

Psychological context effects of participant expectation on pain pressure thresholds as an adjunct to cervicothoracic HVLA thrust manipulation: A randomised controlled trial

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Running title: Context effects on PPTs

Abstract

Background: Chronic pain is a growing global and economically costly problem leading the National Health Service (NHS) in the UK to actively search for novel strategies to improve health outcomes. Some trials have shown a benefit when practitioners use a positive communication style, however, much of the available literature investigating the use of positive language to alter patient expectation utilises subjective reports from patients.

Objectives: To demonstrate whether positive and negative communication before a high-velocity low amplitude (HVLA) thrust spinal manipulation of the C7-T1 spine segments, and within an osteopathic consultation setting, increases and decreases (respectively) pain pressure thresholds (PPT) to form contextual placebo and nocebo effects. **Study design:** pre-test, post-test randomised controlled design. **Methods:** 35 asymptomatic participants were recruited and randomised into three separate condition arms using a repeated measures cross-over design; negative communication (NegC), neutral communication (NeuC), or positive communication (PosC). Each condition included spinal manipulation (HVLA thrust) to the C7-T1 segments. PPTs were measured by an algometer over the spinous process of C7 pre and post each condition setting. **Results:** There was a significant effect of language style on PPT for the three conditions. Post-hoc tests demonstrated that positive communication had a significant effect on PPT (i.e., placebo effect), but the negative communication demonstrated no significant effect (i.e., no nocebo). **Conclusion:** These results were discussed in the context of communication style used during an osteopathic clinical consultation to potentially improve health outcomes in NHS and other clinical settings (Clinical trial registry <https://clinicaltrials.gov/> number: NCT03855254).

Key words: Contextual effects; Pain pressure thresholds; Osteopathy

Implications for Practice

- Placebo effects may enhance HVLA thrust treatment.
- Contextual factors may play an important role in osteopathic care.
- Communication style may be implemented in NHS clinical settings.
- There are ethical considerations when using contextual factors in patient care.

Introduction

Chronic pain can be defined as pain which is not resolved during the normal period of tissue healing time (Fayaz, Croft, Langford, Donaldson, & Jones, 2016), with symptoms lasting a minimum of 3 months (Hildebrandt et al., 2004). During an episode of pain, quality of life can be dramatically reduced and the ability to carry out daily tasks is limited (Schmiemann et al., 2015).

The epidemiological evidence suggests that the most common cause of disability worldwide is chronic pain (Vos et al., 2012). Chronic low back pain, for example, is now the most significant cause of years lived with disability in 86 countries worldwide (Brucki, 2016). Fayaz et al. (Fayaz et al., 2016) found that in the United Kingdom alone, just under 28 million people suffer from chronic pain and showed that there was a relation between age and incidence, where 62% of those over the age of 75 experience the condition. Recent estimations suggest that the economic burden of chronic pain in Europe is approximately €200 billion per year (Van Hecke, Torrance, & Smith, 2013). As a result of the cost and prevalence of this disability locally and worldwide, the National Health Service (NHS) have been actively searching for novel strategies to treat chronic pain in the UK at low cost (Donaldson, 2009).

Currently, the treatment options for chronic pain is multidisciplinary in nature, with the main focus of treatment being educational, medical, and psychosocial (Finlay & Elander, 2016). However, although a multidimensional approach is advised, pharmacological prescription is still the most common treatment (Varrassi et al., 2010). The guidelines for non-invasive treatments for acute, subacute, and chronic pain suggest that pharmaceuticals should be avoided and instead massage, acupuncture, superficial heat, or spinal manipulation should be preferred in the first instance (Qaseem, Wilt, McLean, & Forciea, 2017).

Recent NICE guidelines (Bernstein, Malik, Carville, & Ward, 2017) suggest that an alternative to drug use when treating chronic pain is to use manual therapy as part of a broader package of treatments such as exercise therapy and psychological treatment. One type of manual therapy which has received growing support from empirical evidence is called Osteopathic Manipulative Therapy (OMT), which utilises manipulation and mobilisation techniques. There is, for example, some supportive evidence that thoracic manipulation has been shown to be effective when compared to a control for neck pain, whereas the results for cervical manipulation and mobilisation is more diverse and less clear as reported in a Cochrane review (Gross et al., 2015). OMT has even been shown to reduce several co-morbid pain-related psychological disorders such as anxiety, and to improve immediate mental health status (Edwards & Toutt, 2018). Indeed, OMT (and manual therapy in general) have shown to have psychological benefits which have been supported by a systematic review (Saracutu, Rance, Davies, & Edwards, 2017).

Psychological components can play an important role in pain perception and this has been previously modelled by researchers (Legrain, Iannetti, Plaghki, & Mouraux, 2011; Melzack, 1999) in a Neuromatrix model. Melzack described pain as being entirely subjective and including somatosensory, limbic, and cognitive components. The Neuromatrix model suggests that a person's pain experience will be influenced by the combination of the sensory

input given, the individuals' perceptions, previous experiences, and expectations. The link between the perception of pain, psychological expectation, and experience is also supported by recent research conducted which explores how contextual factors (CFs) influence pain perception (Testa & Rossetini, 2016).

