cork University Maternity Hospital (CUMH) and the Cork Women's Clinic (CWC). CUMH is a large Obstetrics and Gynaecology hospital governed by the Health Service Executive. CWC is a private gynaecology clinic. Female participants will be referred for physiotherapy as deemed appropriate by the inclusion and exclusion criteria (Table 1) given to the gynaecology team at CUMH and CWC.

The primary objective is to evaluate the number of treatments required within the allocated ten treatments to effect improvement in pain in both groups. Pain resolution will be assessed using the 0-10 Numeric Pain Rating Scale (0-10 NPRS). NPRS will be given at baseline, the fourth, the eighth and the tenth treatment or earlier if resolution of symptoms occurred without the requirement of the allocated ten treatments. The secondary objective is to compare the outcomes between the treatment arms for dyspareunia, bladder and musculoskeletal pain, and some menstrual cycle related pain symptoms with the Female Sexual Function Index questionnaire and an abbreviated version of the International Pelvic Pain Questionnaire (IPPQ). These questionnaires will be completed at pre-treatment and at the final session. The Pain Treatment Satisfaction Scale questionnaire (PTSS) measures the treatment satisfaction in both groups which will be provided only at the final treatment.

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Table 1: Inclusion and exclusion criteria for recruitment

Inclusion criteria • Females with non-cyclical CPP including dyspareunia and associated pelvic floor pain-related dysfunctions such as bladder pain, pain with urination or dyschezia. • They should present with palpable high pelvic floor muscle tone and tenderness on vaginal examination in a clinical setting with a pain score of >4/10. • They can present with lower abdominal pain, pelvic pain and/or groin pain and pain on sitting. • Pain worsened with pelvic floor stretching activities like insertion of tampon or intercourse (27). • Visceral conditions like interstitial cystitis are difficult to exclude at gynaecology review, as they can mimic CPP symptoms (1). • Smokers are included. • Nulliparous and parous women included. • Age 18 to 60 years
Exclusion criteria • Body mass index greater than 30, as the required needle length is not available. • Chronic back pain of over 6 month duration and under pain management team. • Orthopaedic back surgeries with implants. • Pelvic pathologies like endometriosis, fibroids, cysts and polycystic ovarian syndrome. • Pregnancy related pelvic girdle pain. • Pregnant during the trial. • Pelvic organ carcinomas. • Undergoing cancer treatment. • After gynaecology surgery of less than 16 weeks. • After cardiovascular, gastroenterology, renal or orthopaedic surgery of less than 6 month's post-operative. • Neurological conditions such as stroke, epilepsy, Parkinson's disease etc. • Fibromyalgia and chronic fatigue syndrome. • Undergoing any treatment such as Botox or analgesic injections which can interfere with physiotherapy outcomes. **Exclusion criteria for dry needling** • Extreme needle phobia, rheumatoid arthritis, prolonged corticosteroid treatment, warfarin treatment, heart implants and blood clotting disorders. • Participant should have no significant learning disability and should be able to understand the procedure to consent for a vaginal examination and for treatment. • Participant should not require a chaperone during treatment in order to avoid administrative issues.

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Recruitment and allocation

Women will be invited for the trial with a letter of invitation. On confirmation of interest in the trial, their medical record numbers and names will be documented onto an excel sheet with the month of referral. In order to accommodate for the CUMH physiotherapy waiting list and to allow for the clinical workings at CUMH, an excel sheet with six names will be emailed to the central appointments office at CUMH. Two CUMH secretaries unrelated to the trial will randomly allocate the names into two opaque envelopes marked as group A and group B.

The staff will allocate appointments for group A among three Chartered Physiotherapists in Women's Health and Continence involved in the trial, including the researcher. The participating physiotherapists will have no input in the allocation process and they all have clinical experience of over 15 years.

Group B will be treated only by the researcher who has a clinical experience of eight years using trans-perineal TrDN. An identical procedure will be piloted at the CWC. The researcher will provide the treatment for both groups at the CWC. The participant's file will be marked as Group A or B to inform about allocation. The recruitment process will ran from April 2016 to November 2017.

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Withdrawal from participation

An individual can decline participation in the trial at any stage of the trial. If a participant reports needle phobia after group allocation, she will be transferred to group A. If a participant refuses dry needling treatment after starting the treatment in group B, she will be removed from the trial but care will continue.

