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# **Immediate effects and associations between interoceptive accuracy and range of motion after a HVLA thrust on the thoracolumbar junction: A randomised controlled trial**

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**Short title: Associations between interoception and ROM**

## Abstract

**Background.** There is paucity in the literature regarding the role of interoceptive accuracy (IAc) at predicting the effectiveness of osteopathic techniques which increase spinal mobility when directed specifically at the thoracolumbar junction (TLJ). **Aims.** The study aimed to explore whether a high velocity, low amplitude (HVLA) thrust of the TLJ would increase spinal mobility (measured through Range of Motion; ROM) and change IAc. Also, whether baseline IAc correlated with the post-ROM measures and change in ROM. **Method.** 21 asymptomatic participants were allocated into three conditions in a randomised order. These were; (1) a high velocity low amplitude manipulation of the TLJ; (2) sham (basic touch); and (3) a control (laying supine on a plinth). Before and following each intervention, the participants' spinal ROM was measured using an Acumar digital inclinometer. In addition to this an ECG was used to measure their pre and post condition IAc. **Results.** There were significant increases in ROM for all condition, however, the HVLA thrust led to a significantly greater increase in ROM ( $p < 0.001$ ) when compared to the control and sham. Baseline IAc was inversely associated with post-ROM but there was no association with change in ROM. The HVLA thrust did not significantly change IAc scores from pre to post intervention. **Conclusions.** HVLA thrust over the TLJ is a useful intervention for increasing spinal ROM. IAc maybe a useful predictor for intervention effectiveness of this technique and spinal area which could in the future be utilised by osteopaths as part of their diagnostics.

## Keywords

Osteopathy; HVLA thrust; Thoracolumbar Junction; Range of Motion; Interoception

## Introduction

Low back pain (LBP) is a common cause of pain and disability, which the majority of the population will experience at some point in their lives (Bhangare, Kaye, Knezevic, Candido, & Urman, 2017; Klyne, Barbe, & Hodges, 2017; Yang, Haldeman, Lu, & Baker, 2016). It is also one of the leading causes of global disability (Freburger et al., 2009), and leads to the greatest frequency of medical claims, pharmacological prescriptions and catalogued authorised leave worldwide (Driscoll et al., 2014).

Thoracolumbar junction (TLJ) syndrome has in the past been posited as a source of LBP (Maigne, 1980). TLJ syndrome characteristically presents as LBP, pain surrounding the iliac region and pseudo-visceral pain which can facilitate irritable bowel like symptoms (Aktas, Palamar, Ozkan, & Akgun, 2016). In addition to direct pain, deviation from optimal vertebral compliance in this area can lead to restriction of movement which can perpetuate into additional pain to the corresponding surrounding regions (Balagué, Mannion, Pellisé, & Cedraschi, 2012). Restriction of movement is commonly measured through range of motion (ROM), where, as pain intensifies, ROM typically reduces (Rudolfsson, Björklund, & Djupsjöbacka, 2012).

The TLJ is thought to typically span from the vertebra of T12 through L1, though when individual differences are taken into consideration, it is typically more clinically practical to take it from the region of T11 to L2 (Tokuhashi, Matsuzaki, Uematsu, & Oda, 2001). In addition to this, T10-L2 (Benson, Burkus, Montesano, Sutherland, & McLain, 1992) and T9-L2 (Panjabi & White, 1978) have both been suggested as viable TLJ spans. The TLJ is anatomically complex, inclusive of the 12<sup>th</sup> rib, intertransverse ligament, the diaphragm, the lumbar and thoracic erector spinae, iliopsoas quadratus lumborum, latissimus dorsi muscle, thoracolumbar fascia, cisterna chyli, as well as the dorsal rami and superior

cluneal nerves (Dakwar, Ahmadian, & Uribe, 2012). This region is of particular risk, should trauma occur, due to the junction being anatomically complex and an important transitional area (Smith et al., 2010).