CFs have been found to be crucial for the management of musculoskeletal pain as identified in a recent review (Testa & Rossetini, 2016). For example, they are recognised as having influence over every complex musculoskeletal intervention, but are currently considered as incidental rather than being used intentionally by clinicians (Paterson & Dieppe, 2005). CFs can produce a therapeutic effect through the same pain modulation pathways as activated by hands-on (e.g., manual therapy) and hands-off (e.g., pain neuroscience education) commonly practiced therapies (Bialosky et al., 2018; Bialosky, Bishop, Price, Robinson, & George, 2009; Bishop et al., 2015). CFs can also serve as an additional tool to facilitate clinicians in relation to the complexities of pain management (Dieppe, Goldingay, & Greville-Harris, 2016).

More specific examples for the effectiveness of CFs have been demonstrated in cases of placebo and nocebo effects. A placebo effect can be defined as an inert therapeutic procedure which produces a beneficial effect, but which cannot be attributed to the properties of the placebo itself but to the patients belief in the treatment's effectiveness (Gottlieb, 2014). Or more simply, it can be defined as a form of contextual healing (Miller & Kaptchuk, 2008). A nocebo effect refers to the negative psychosocial context attributed to the patients beliefs about the therapeutic treatment's effectiveness, and the negative effects this has on the patient's brain or body (i.e., either a reduction of treatment effectiveness or actual harmful effects to the patient) (Enck, Benedetti, & Schedlowski, 2008).

Placebo effects have been shown to have beneficial clinical effectiveness in situations when deliberately given to patients with fibromyalgia, as demonstrated in a recent meta-analysis (Chen et al., 2017). It has also been shown to have clinical effectiveness in the treatment of osteoarthritis, as demonstrated through a meta-analysis (Zhang, Robertson, Jones, Dieppe, & Doherty, 2008). Nocebo CFs, induced through negative suggestion, have been shown to increase pain across osteoporosis (Dieppe et al., 2016), rheumatoid arthritis (Chen et al., 2017) fibromyalgia (Goossens, Vlaeyen, Hidding, Kole-Snijders, & Evers, 2005) and headaches (Benedetti, Durando, & Vighetti, 2014). CF effects have, in some cases, been found to be larger than the actual treatment effects. This was demonstrated in a meta-analysis which found that in cases of spinal manual therapies for both acute and chronic pain; respectively 81% and 66% of the pain variance were ascribed to CFs (Menke, 2014).

To-date, the existing literature on CFs have focused on outcome measures such as; (1) patient satisfaction measures such as those identified in various systematic reviews (Hush, Cameron, & Mackey, 2011; Oliveira et al., 2012); (2) therapeutic alliance measures such as trust, rapport, and agreement between patient and the therapist (Pinto et al., 2012); (3) qualitative measures which focus on the influence of patient-therapist interactions, as identified in a systematic review (O'keeffe et al., 2016); (4) Visual Analogue Scales (VAS) for pain such as those identified in a meta-analysis for arthritis (Chen et al., 2017); (5) other subjective self-report measures (Goossens et al., 2005); (6) neurochemical enzymes such as cyclooxygenase in the saliva (Benedetti et al., 2014); (7) and other hormones such as cortisol and growth hormones (Benedetti et al., 2003).

One outcome measure which has not been utilised frequently in relation to CF effects is the use of pain pressure thresholds (PPT). The need to explore a comprehensive range of outcome measures in relation to CFs has been highlighted previously (Bialosky et al., 2009), and this includes pain thresholds, which would add to the growing body of evidence on CF

effects. Pain thresholds are commonly used in OMT and other manual therapy research (Cathcart, McSweeney, Johnston, Young, & Edwards, 2019; McCoss, Johnston, Edwards, & Millward, 2017; Paungmali, O'Leary, Souvlis, & Vicenzino, 2003; Vicenzino, Paungmali, Buratowski, & Wright, 2001). Pressure algometry was designed to record the smallest measurement of mechanical stimuli that can be perceived as pain (Fischer, 1987). There is some literature supporting the algometer as a reliable, valid, and easy method of measuring the hypoalgestic effects of manual therapy, with intraclass correlation coefficients found to be between 0.78 and 0.99 (Cathcart et al., 2019; Ylinen, Nykänen, Kautiainen, & Häkkinen, 2007).

