Title:

Acupuncture applied as a sensory discrimination training tool decreases movement related pain in chronic low back pain patients more than acupuncture alone. A randomised cross-over experiment.

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Key words:

Chronic low back pain; acupuncture; sensory discrimination; body image.

Word count:

3113

ABSTRACT

Background/Aim: High quality clinical evidence suggests that while acupuncture appears superior to usual care in the management of chronic low back pain, there is little meaningful difference between true and sham acupuncture. This suggests that the benefits of acupuncture are mediated by the placebo response. An alternative explanation is that sham acupuncture is an active treatment and shares a mechanism of action with traditionally applied acupuncture. One plausible candidate for this mechanism is improvement in self-perception mediated through the sensory discrimination-like qualities of acupuncture. We aimed to compare the effects of acupuncture with a sensory discrimination training component to acupuncture without.

Methods: Twenty-five people with chronic low back pain were enrolled in a randomised cross-over experiment. We compared the effect of acupuncture delivered in a way in which sensory discrimination is optimised to acupuncture delivered when it is not on movement related back pain immediately after each intervention.

Results: We found that the average pain intensity after participants had received acupuncture with sensory discrimination training (2.8±2.5) was less than when they received acupuncture without sensory discrimination training (3.6±2.0). This difference was statistically significant (after adjustment; mean difference = -0.8, 95% CI: -1.4 to -0.3; $p = 0.011$).

Conclusions: Our findings are consistent with the idea that acupuncture may offer specific benefit that is not dependent on precisely where the needles are inserted so much as that the patient attends to where they are inserted. If so, the location of the needles might be better focussed on the painful area and the need for penetration of the skin may be mitigated.

INTRODUCTION

There are numerous clinical trials on the use of acupuncture in the management of chronic low back pain (CLBP) and a consistent finding from high quality research is that while acupuncture performs better than usual care, there is strong evidence of no difference between true and sham acupuncture [1-4]. This result suggests that the benefits of acupuncture are likely mediated through the placebo response.

While we agree that this is the most appropriate interpretation of the literature, an alternative explanation is that sham acupuncture is an active treatment and shares a mechanism of action with traditionally applied acupuncture. This view has significant support from advocates of acupuncture [5-7] and is consistent with the finding that while acupuncture and sham acupuncture show equivalence, true acupuncture often outperforms non-acupuncture placebos [2]. Some plausible mechanisms have been suggested [8-13] but there is little direct clinical evidence to support these claims; most of the mechanisms are likely to have only very short term effects and many would be difficult to test.

One possible mechanism that can be tested and is potentially long lasting, at least with repeated application, is improvement in self-perception of the lumbar spine. There is evidence that patients with CLBP exhibit significant alterations in cortical areas that are thought to subserve self-perception [14] and display characteristics that are consistent with a disturbance in lumbar spine self-perception [14]. How altered self-perception contributes to chronic pain is not resolved, but recent reviews have highlighted the relationship between disturbances in self-perception and severity of the condition and argue that altered self-perception may represent a legitimate target for therapy [15-17].

One method of normalising distorted self-perception is tactile discrimination training. In this approach, stimulation of some form is applied to the painful area and the patient is asked to make a decision about the locality or type of stimulation, an approach which has been shown to be effective in the management of some chronic pain problems [18-20]. Acupuncture likewise often delivers sensory stimulus to the painful area in the form of needling, however the precise location of the needles within the painful area seems to have little effect on outcome [21]. That acupuncture appears to relieve pain regardless of the exact needle location leads to the idea that acupuncture may have tactile discrimination-like effects.

We can test whether or not acupuncture has a tactile discrimination-like effect by comparing the effects of acupuncture with a sensory discrimination training component to acupuncture without. Our hypothesis is that CLBP patients will have greater pain relief from acupuncture used as a sensory discrimination training tool, in which they need to attend to the site of needle stimulation, than they will with acupuncture applied in a way in which sensory discrimination is less.

METHODS

Design

This randomised, repeated measures, cross-over experiment received institutional ethical approval and was registered with the Australian clinical trial registry, (ACTRN12611000614998). Participants provided informed consent and all procedures conformed to the Declaration of Helsinki.

Participants

A convenience sample of 25 CLBP patients was recruited from a community physiotherapy practice. Participants were eligible if they were aged between 18 and 60 years of age; were proficient in written and spoken English; reported LBP as their main complaint; had experienced non-specific LBP for a minimum of six-months and rated their LBP as at least moderate on item seven of the Short-Form 36 [22]. Patients were excluded if they presented with nerve root pain or evidence of specific spinal pathology; were pregnant or less than six-months post-partum; had undergone any lumbar surgery or invasive procedure within the previous 12-months; were involved in litigation in relation to their LBP; were judged by their treating clinician to be unsuitable for acupuncture treatment, had significant uncorrected visual disturbance or significant medical or psychological illness.

Procedure

After consent was obtained, participants were assigned a research number, provided basic demographic and clinical information and completed a set of standardised questionnaires. Disability was assessed using the Roland Morris disability questionnaire [23]. Average LBP intensity over the last week was measured using a numerical rating scale (NRS). Kinesophobia was estimated using the Tampa Scale of Kinesiophobia [24]. Pain-related catastrophization was measured using the Pain Catastrophizing Scale [25] and the 21-item Depression Anxiety and Stress Scale [26] was used to assess for the presence of depressive symptoms and anxiety. In addition, participants performed a lumbar spine active movement assessment and nominated which direction of movement was most provocative for their LBP.