As one of the principal characteristics of Maigne's syndrome is restriction of the TLJ, primary treatment methods are focused upon improving this (Smith et al., 2010). A common form of manipulation utilised by osteopaths is the high velocity low amplitude (HVLA) thrust manipulation, as it is proficient and a relatively safe method utilised to address spinal restriction (Goertz et al., 2016). It is also cost effective in comparison to pharmaceutical interventions (Hebert, Stomski, French, & Rubinstein, 2015). Spinal manipulation is primarily utilised when restriction or decreased motion is palpated at specific spinal segments, and it is evidenced to significantly increase ROM of the targeted segment (Vieira-Pellenz et al., 2014).

Although there are many studies conveying the efficacy of spinal manipulation, they are primarily fixated on the cervical, lumbar spine, hip, and jaw areas (Millan, Leboeuf-Yde, Budgell, Descarreaux, & Amorim, 2012). In addition to this, though spinal manipulation has shown a pain reducing effect (Coronado et al., 2012; Millan, Leboeuf-Yde, Budgell, & Amorim, 2012), there is limited evidence on how it effects ROM. A systematic review identified only 15 studies which had utilised spinal mobilization and ROM as an outcome (for the cervical, lumbar spine, hip, and jaw areas), and none of these included the TLJ specifically (Millan, Leboeuf-Yde, Budgell, Descarreaux, et al., 2012). So, this is one of the motivations for the choice of TLJ and ROM specifically, i.e., a lack of existing evidence to support an increase in ROM after spinal manipulation and for this area. This area was also chosen as it is anticipated with confidence that there will be an increase in ROM after manipulation and therefore the baseline measure of interoception could be explored (with confidence) as a predictor of outcome.

Indeed, few studies have been conducted depicting the effect of spinal manipulation upon the TLJ and no studies have been identified which have focused on the effects of a HVLA thrust specifically for this spinal region. One recent case study (Aktas et al., 2016) reported through patient feedback that manipulation of the TLJ had positive effects in reducing pain, however, being a case study no statistical analysis was reported. As the use of HVLA manipulation on the cervical spine have shown an immediate reduction in neck pain and an increase in ROM (Martínez-Segura, Fernández-de-las-Peñas, Ruiz-Sáez, López-Jiménez, & Rodríguez-Blanco, 2006), this should also be the case for the TLJ. Therefore, as the HVLA thrust has been found to be effective in increasing ROM for other areas of the spine, it can be reasonably hypothesised that it will also improve the ROM of the TLJ significantly more than a sham and control condition.

Another contributing factor to any increase in ROM may come about through the fact that spinal manipulation has been found to alter the discharge of Group I and II afferent fibres (Pickar, 1999). This has been found to reduce the mechanosensitivity at the mechanoreceptive nerve endings such as proprioceptors (e.g., muscle spindles, Golgi tendon organs) (Behm et al., 2013; Pickar & Wheeler, 2001) and could therefore lead to an increase in ROM.

In addition to this, very few studies have explored the role of interoceptive accuracy (IAc) in predicting ROM outcomes. This, therefore, is the second primary motivation for this study, i.e., to explore the effect of spinal manipulation of interoception, and to investigate whether baseline interoception could be associated with post spinal manipulation ROM. Interoception refers to a set of neuro-anatomical pathways which allow bodily signals to travel through to the brain, to form bodily awareness (Craig, 2004; Garfinkel & Critchley, 2013; Garfinkel, Seth, Barrett, Suzuki, & Critchley, 2015). More specifically, it involves an ongoing homeostatic and sensory afferent pathway of the autonomic nervous system (ANS)

which send signals from small diameter A delta and C primary afferent fibers from all bodily tissue to the insular cortex (Craig, 2013). Altered interoceptive awareness is associated with chronic pain and mental health disorders (Schmidt, Gierlings, & Peters, 1989). Some researchers (Pollatos, Füstös, & Critchley, 2012) have observed that individuals with higher interoceptive sensitivity had lower pain thresholds and tolerance, higher pain perceptual experience and higher levels of anxiety. In addition to this, baseline interoception has been found to correlate with post-manipulation ROM (of the temporomandibular joint) (Edwards, Young, & Johnston, 2018). So, given these relations, it may be hypothesised that baseline interoceptive accuracy (IAc) will be associated with post-condition ROM outcomes after spinal manipulation.