Given the clinical significance of this test in manual therapy practice, it is perhaps surprising that not more studies relating to CFs have focused on PPT within OMT. One study, however, did use PPTs in relation to a thermal pain sensitivity threshold with the use of a hand-held peltier-element-based stimulator. They found that when using spinal manipulation therapy for the low back on asymptomatic participants (without pain), positive expectation CF lowered thermal pain sensitivity (thus increased thermal pain threshold), and negative expectation CF increased pain sensitivity (thus decreased thermal pain threshold) (Bialosky, Bishop, Robinson, Barabas, & George, 2008). The present study expands on this work by focusing on a different type of pressure threshold, that being algometry induced PPT instead of a thermal threshold, and also with an asymptomatic population. **The key difference between this present study and that of Bialosky et al. is that in this present study we will explore the use of a high velocity low amplitude (HVLA) thrust of the cervicothoracic junction (C7-T1) instead of the spinal manipulative therapy (SMT) which Bialosky used.**

This study is therefore unique as it investigates the impact of CF in an OMT setting with pain pressure thresholds (PPTs) and with the use of the HVLA thrust. Though there are many potential OMT techniques, the HVLA thrust is a particularly advantageous method to

decrease chronic spinal pain, which has been seen to increase pain pressure threshold (PPT) both locally and distally (Coronado et al., 2012), particularly over the zygapophyseal joints (Fernández-De-Las-Peñas, Alonso-Blanco, Cleland, Rodríguez-Blanco, & Albuquerque-Sendín, 2008) and spinous process (de Camargo et al., 2011).

Therefore, the aim of this present study is to explore how CFs impact on PPT after a HVLA thrust. Firstly, as the HVLA thrust has previously shown to increase PPT in a similar area (de Camargo et al., 2011) then it is (1) hypothesised that the HVLA thrust over the C7-T1 spinal segments will lead to a significant interaction effect between time (pre and post intervention) and condition. As a secondary hypothesis, it is also hypothesised that (2) there will be a significant increase in PPT overall (significant main effect of time; pre and post intervention). However, as studies have shown that negative communication have led to a significant reduction in thermal pain threshold (Bialosky et al., 2008) then it is (3) hypothesised that PPT will be significantly lower for the NegC condition when compared to the NeuC condition (i.e., nocebo effect). Finally, as positive communication has been shown to improve health outcomes (Little et al., 2001) and reduce pain activity in the brain (Keltner et al., 2006), as well as increase thermal thresholds (Bialosky et al., 2008); it is (4) thus hypothesised that PPT will be significantly greater in the PosC condition when compared to the NeuC condition (i.e., a placebo effect).

Method

Design

This was a three arm repeated measures crossover randomised controlled trial. The crossover design has the advantage of removing any individual differences in the population across the conditions as the same individuals are used for each condition. The chances of obtaining a type 2 error can be reduced as a repeated crossover design has greater power than a between

groups design (Sibbald & Roland, 1998). The CONSORT statement (Consolidated Standards of Reporting Trials) (Moher et al., 2010; Schulz, Altman, & Moher, 2010) was used for the reporting of this study.

Participants

Thirty-five asymptomatic (22 Female, 13 Male) first- and second-year undergraduate students participated in this study and were recruited via posters which were placed in the student communal areas. The inclusion criteria for this study included participants being aged between 18-45, having good comprehension of English to acquire valid informed consent, good or corrected to good vision, and having no present symptoms of pain. Participants were excluded if they had any existing or previous persistent pain (lasting for more than three months) or whiplash to the cervical spine (Csp) in the last year, were taking any analgesic or anti-inflammatory medication, or had hypermobility of the C7-T1 segments. Relevant health information was obtained via a medical history questionnaire completed by participants before involvement in the study. The selected participants (once consent was taken) were then randomly assigned into a sequence of study conditions through the use of a computer research randomiser (see randomisation section). All of the participants participated in the three condition arms (see CONSORT diagram in Figure 1). These included a neutral communication condition (NeuC), a positive communication condition (PosC) and negative communication condition (NegC).

-----**Figure 1 Here**-----

Participant crossover randomisation

There were three condition arms and with six possible sequence combinations in this crossover randomisation design; [1, 2, 3]; [1, 3, 2]; [2, 1, 3]; [2, 3, 1]; [3, 1, 2]; [3, 2, 1]. In order to remove order effects, a computer-generated randomiser (Urbaniak & Plous, 2013) was then used to allocate the participants into one of the six condition sequences. This was conducted by researcher 3 (who was separate from the intervention and measurement stages of the actual experiment). A one-week washout period was employed between study conditions to prevent any within conditions intervention contamination. The allocation assignment was held by the experimenters (researcher 2 and 3) and not revealed to the participants at any time. The participants were simply asked (by researcher 3) to attend three sessions on different dates and without knowing what their random allocation sequence was. Once allocated, the study was conducted over three weeks (January – February 2018) with immediate (same day) follow-up (post intervention) and ended once the required sample was met.

Ethical approval

Ethics were approved through the University Research Ethics Council (REC) which included participant consent, right to withdraw and a full debriefing at the end of the study.