Interventions

Group A: Manual therapy

The assessment includes a musculoskeletal assessment for pelvic anatomy and the pelvic and abdominal muscles. The PFM tone will be reviewed with a vaginal and/or rectal assessment (27, 28). The treatment consisted of myofascial TPR of MTrPs in the abdominal, pelvic and pelvic floor muscles and the appropriate stretching for the required muscles. If symptoms included lumbo-pelvic symptoms (27, 29), TPR and stretches for the lumbo-pelvic area will be provided. As a cohort of heterogeneous symptoms is expected to be recruited, an HEP of stretches for the muscles is to be prescribed as per the clinicians' judgement.

Group B: Trans-perineal TrDN with manual therapy

Group B will receive an identical assessment as group A. The treatment consists of the addition of trans-perineal dry needling for the PFM and TrDN for the pelvic and the abdominal muscles. The HEP for group B will be prescribed as per the clinician's judgement. Manual therapy is utilised in pelvic floor areas difficult to access with acupuncture needles.

With pelvic floor hypertonicity, pelvic floor contractions are painful and difficult to initiate and the PFM is slow to return to the normal vaginal resting tone (VRT). Performing a few contractions during vaginal assessment can help assess hypertonicity and tightness in the PFM however, Kegel's based pelvic floor muscle training (PFMT) is contraindicated as they can increase pain and hypertonicity and hence PFMT was not advised (7 p.8). The HEP for both groups are lengthening exercises for the PFM assisted with diaphragmatic breathing. Diaphragmatic breathing is influenced and altered by MFPP. An altered breathing pattern can influence the VRT, where the woman guards and holds her PFM with an apical inspiration instead of using a diaphragmatic inspiration to normalise the VRT. Re-education on the breathing patterns is considered as an important HEP for both groups to help prevent guarding and increasing the VRT. (30 p.333-334, 31,32).

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Standardisation of assessment

Standardised assessment for both groups will be as follows

1. Subjective assessment
2. Gynaecological evaluation of PFM
    - Dermatome and myotome examination
    - Intra-vaginal identification of PFM as per Haslam J et al. (28)
    - Muscle status (28)
3. Criterions for MTrPs identification in the pelvic muscles and the PFM (33)
    - The muscle should elicits tenderness on palpation
    - Pain reproduced on palpation of an MTrP in the muscle
    - Pain reproduced in the referred zone on palpation, i.e., the area of complaint.

4. Standardized assessment for the lumbo-pelvic region if required

    The European Guidelines standardised tests for the diagnosis of pelvic girdle pain are to be used if indicated in a non-aetiology specific presentation of CPP symptoms (34). The tests are as follows:

    - Distraction sacroiliac joint pain provocation test
    - Posterior pelvic pain provocation test
    - Long dorsal ligament test
    - Active straight leg raise test

A positive test finding in any of the above tests requires further assessment for pelvic muscle tenderness (3). Pelvic-related pain patterns are to be evaluated based on Table 2.

Table 2: Pelvic muscle related pain patterns (3,7,35,36)

Pelvic-pain patterns	**Muscles involved**
Suprapubic pain	1.Illio-psoas 2.Lower quadrant abdominal muscles (7) 3.PFM (36)
Groin pain	1.Adductor group of muscles 2.Lower quadrant abdominal muscles (7) 3. Pectineus 4. PFM (3)
Posterior pelvic pain	1.Gluteal muscles 2. Illio-psoas (7) 3.Piriformis 4. QL (35)
Deep pelvic pain	1.Adductor group of muscles 2. PFM (7)

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Standardisation of interventions

Standardisation of interventions is only required for group A as three clinicians provided the treatment for this group. Physiotherapists specialising in gynaecology have in-depth knowledge about intra-vaginal PFM palpation. For assessment, the PFM is divided into the superficial PFM and the deep PFM. To access MTrPs and perform TPR in the individual PFM, palpation varies based on the depth and the bulk of a muscle. On identification, manual pressure of a recommended two kilograms (36) is to be applied to activate the MTrP, while keeping the patient's tolerance in consideration. The pressure varies from five seconds up to 60 seconds based on the individual's tolerance or when the spontaneous pain generated eases to a comfortable level. A rest period of 15 to 60 seconds is recommended between each TPR (37). The treatment can last from 30 to 45 minutes depending on the number of muscles involved. Tables 3.1 and 3.2 provides the procedure, frequency and treatment for group A and B.