In summary, this study has four objectives; (1) to explore the effectiveness of a HVLA manipulation on the TLJ, when compared against a sham and control, using ROM as an outcome measure. It is hypothesised that the HVLA thrust will be more effective than the sham and control at increasing ROM (the null hypothesis is that there will be no difference in ROM for these conditions); and (2) to explore whether baseline IAc associates with post ROM outcomes, where it is hypothesised that there will be an association (the null hypothesis is that there will be no associations between IAc and post ROM). (3) To explore whether there would be an association between baseline-IAc and change in ROM for any of the conditions (the null hypothesis is that there will be no association with change in ROM and IAc). (4) To explore whether the HVLA thrust intervention would lead to a change in IAc, and if so whether this would be greater than that of the sham and control (the null hypothesis is that there will be no change in IAc for the conditions).

## **Methods**

## **Participants**

A purposive sample of 21 asymptomatic (18 males and 3 females) osteopathic students were recruited to participate in this study (originally 26 before exclusion), all of which were first- or second-year students. A purposive sample was obtained as opposed to a convenience sample which would encompass all osteopathic student years, as first and second year students were less familiar with the HVLA thrust and sham (visceral) osteopathic techniques, which limits any explication bias (see Consort flow diagram, Figure 1).

For the inclusion criteria, participants needed to be between the ages of 18-35, have completed the consent form, were English speaking, and not experiencing any form of musculoskeletal complaint. Participants were excluded if they did not complete the consent form, did not attend the initial session, took part in contact sports, or had received a HVLA thrust three days prior to any of the sessions.

Five participants were excluded from the study. Three were excluded due to not meeting the inclusion criteria stipulated in the brief and consent documents (i.e., they were experiencing musculoskeletal pain), and two were excluded due to not consenting to the study.

-----Insert Figure 1 here-----

## **Research Design**

This experimental design method consisted of a triple-blind, randomised, placebo-controlled, within subjects (repeated measures), crossover study design.

## **Ethical approval**

Ethical approval was obtained through Swansea University College of Human and Health Science.

### **Examiner Repeatability**

Intra-rater reliability tests in the form of Intraclass Correlation Coefficients (ICC) were conducted to ensure examiner reliability of the ROM measures. This was conducted as described by Fleiss (Fleiss, 2011). The classification system of Shrout and Fleiss (Shrout & Fleiss, 1979) was utilised, where:  $>0.75$  was determined as excellent; 0.6-0.75 as good; 0.4-0.59 as fair; and  $<0.04$  as poor.

### **Internal validity**

#### **Blinding**

This was a triple-blind study which included the participants and two examiners (E1 and E2). Participants were blinded to which intervention they received (first blinding) on entering the laboratory and were given no information about the other study conditions. The osteopathic practitioner (E1) was absent from the room when the pre and post ROM measures were obtained from examiner two (E2), thus E1 was blinded to ROM readings (second blinding). The examiner recording the ROM (E2) left the room during the intervention and was therefore blind to which condition the participant was in (third blinding). The order of interventions were randomised (see randomisation).

#### **Randomisation**

The simple sealed envelope method (Schulz, 1995) was used to ensure random allocation, and this method has been validated by Suresh (2011). This involved placing a sequenced intervention code (i.e., control =3; sham = 2; HVLA = 1) (e.g., 2,1,3) into a sealed envelope

and only the practitioner (E1) knew of the condition assignment. All combinations of condition orders were included in this repeated design (e.g., 1, 2, 3/ 3, 2, 1/ 2, 3, 1 etc.) which was produced through a Latin square design. This ensured that order effects were balanced.

## **Materials**

ROM measurements were obtained utilising a digital inclinometer (Acumar Digital Inclinometer) which are known to have good inter-rater reliability (ICC = 0.6–0.9) (MacDermid, Arumugam, Vincent, & Carroll, 2014; MacDermid, Arumugam, Vincent, Payne, & So, 2015; Prushansky, Deryi, & Jabarreen, 2010).