Blinding

Researcher 1 (R1) conducted the measurements only, whilst Researcher 2 (R2) conducted the intervention only. Researcher 3 (R3) randomised the participants into the sequence allocations and was not part of the intervention delivery or measurement stages. Sequence allocation was only revealed to R2. R1 left the laboratory during the intervention phase and was thus blind to the type of intervention given. R2 left the laboratory during the measurement phase and was thus blind to the measurements taken. Of course, despite the

researcher blinding, it is acknowledged that participants may have inferred elements of the study design (though these details were not given to them) given the repeated nature of it. For this reason, it was difficult to blind participants.

Materials

Primary outcome measure

Pain pressure thresholds (PPT). Pain pressure thresholds were measured obtained using a handheld Wagner FDX digital force gauge manufacturer calibrated algometer. The algometer had a rubber tip of 1cm and pressure was applied at a rate of 10 newtons/second.

Pressure algometry is designed to record the smallest measurement of mechanical stimuli that can be perceived as pain (Fischer, 1987; Kinser, Sands, & Stone, 2009). Pressure algometry is frequently utilised to quantify whether there are any alterations in the participants' pain perception following a treatment intervention (McCoss et al., 2017). There is some literature supporting the algometer as a reliable, valid, and an easy method of measuring the hypoalgestic effects of manual therapy (ICC = 0.78-0.99) (Antonaci, 1998; Cathcart et al., 2019; Ylinen et al., 2007). Another paper have also reported good inter-examiner reliability (ICC = 0.75) and excellent intra-examiner reliability (ICC = 0.84)(Antonaci, 1998) .

Procedure

First the inclusion and exclusion criteria were applied to the participant selection (see participants section) and the selected participants were then randomised into one of the six condition sequences (see randomisation section). Participants participated in all three study conditions based on the determined randomised sequence they were allocated to. This included a one-week washout period between the conditions to reduce cross-condition

contamination effects. The study was conducted in a quiet research laboratory room with no clock. In all conditions the algometer was applied slowly to the allocated area at a steady rate of 10 (newtons per second) Ns^{-1} . The participants were instructed to say 'stop' when they felt that pain was immediately uncomfortable, which is a subjective response. This was instructed as follows; 'Please respond with the word stop when you feel the pain is immediately uncomfortable'. The study conditions were as follows:

Neutral communication (NeuC).

Baseline outcome readings of PPT over the C7 spinous process and demographic data (in the case that this was the first condition they participated in) were initially assessed by R1. R1 then left the room whilst R2 entered and then told the participant: "I am going to carry out a spinal manipulation to an area at the bottom of your neck. There is limited evidence supporting the use of this technique, but it could reduce pain in this area." R2 then carried out a seated HVLA thrust manipulation to the C7-T1 segments (see Figure 2). R2 then assessed the mobility at the segment but made no comment to the participant. After this, R2 left the room to be replaced by R1 who recorded the post intervention PPT measure.

Positive communication (PosC).

A baseline outcome readings of PPT over the C7 spinous process and demographic data (in the case that this was the first condition they participated in) were initially assessed by R1. R1 then left the room whilst R2 entered and then told the participant: "I am going to carry out a spinal manipulation to an area at the bottom of your neck. There is a lot of evidence supporting the use of this technique, it will reduce pain in this area." R2 then carried out a seated HVLA thrust manipulation to the C7-T1 segments. R2 then assessed the mobility at the segment and explained to the participant that the tissue quality in the area had improved.

After this, R2 left the room to be replaced by R1 who recorded the post intervention PPT measure.

Negative Communication (NegC).

A baseline outcome readings of PPT over the C7 spinous process and demographic data (in the case that this was the first condition they participated in) were initially assessed by R1. R1 then left the room whilst R2 entered and then told the participant: “I am going to carry out a spinal manipulation to an area at the bottom of your neck. There is no evidence supporting the use of this technique to reduce pain in the area, so I am expecting no change”. R2 then carried out a seated HVLA thrust manipulation to the C7-T1 segments. R2 then assessed the mobility at the segment and explained to the participant that the tissue quality had not improved. After this, R2 left the room to be replaced by R1 who recorded the post intervention PPT measure.

Application of the algometer and responses

-----**Figure 2 Here**-----

Site Location and Justification

Though this study was concerned with context effects, a genuine (unbiased by context) treatment effect was sought for the neutral condition. This was sought to identify whether the context effects in the positive and negative conditions increased or decreased this genuine effect through comparison with the neutral condition. The site chosen to measure PPT was on the skin over the spinous process of C7. This site was located by passively assessing the participants cervical spine through flexion and extension. It is identified as extension of the

C6 spinous process moves anteriorly and the C7 spinous process does not move (Shin, Yoon, & Yoon, 2011). Shin et al. (Shin et al., 2011) have suggested the flexion and extension method of locating the C6 and C7 vertebrae is the most accurate method.