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Table 3.1: Procedure, treatment and frequency for group A

Procedure	Treatment and Frequency
Group A: **1st treatment** – Trial checklist to be completed by the physiotherapist. Consent forms to be filled by the participants. Complete three baseline questionnaires (NPRS, FSFI, IPPQ). Subjective and objective assessment along with education of muscle involvement and treatment entailed. Education on good bladder, bowel and dietary habits if indicated. Signing of consent forms for treatment and the trial. Assess and treat with TPR and distention for the PFM, pelvic and abdominal muscles as per presentation. **4th treatment** – complete NPRS **8th treatment**-complete NPRS **10th treatment or when ceasing treatments due to positive outcomes** – to complete four final questionnaires (NPRS, FSFI, IPPQ, PTSS). **10th treatment**s – if no resolution is achieved, complete the final questionnaires and discharge from the trial but care continues.	Initial assessment of posture, spine and the PFM. Treatment is for 30-45 minutes on consent for treatment. Assess and treat with manual therapy for the PFM, pelvic and abdominal muscles if indicated. **Frequency** – The treatment is scheduled for every two weeks unless the participant has her menstrual cycle or due to personal issues. The appointment was then rescheduled for the week after. The HEP are stretches for the pelvic musculature as per presentation of CPP pain patterns. The patient is advised the application of cryotherapy for 15 minutes if she was sore after treatment.

Table 3.2: Procedure, treatment and frequency for group B

Procedure	Treatment and Frequency
Group B: **1st treatment** – Trial check list to be completed by the physiotherapist. Consent forms to be filled by the participants. Complete three baseline questionnaires (NPRS, FSFI, IPPQ). Subjective and objective assessment along with education of pelvic muscle involvement and treatment entailed. Education on good bladder, bowel and dietary habits if indicated. Signing of consent forms for treatment, TrDN and trial. Assess and treat with TrDN, TPR and distention for the PFM, pelvic and abdominal muscles per presentation. **4th treatment** – complete NPRS **8th treatment**-complete NPRS **10th treatment or final treatment-** due to positive outcomes, complete four final questionnaires (NPRS, FSFI, IPPQ, PTSS). **10th treatment**s – if no resolution is achieved, complete the final questionnaires and discharge from the trial but care continues.	Initial assessment of posture, spine and PFM. Treatment is for 30-45 on consent for treatment. Only introduce TrDN if the participant is happy to start treatment. **2nd treatment**- To perform superficial TrDN technique for the PFM as an introduction to the deep needling technique if the patient is apprehensive about TrDN followed by compression and stretching of the PFM. If the participant is particularly nervous, start with needling muscles that are segmentally-related to the PFM such as the piriformis, rectus abdominous, gluteus and adductors. For trans-perineal TrDN for the PFM, start with needling the Levator-ani muscles followed by the required deep PFM and then if required needle the superficial PFM. The patient is advised application of cryotherapy for 15 minutes if sore after treatment. **Frequency-** Identical to group A.

Statistical analysis and power calculation

Since this is the first study to analyse TrDN for the PFM, the power in these studies (12,13,25) were compared and it was estimated that in order to determine a $p<0.05$, with 80% power, $\alpha=0.05$, $\beta=0.2$, SD=1 for the outcome in the population and an effect size of 0.634, a total of 80 participants will be required. One hundred and twenty four participants will be invited as a participation rate of 70% is expected. Since studies analysing manual interventions for pelvic floor pain were not statistically significant (12,13), MCID was considered to be of practical significance. In chronic pain management, a 50% decrease in pain from baseline is rated as significant improvement, while a 30% decrease is rated as a meaningful improvement (38). Statistical analysis will be carried out using the IBM corp. SPSS software 24. Visual inspection of Histograms and Q-Q plots will be utilised to check the distribution of variables. A General Linear Model will be used to determine if the groups differed with regard to mean pain level at the endpoint of the study with pre-treatment score as the covariate in the analysis. The Kaplan Meier, non-parametric tests and Related Sample Wilcoxon Signed rank test are to be used for between-groups and within-group analysis.

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

Data monitoring

All questionnaires will be filled by the participants prior to their session at CUMH, CWC or at their homes. The data will be stored in secure locked storage at the Physiotherapy department at CUMH. The data collection will be undertaken by the researcher and a physiotherapist unrelated to the trial. On completion of the trial, the data will analysed for correct input by two doctors and one physiotherapist at CUMH who will be appointed as the data monitoring committee. An interim analysis will not be conducted for this trial.

Trial Duration:

The trial aims to run for two years.

Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Ref no: EMC 4 (kk) 01/03/16 & EMC 3(jj) 04/04/17.

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