Interoceptive accuracy (IAC) was measured through an electrocardiogram (ECG) analysis BioPac which has been used in other studies (Buttagat, Eungpinichpong, Chatchawan, & Kharmwan, 2011). The current study used the BioPac MP160 version.

## **Experimental Conditions**

### **HVLA manipulation of the TLJ**

The practitioner (E1) positioned the patient side-lying, in the ‘lumbar roll’ position (Gudavalli, DeVocht, Tayh, & Xia, 2013), palpated the spinal segments at T12 and L1, then administered a HVLA thrust at the TLJ segments T12-L1 (see Figure 2).

### **Sham Intervention**

The technique mimicked a visceral osteopathic technique directed at the epigastrium for two minutes by E1, however, no therapeutic barrier was engaged (see Figure 2).

### **Control**

E1 instructed the participants to lay supine on the plinth with their head on a pillow for two minutes (see Figure 2).

-----Insert Figure 2 around here-----

## **Dependent Variables**

### **ROM**

ROM, i.e., tolerable stretch, has been argued to be one of the most applicable clinical outcome measures in manual therapy. It has been used extensively, and this includes studies which have utilised the HVLA thrust (Martínez-Segura et al., 2006). In addition to this, the relation between reduced pain and increased ROM has been established (Rudolfsson et al., 2012). As there were several definitions of where exactly the TLJ spanned from, this study utilised a broader definition of T10-L2 in compliance with Benson et al. (Benson et al., 1992). As in previous studies, the inclinometer was positioned directly between this designated area. The measurements were taken via forward flexion and accounted for angular changes at each functional unit. It should be noted that the actual HVLA thrust was conducted at a more limited area of the TLJ, that being T12-L1.

### **Interoceptive accuracy (IAc)**

In terms of the best possible way to determine interoception, heartbeat detection has emerged as the dominant method (Brener & Kluitse, 1988; Critchley, Wiens, Rotshtein, Öhman, & Dolan, 2004; Mandler & Kahn, 1960; Schandry, 1981; Whitehead, Drescher, Heiman, & Blackwell, 1977). This involves using a formula;  $1 - \frac{|n \text{ beats}_{actual} - n \text{ beats}_{perceived}|}{(n \text{ beats}_{actual} + n \text{ beats}_{perceived})/2}$  (D. J. Edwards, H. Young, & R. Johnston, 2018; Mallorqui-Bague et al., 2014) to calculate actual beats vs. perceived beats. Typically, heart beats are recorded for a period of approximately

30 seconds (actual beats) and the individual must guess how many beats there were (perceived beats). This is typically repeated three to six times and the interoceptive accuracy score is that which is computed through the formula for each of the three trials and then divided by the number of trials to get an average. In the present study, this was averaged by three as there were three trials.

### **Procedure**

Communication between practitioner and participant was limited to gaining consent and brief instructions. Before each intervention (control, sham, and HVLA thrust), the spinal segments of T10 and L2 were palpated, then marked with a washable marker. The digital inclinometer was placed directly within the plane of these markings and the participant was then asked to flex forward as far as comfortably possible. After this, the reading on the inclinometer was noted to establish the baseline ROM. This was repeated an additional time to assess intra-rater reliability of the inclinometer measurements. This procedure was then repeated post condition (control, sham, or HVLA thrust). See the blinding and randomization sections for these specific procedures.

### **Data Analysis**

A Shapiro-Wilk test was used to confirm that the data was normally distributed ( $p > 0.05$ ), thus justifying the use of parametric tests. A general linear model, consisting of a one-way univariate Analysis of Variance (ANOVA) was used to compare differences in ROM as well as IAc between the control, sham, and experimental conditions. In addition to this, comparisons were made between pre and post ROM measures for all three conditions using

paired samples *t*-tests. Finally, a series of bivariate correlations were conducted between baseline-IAC and post ROM, as well as between baseline-IAC and change in ROM.