The site location of the C7 spinous process was chosen for PPT measurement as previous research has demonstrated that the application of a HVLA thrust manipulation to the C5-6 joint increases PPT over the C5 spinous process (de Camargo et al., 2011) and the zygapophyseal joints (Fernández-De-Las-Peñas, Pérez-De-Heredia, Brea-Rivero, & Miangolarra-Page, 2007). However, as the spinal manipulation aimed for cavitation of the C7-T1 zygapophyseal joints, like in other studies (de Camargo et al., 2011), PPT was therefore measured at the spinous process of the superior vertebrae (C7) in this study.

Power calculation

A G*Power 3.1 calculation (Faul, Erdfelder, Lang, & Buchner, 2007) gives an ideal sample size of 35, for a repeated measures ANOVA, where the effect size was set to an a priori moderate effect size of $d = 0.5$ ($\eta_p^2 = 0.06$), alpha at 0.05 and power at 0.9¹, according to Dattalo's text book on determining sample size using G*Power (Dattalo, 2008). In this study, 35 participants were recruited which had a power of 0.9 with only a 10% probability of making a type 2 error.

Statistical analysis

IBM's SPSS software version 23 was used to conduct the data analysis. A logarithmic transform (log 10) was conducted to correct for positive skewed distributions. A Shapiro-Wilk test was then used to test the goodness of fit which confirmed that the data was sampled

¹ Number of groups = 1 (within factor) by three intervention measures for a 2x3 repeated measures, within factors ANOVA.

from a normally distribution and thus the model was parametrically valid ($p > 0.05$). This, therefore, justifies the use of parametric tests. Correcting non-normality through transformation does not affect the statistical relationship between variables (Field, 2009). A general linear model consisting of a two (baseline / after intervention) by three (NeuC / PosC / NegC) repeated measures analysis of variance (ANOVA) was conducted with PPT as the dependent measure. All participants (35) were included in the analysis. Outliers were assessed through visual boxplots, but no data were identified as extreme and no data were removed.

Results

Demographics

The demographics of the participants were are described in Table 1. There were 22 females and 13 males.

-----Table 1 Here-----

Descriptive statistics

As can be seen in Table 1 and Figure 3 (for a bar chart representation of the differences), there was a post-condition increase in PTT for all study conditions. PosC demonstrated the greatest post-condition increase in PPT.

-----Table 2 Here-----

-----Figure 3 Here-----

Inferential statistics

The assumptions of the parametric test were met (see statistical analysis section) as the data were normally distributed. See Table 3 for the inferential statistics. The main effect for condition (NeuC, NegC, and PosC) was significant and with a medium effect size. The main effect for time (pre-post) was also significant with a large effect size. Crucially, the interaction between time and condition was also significant. Bonferroni pairwise comparison was then used which indicated that the difference between NegC and NeuC was not significant (mean difference = 0.08, SE = 0.15, $p = 0.59$, CI = -0.22 to 0.38); the difference between NegC and PosC was significant (mean difference = -0.39, SE = 0.17, $p < 0.01$, CI = -0.74 to -0.41); the difference between NeuC and PosC was also significant (mean difference = -0.47, SE = 0.18, $p < 0.01$, CI = -0.82 to -0.11). The hypothesised assumptions for hypothesis 1, 2, 4 but not 3 were therefore met.

-----**Table 3 Here**-----

Discussion

The present study sought to investigate whether contextual effects would arise in the case of a HVLA thrust technique of the C7-T1 spinal segments. It was hypothesised that (1) there would be a significant interaction effect between time (pre and post intervention) and condition. The second hypothesis (2) predicted that there would be a significant increase in PPT for all three conditions (significant main effect of time; pre and post intervention). It was also hypothesised that (3) PPT will be significantly lower for the NegC condition when compared to the NeuC condition (i.e., placebo effect). Finally (4), it was hypothesised that PPT would be significantly greater in the PosC condition when compared to the NeuC condition.

The findings showed that for the primary hypothesis of an interaction between time and condition was observed and the null hypothesis can be rejected (significant interaction effect). For the second hypothesis the null hypothesis can be rejected, thus all conditions significantly increased after the HVLA technique (a significant main effect of time; pre and post). However, for the third hypothesis the null hypothesis cannot be rejected, thus there was no significant decrease in PPT in the NegC. For the fourth hypothesis, the null hypothesis can be rejected, and it was found that the PosC PPT was significantly greater when compared to the NeuC condition.

These findings are interesting and add to the growing body of evidence which demonstrate CFs can enhance treatment effects. These include specific studies which have shown the effectiveness of placebo (positive) CFs such as in cases for the treatment of fibromyalgia, as demonstrated in a recent meta-analysis (Chen et al., 2017) and in a meta-analysis for the treatment of osteoarthritis (Zhang et al., 2008).