## **Results**

### **Demographic results**

Table 1 shows the demographical data for age, height, weight, and body mass index. As these were the same individuals tested over the three condition (repeated measures, crossover design) homogeneity tests were not needed.

-----Insert Table 1 about here-----

### **ICC results**

Intra-rater reliability tests in the form of intraclass correlations were used to measure the repeatability validity of the ROM and heart rate (ECG) measures, which were shown to be excellent (see Table 2).

-----Insert Table 2 about here-----

### **Descriptive statistics**

Table 3 shows the pre-post change ROM scores and participant number for each condition. As can be seen, the mean change in ROM is larger for the HVLA thrust condition when compared against the sham and control conditions. Table 4 shows the pre and post IAC scores and participant number for each condition. As can be seen, there seems to be only small differences between the pre and post condition IAC measures.

-----Insert Table 3 about here-----

-----Insert Table 4 about here-----

## **Inferential statistics**

### **Range of Motion (ROM)**

A one-way univariate Analysis of Variance (ANOVA) was utilised comparing the control, sham, and HVLA thrust conditions, and using change data (delta value) from the post subtracted by pre-ROM data. This was significant, with a large effect size according to Cohen's classification (Cohen, 1992) ( $F(2) = 13.234, p < 0.001, \eta_p^2 = 0.398$ ) and included a large observed power of 0.99. In addition to this, post-hoc Bonferroni Pairwise comparisons were conducted comparing Control vs. HVLA thrust which was significantly different ( $p < 0.001$ ), as well as Sham vs. HVLA thrust which was also significantly different ( $p < 0.001$ ). As expected, the Control vs. Sham comparison was not significantly different ( $p = 0.626$ ) (also see Table 3).

Paired samples *t*-tests were also conducted comparing differences between the pre and post ROM measures for the Control, Sham, and HVLA thrust conditions, which showed significant differences for all three conditions; Control ( $t(20) = -2.633, p < 0.05, CI -3.414, -0.396$ ); Sham ( $t(20) = -3.399, p < 0.01, CI -2.382$  to  $-0.570$ ); HVLA ( $t(20) = -8.041, p < 0.001, CI -7.317$  to  $-4.302$ ). However, crucially, given the ANOVA, the HVLA manipulation condition increased ROM significantly more than the control and sham conditions.

### **IAC relationships**

In addition to this, the relationship between IAc and ROM were explored for each condition as well as any change in IAc due to the interventions (see Table 4 for IAc pre and post scores). A significant negative correlation was identified between baseline-IAc and post-ROM for the HVLA thrust condition ( $r = -0.357, p < 0.05$ ), but not for the sham condition ( $r = -0.292, p = 0.10$ ) (though this was negative) nor the control condition ( $r = 0.181, p = 0.22$ ). There were no significant associations between baseline IAc and change in ROM for any of the conditions (all  $p > 0.05$ ). There were also no significant changes in IAc for any of the conditions.

## Discussion

This study sought to investigate four separate outcomes; (1) whether there would be a greater increase in ROM over the TLJ area after a HVLA thrust and in comparison to a sham and a control. (2) Whether there would be an association between baseline-IAc and post-ROM outcomes. (3) Whether there would be an association between baseline-IAc and change in ROM for any of the conditions. (4) Whether the HVLA thrust intervention would lead to a change in IAc, and whether this would be greater than that of the sham and control.

The findings revealed that the HVLA thrust did significantly increase ROM more than the sham and control conditions. It also showed that there was a significant negative association between baseline-IAc and the post-ROM outcome. However, there were no significant associations between baseline-IAc and change in ROM, and there was no significant change in IAc after any of the conditions.

This work provides support for the use of the HVLA thrust on the TLJ which had been previously ignored. It also supports other work which has used the HVLA thrust on the

cervical spine to increase ROM more generally (Martínez-Segura et al., 2006). In addition to this, the findings provide some support for the use of a baseline-IAC measure to predict post-ROM outcomes. This area of work is particularly novel and should be explored further in the future.

One possible explanation for the significant increase in ROM caused by the HVLA thrust may be that as mechanical thrust influences are inputted into the vertebral column and surrounding structures, it induces augmented vertebral movement (Cramer et al., 2002). HVLA manipulation is theorised to have efficacious modulatory neurophysiological effects via the modification of the inflow of sensory signals received from paraspinal tissues to the brain which may account for the augmentation of physiological functioning, i.e., the increase in ROM (Currie, Myers, Durso, Enebo, & Davidson, 2016; Pickar, 2002; Reed, Long, Kawchuk, & Pickar, 2014). Similarly, spinal manipulation has been shown to modify the discharge of Group I and II afferent fibres (Pickar, 1999) and reduce the mechanosensitivity at the mechanoreceptive nerve endings such as proprioceptors (e.g., muscle spindles, Golgi tendon organs) (Behm et al., 2013; Pickar & Wheeler, 2001) which, again, could account for the increase in ROM.

Another possible explanation is that the HVLA thrust could have stimulated the thoracic splanchnic nerves which can activate the sympathetic component of the autonomic nervous system (ANS) and the sympathetic adrenal medullary system (SAM) (Furquim, Flamengui, & Conti, 2015; McBride et al., 2001). As this is an excitation response, this may have led to the increase in ROM as the adrenal system may have allowed for greater mobility and therefore ROM.

In terms of the baseline-IAC predicting the post-ROM outcomes, this relates to the set of neuroanatomical pathways which allow bodily signals to travel through to the insular cortex to form bodily awareness (Craig, 2004; Garfinkel & Critchley, 2013; Garfinkel et al.,

2015). Some researchers (Pollatos et al., 2012) have observed that individuals with higher interoceptive accuracy had lower pain thresholds and tolerance, higher pain perceptual experience, and higher levels of anxiety. This seems to be consistent with the present finding which demonstrated that there was a negative association between baseline-IAC and post-ROM outcomes, as higher IAC would mean greater sensitivity, lower pain tolerances, and therefore lower mobility expressed in the form of ROM.

The role of the interoceptive system seems to be complex as it combines both the physiological and psychological structures. It seems to determine the intensity of pain and other experiences such as related anxiety and ROM. This means it is likely to be a useful variable in predicting individual ROM outcomes after spinal manipulation. This, therefore, may become a useful measure in the diagnosis of patients of osteopathic practice. An example of this could be where a patient with back pain is given some advice about how likely spinal mobility (ROM) may increase given manipulation and based on their baseline interoceptive state. So, this could be used as a diagnostic measure to assess potential clinical effectiveness given their individual differences around baseline interoceptive states. However, more confirmatory RCTs are needed and with clinical populations to be certain of the effectiveness of this measure in prediction of patient post ROM outcomes.

In addition to this, psychological variables which may impact on the outcomes of any intervention are important to consider. One theoretical example of this is pain gate theory (Melzack & Wall, 1965) which explained a psychophysiological mechanism for pain modulation from non-noxious sensory input. Other examples of psychological variables include placebo effects and expectation bias which have been explained by Bialowsky et al. (Bialosky, Bishop, Price, Robinson, & George, 2009), who suggested that manual therapy initiates a neurophysiological cascading response through peripheral and the central nervous system (CNS) leading to psychological biases. Psychological biases such as expectation bias

may have led to the global (i.e., in all conditions) increases in ROM found in this present study as well as in others (McCoss, Johnston, Edwards, & Millward, 2017; Whelan, Johnston, Millward, & Edwards, 2018).

This work on interoception within the area of osteopathy could be further expanded upon through further exploration of cognitive components such as categorization and interoception (Petersen, Schroyen, Molders, Zenker, & Van den Bergh, 2014), as well as other areas of perceptual biases (Edwards, Perlman, & Reed, 2012; Edwards & Wood, 2016; Pothos, Edwards, & Perlman, 2011). Further research could use these approaches to understand how cognitive expectation biases and placebo effects emerge to from conscious perceptions within brain regions such as the claustrum of the neocortex (Crick & Koch, 2005) and interoceptive awareness of the insular cortex (Craig, 2004) through the use of neuroimaging techniques. This seems consistent with work of Bialosky et al. (Bialosky et al., 2009) who is seeking to develop a unified model of psychological and physiological properties which explain the pain experience more detail.