There were, however, some differences in the present results and those found in other studies. For example, researchers such as Bialosky (Bialosky et al., 2008) found that positive CFs (communication style; placebo effect) increased thermal pain thresholds which is consistent with the present findings, but they also found that negative CFs (communication style; nocebo effect) decreased thermal pain thresholds which is inconsistent with the present study findings. Similar findings have been demonstrated in other research such as that of Little et al. (Little et al., 2001) who found that a positive approach (positive CF) led to increased satisfaction, increased feelings of enabledness, and reduced number of referrals, but also found that negative approaches (negative CF) led to greater symptom burden.

Nocebo CFs have been found in many other studies, for example, in the worsening effects of pain in cases of negative communication in areas of osteoporosis (Dieppe et al., 2016), rheumatoid arthritis (Chen et al., 2017) fibromyalgia (Goossens et al., 2005) and

headaches (Benedetti et al., 2014). The fact that nocebo effects were not found in the present study maybe due to the measurement type used (e.g., PPTs as opposed to VAS and other subjective measures) or perhaps that the participant sample used in this study were asymptomatic rather than a clinical population.

One practical applications for this modulated patient perception of pain and treatment effectiveness could be to apply this as a novel health care protocol for clinical practice and this includes the NHS. The conscious use of communication styles could be reinforced to improve healing times and health outcomes (Bialosky et al., 2008). A review by Testa and Rossetini (Testa & Rossetini, 2016) suggested that placebo enhancement should be sought in clinical practice whilst nocebo should be avoided. However, further clinical trials would first be needed to be conducted on a pain population and which would also explore potential adverse effects (for example, to explore what the effects would be if the placebo is later removed, which may alter the treatments genuine effectiveness).

There are of course ethical considerations when trying to enhance the treatment outcomes through the use of CFs which lead to placebo effects. However, amongst healthcare providers, the adoption of placebo strategies seem to be commonplace (Fässler, Meissner, Schneider, & Linde, 2010). Examples of professionals who condone the use of CFs for musculoskeletal pain specifically include; orthopaedic surgeons, rheumatology physicians and nurses, who all feel that placebo effects are real and permissible within the ethical boundaries of health care (Baldwin, Wartolowska, & Carr, 2016; Berthelot, Maugars, Abgrall, & Prost, 2001; Wartolowska, Beard, & Carr, 2014). Also, it is not just professional staff who feel this practice is permissible. Patients with chronic musculoskeletal pain and rheumatologic complaints also feel that CF effects are an acceptable adjunct treatment alongside actual treatment. (Berthelot et al., 2001; Hughes et al., 2017; Kisaalita, Staud, Hurley, & Robinson, 2014).

Some scientific and medical communities have focused on the transparent disclosure of placebo treatments (Alfano, 2015; Blease, Colloca, & Kaptchuk, 2016; Miller & Colloca, 2009, 2011), whereby, for example, a sham treatment could be given with prior consent (Bishop et al., 2017). The general consensus seems to be that in order to maintain best evidence-based therapy then this informing of the participants and without deception should be sought (Annoni & Miller, 2016; Blease et al., 2016; Charlesworth et al., 2017). Surprisingly, despite the common belief that disclosing the placebo intervention reduces its efficacy, this has not been found to be true as the placebo effect has still been found in open label trials with full condition disclosure given to patients (Bialosky & Robinson, 2017; Carvalho et al., 2016). So, the consensus so far seems to be to establish ethical mindful manipulation of CF effects where there is disclose, which may represent a useful opportunity to enrich well-established therapies (Miller & Colloca, 2009). This would allow for the implementation of CF knowledge in daily therapeutic practice rather than labelling CFs as unknown confounding factors (Linde, Fässler, & Meissner, 2011; Rossetini & Testa, 2017).

However, much work still needs to be carried out on CFs as there has been quite a lot of work done to understand how CFs affect pain (Carlino & Benedetti, 2016; Carlino, Frisaldi, & Benedetti, 2014) but there is still much that is not known in relation to the impact of CFs on different populations. For example, little is known about the impact of CF effects on young and old sufferers of musculoskeletal pain (Simmons et al., 2014), in chronic and acute conditions (Müller et al., 2016) and between different pain mechanisms such as nociceptive, neuropathic, and central sensitisation (Nijs et al., 2015). It is suggested that it is of paramount importance to understand the psychological, psychophysiological, neuroendocrine and genetic elements that predict the responsiveness of certain CFs (Enck, Bingel, Schedlowski, & Rief, 2013), so perhaps this is where future studies should focus in relation to CF effects.