## **Limitations**

In terms of limitations, it is recognised that an asymptomatic population has been used and this study would have benefited from a clinical population to improve ecological validity. In addition to this, the study could have benefited from a greater number of participants to improve the overall power of the results. This was also called a triple-blind study, but it is unclear as to whether the participants understood the different conditions they participated in. For example, they may have known that when they received the HVLA thrust, this was a study about spinal manipulation. So, the degree to which they were truly blind may be questioned. Finally, it should be noted, the intervention was taken at T10-L1 and referred to

as the TLJ, however many other studies have used different segments usually involving the L2.

## **Conclusion**

In summary, the findings of this study demonstrated that the HVLA thrust led to a significant increase in ROM when compared with the sham and control conditions. In addition to this, the baseline-IAC was negatively associated with post-ROM outcomes. This provides some exciting avenues of research for the future which can explore the use of IAC as a possible predictor for ROM and pain outcomes perhaps in clinical populations. IAC maybe therefore be a useful tool for osteopaths in the future as part of their clinical diagnosis.

## **Clinical relevance**

- This provides evidence that a HVLA thrust may be effective at increasing ROM at the TLJ.
- Baseline-interoception may be a useful means to assist with diagnostics in terms of identifying the likelihood of improvement in ROM across the TLJ.
- Psychological components need to be explored more thoroughly in the future in relation to patient expectation and outcomes.

## **Acknowledgments**

None.

## **Conflict of Interest**

The authors report no conflict of interest.

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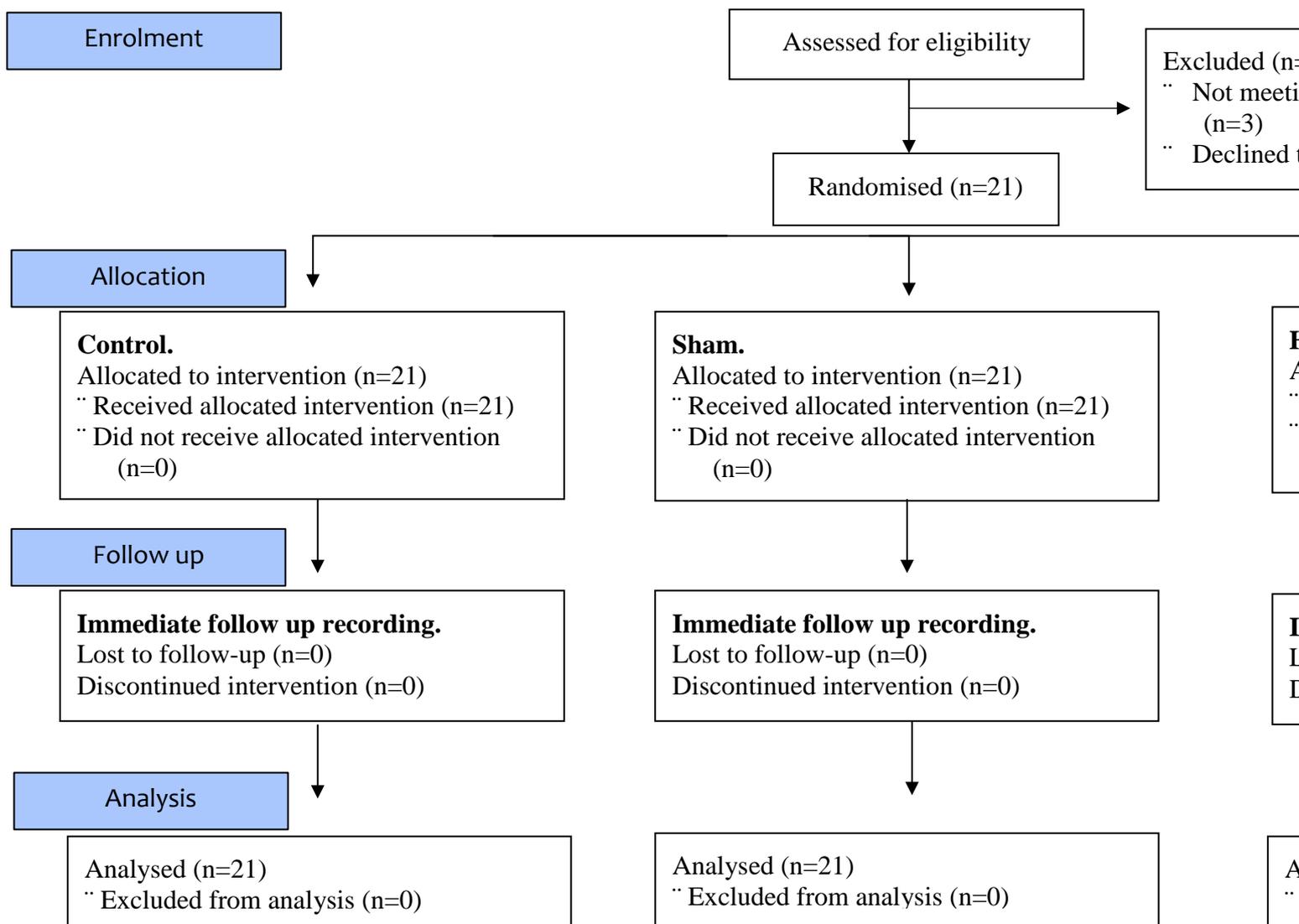
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**Figure 1.**  
CONSORT Flow Diagram with three groups and with immediate effects recorded.



**Figure 2:**  
Top left, lying supine (control); Top right (sham); bottom, HVLA manipulation of the TLJ.



**Table 1.**  
Demographic data.

Measurement	Total Participant	Mean	SD	SE	Range	
					Minimum	Maximum
Age (Years)	21	22.71	5.10	1.11	17	35
Height (CM)	21	77.43	18.38	4.01	52.00	140.00
Weight (KG)	21	178.52	9.17	9.17	157.00	198.00
BMI	21	24.21	5.09	5.09	18	43.70

SD=Standard Deviation; Age=years; Weight=kilograms; Height=Centimetres; BMI= Body Mass Index. Male (N=11), Female (N=19). Total N = 30

**Table 2.**  
Intra-rater reliability ROM.

	<b>Interclass Correlation</b>	<b>95% Confidence interval</b>		<b>Level of reliability</b>	<i>p</i>
		<b>Lower bound</b>	<b>Upper bound</b>		
Pre-control ROM	0.992	0.981	0.997	Excellent	<0.001
Pre-control Heart Rate	0.982	0.955	0.993	Excellent	<0.001

Note: Shrout and Fleiss (1979) classification reliability >0.75, excellent; 0.6-0.75, good; 0.4-0.59, fair; and <0.4, poor.

**Table 3.**

Mean, standard deviation (SD) and standard error (SE) of the Pre-post change Range of Motion scores and participant number for each condition.

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<b>Study Condition</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>SE</b>	<b>Range</b>
Control change	21	1.90	3.315	0.723	15
Sham change	21	1.48	1.990	0.434	9
HVLA change	21	5.81	3.311	0.722	11

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**Table 4.**

Mean, standard deviation (SD) and standard error (SE) of the pre and post IAc scores and participant number for each condition.

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<b>Study Condition</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>SE</b>	<b>Range</b>
Baseline-Control	21	0.97	0.29	0.06	1.39
Baseline-Sham	21	0.89	0.18	0.41	0.78
Baseline-HVLA	21	0.87	0.26	0.06	1.23
Post-control	21	0.92	0.21	0.04	1.10
Post-sham	21	0.88	0.17	0.04	0.83
Post-HVLA	21	0.79	0.13	0.03	0.56

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