One potential limitation is that this was a repeated measures design and that this can be subject to order effects. However, this was mitigated largely due to the fact that the sequences were counterbalanced thus balancing any bias of order effects. Of course, the advantage of using a repeated study design is that it removes any individual difference bias and increases the statistical power when compared to a between design. A second potential limitation of this study is that it used an asymptomatic population and not a pain population, so generalisability is always questionable. As the intention was to test the proof-of-concept first for this specific HVLA thrust context, before testing on a chronic pain population (for ethical reasons), this was deemed an appropriate first study step. This study was motivated in part to compare with study results of Bialosky et al. (Bialosky et al., 2008), who also used asymptomatic patients. The justification of use and generalisability of asymptomatic patients has been made by Bialosky et al. (Bialosky et al., 2008) in this context as a valid means to assess placebo and nocebo effects. They stated that participants experiencing clinical pain have a greater desire for pain relief with greater expectations for the benefits of treatment, so studies would likely find an increase in placebo effect with a pain population. The use of asymptomatic participants, therefore, may have limitations but it does allow for comparisons to be made with other relevant work such as that from Bialosky.

The fact that the CF effects seemed to have a greater impact than the HVLA thrust condition could be attributed to the fact that the patients were asymptomatic. Hence, there is a clear need to explore a population in pain. More studies are also needed in the area like this and Bialosky et al. (Bialosky et al., 2008) to effectively compare how CF effects modulate specific outcomes of techniques for different bodily areas for both pain and asymptomatic populations.

In conclusion, the present study findings provide further evidence for CF effects in relation to a HVLA thrust technique in manual therapy. Given this and the fact that UK

Health Boards are actively looking for novel methods to reduce costs and increase the efficacy of treatment (Magalhães et al., 2015), then further investigation into CF effects are much needed, as this is perhaps one effective way of increasing efficacy at low cost. Exploring CFs in the context of OMT seems to be particularly useful given its focus on producing a patient centred and personalised treatment plan which could easily incorporate CFs into the plan. However, much further research is needed to support a more conscientious therapeutic approach to the use of CFs in health professional practices such as physiotherapy, chiropractic, osteopathathy, nursing, occupational therapy, rheumatology, and orthopaedic practice, who all work with musculoskeletal pain patients. These may include; (1) defining how CFs work from a neurophysiological perspective; (2) to define the clinical relevance in pain management; (3) to consider the use of CFs within established ethical boundaries; (4) and to suggest how to utilise this wealth of knowledge when utilising CFs in clinical practice. Perhaps once these are further understood, the conscientious use of CF effects will become more prevalent in day to day healthcare practice, and this is becoming an exciting area for OMT research.

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Figure 1.
CONSORT flow diagram with three arms and with immediate effects recorded.

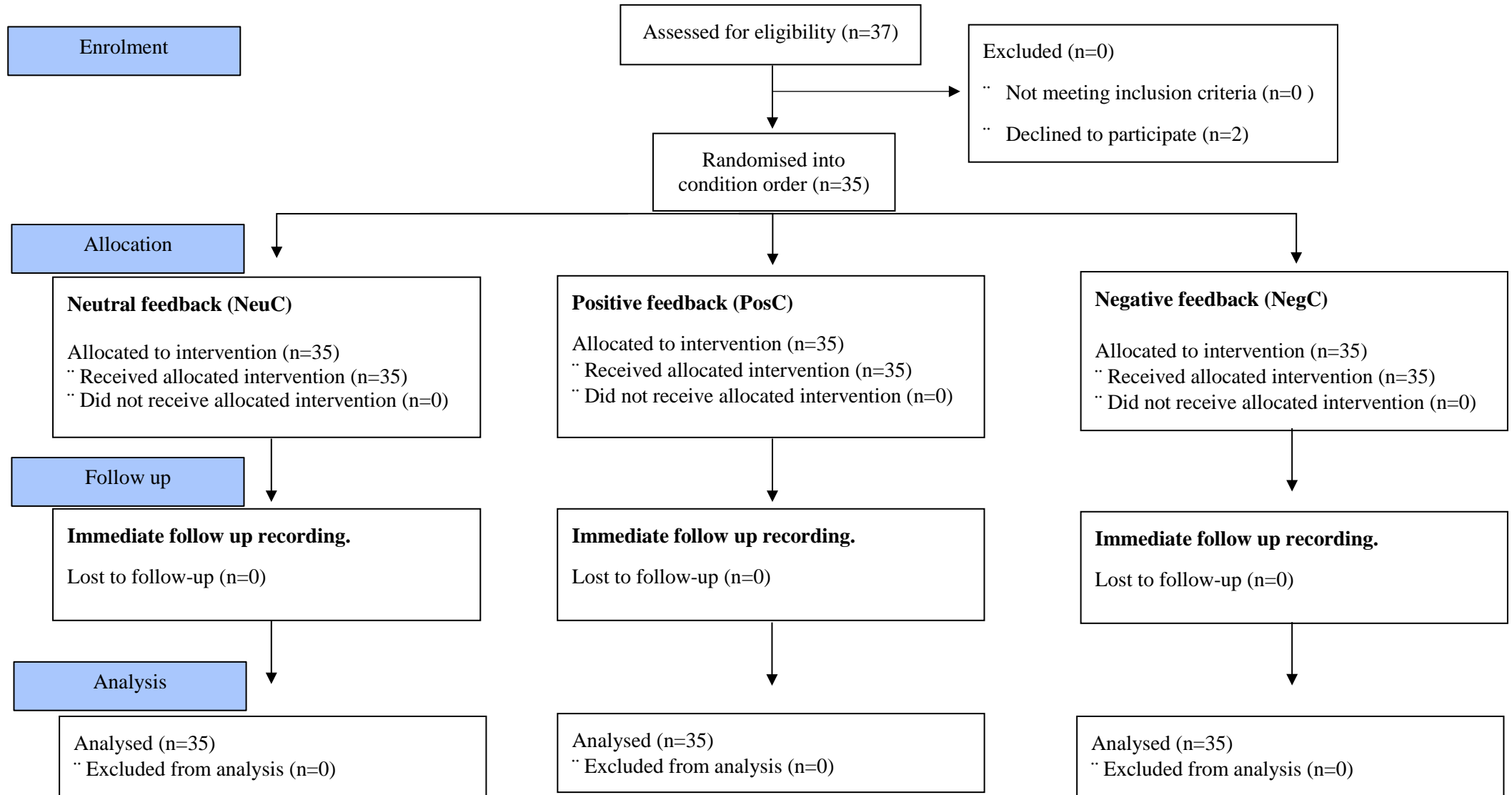


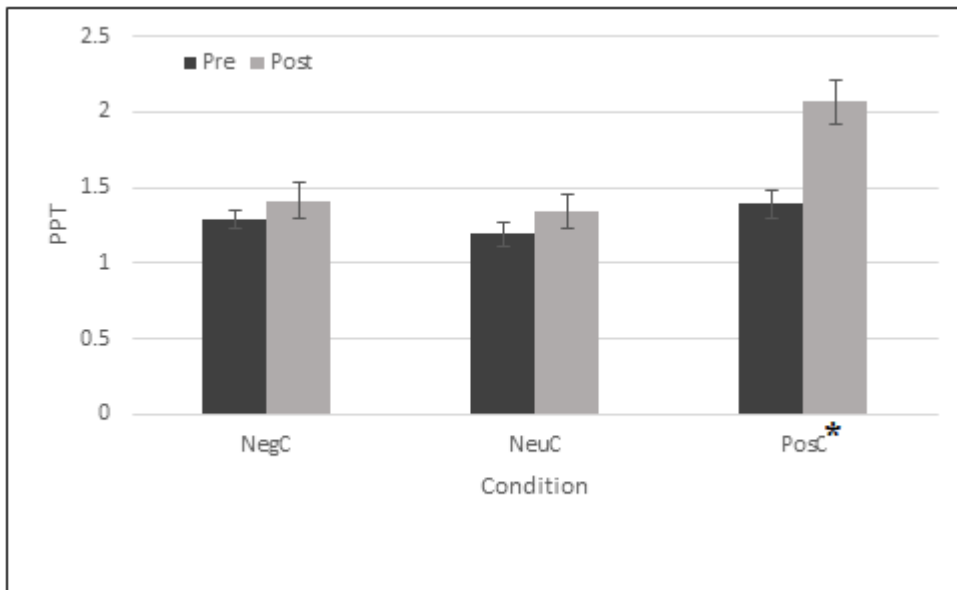
Figure 2.

An illustration of the HVLA manipulation of the cervico-thoracic joint.



Figure 3.

Bar chart showing the average PPT scores for each condition with error bars representing 1 standard error of the mean.



Note: * indicates a significant difference between pre and post condition at $p < 0.05$. NegC = negative condition; NeuC = neutral condition; PosC = positive condition.

Table 1.**Demographic data, 16 males and 19 females (Total N = 35)**

Measurement	Mean	SD
Age (Years)	21.50	4.26
Height (CM)	175.63	9.65
Weight (KG)	70.90	10.64
BMI	22.97	2.33

SD=Standard Deviation; Age=years; Weight=kilograms;
Height=Centimetres; BMI= Body Mass Index.

Table 2

Descriptive statistics of the PPT measure for each condition pre and post intervention.

Condition	Pre-Mean (SD)	Post-Mean (SD)
NegC	1.28 (0.47)	1.41 (0.66)
NeuC	1.19 (0.59)	1.34 (0.58)
PosC	1.39 (0.64)	2.07 (0.97)

NegC = Negative communication condition; NeuC = Neutral communication condition;
PosC = Positive communication condition

Table 3

Inferential statistics of the PPT measure for each condition pre and post intervention.

Condition	<i>F</i> (<i>df</i>)	Sum of Squares	Mean Square	<i>p</i>	η_p^2
Condition (main effect)	4.61 (2)	8.76	4.38	=0.013	0.12
Time (main effect)	76.71 (1)	5.25	5.25	<0.001	0.69
Interaction (Condition x Time)	26.94 (2)	3.27	1.64	<0.001	0.44

NegC = Negative communication condition; NeuC = Neutral communication condition;
PosC = Positive communication condition