A random number sequence was independently computer-generated and each number was placed in consecutively numbered, sealed, opaque envelopes. After completion of the baseline assessment questionnaires, the therapist opened the envelope that corresponded to

the participant's research number and participants were randomised by odd/even allocation into either sensory discrimination acupuncture or usual acupuncture as their initial condition. After the first condition, participants rested for ten minutes before undertaking the alternate condition. A previous study of similar design suggests that this time frame is likely sufficient to avoid any carry-over effects [27]. Participants were informed that the purpose of the study was to compare two different types of active acupuncture and were blinded to the study hypothesis.

Participants first removed their shirt and lay prone on an examination table. The participant's position was adjusted to ensure maximal comfort in the prone position and the same position was used for both conditions. The points to be needled were lightly marked on the participants back to make sure the same points were stimulated for each condition. A total of 14 points were used, seven on the right side of the lumbar spine and seven on the left. We chose acupuncture points that have been used in previous clinical trials of acupuncture for CLBP [21 28 29] and which enabled us to cover as much of the lumbar spine as possible. The points were urinary bladder 52, 23, 24, 25, and 26 bilaterally and two non-standard acupuncture points bilaterally. To identify the points, each subject's thumb width (cun) was measured using a cunometer. The lumbar spinous processes were used as the points of reference and the cunometer was employed to find the acupuncture points. The non-standard points were standardised as six cun lateral to the spinous processes of L2 and L5.

After locating the points, the 14 needles were inserted. We used 15mm needles fully inserted to ensure that the depth of needling was the same across conditions. In the experimental condition, subjects participated in a sensory discrimination training task similar to that described by Moseley et al. [19]. A picture of a back with the position of each needle

numbered (see Figure 1) was positioned so it could be comfortably viewed by the participant. The clinician then rotated a single needle in accordance with a random number sequence and the subject was required to nominate which needle was being stimulated, if the participants made an error, they were told which point had in fact been stimulated. Each needle was stimulated for 3 seconds with a 10 second interval between each stimulus. This task was performed with visualisation of the back via a mirror in the first 10 minutes and progressed to no visualisation in the last 10 minutes. In the control condition participants were asked to lay comfortably and relaxed and to not attend to the needles. During the 20 minute control condition the therapist manipulated needles at the same rate and using the same random sequence as they did in the experimental condition. Both acupuncture treatments were provided by the same clinician, a physiotherapist with post-graduate acupuncture qualifications and five years of clinical experience in the use of acupuncture.

Outcome

The primary outcome measure was pain intensity immediately after performance of ten repeated lumbar spine active movements, measured using a NRS. Participants were asked "Please rate your back pain by circling the one number that tells how much pain you have *right now*". The movement direction deemed most painful by the patient during the initial physical examination was used for both conditions. The start and end points for each task were standardised for each individual based on their initial examination findings and the speed of task performance was kept constant by use of a metronome.

Sample size

A power calculation for a cross-over design [30] was performed for the primary outcome measure of pain intensity immediately after repeated lumbar spine movement. The standard

deviation of the NRS was estimated at 2 points and the within-subject correlation of scores was set at 0.6. A sample size of 25 participants provides 80% power to detect a treatment effect of 1 point on the NRS, when α=0.05.

Data analysis

Descriptive statistics were used to present demographic information and to describe clinical status. A series of t-tests (CROS analysis) [30] was used to estimate treatment, period, and treatment by period interaction effects for the primary outcome measure. Statistical significance for carryover (treatment-by-period interaction) was set at $p<0.1$. Significance for all other tests was set at $p<0.05$. Plots of residuals versus fitted values were examined to check the assumptions of normal distribution of within and between-subject residuals. Non-parametric Wilcoxon matched-pairs tests were also performed to confirm conclusions based on parametric analyses. All analyses were undertaken using Stata/IC 10.1 for Windows (Statacorp LP, College Station, TX).

RESULTS

Group characteristics

Participants were recruited between September 2011 and June 2012. Table 1 describes the demographics and clinical status of the participants. All 25 participants completed both phases of the experiment and there were no missing data.

TABLE I. Demographic and clinical information on all participants (N=25)

	Mean (SD) or N(%)
Demographic information	
Gender (female)	9 (36%)

Age (years)	41.5 (13.8)
Height (cm)	172.5 (9.5)
Weight (Kg)	78.1 (14.0)
Work Status	
At work (or studying)	21 (84%)
Off work due to LBP	3 (12%)
Off work other reasons	1 (4%)
Clinical status	
Duration of LBP (years)	6.7 (11.5)
Pain Area	
Back pain only	17 (68%)
Back pain and leg pain	8 (32%)
Taking opioid medication	2 (8%)
Average Back Pain Intensity (0-10)	4.9 (1.5)
Disability (RMDQ[a], 0-24)	9.6 (5.9)
Pain Catastrophization (PCS[b], 0-52)	16.0 (12.1)
Kinesiophobia (TSK[c] 17-68)	31.4 (7.4)
Depression (DASS-21[d] 0 – 42)	8.6 (10.8)
Anxiety (DASS-21[d] 0 – 42)	5.4 (7.1)

[a]The Roland Morris Disability Questionnaire

[b]The Pain Catastrophizing Scale

[c]Tampa Scale of Kinesiophobia

[d]Depression Anxiety Stress Scale – 21

The effect of condition on pain

There was evidence that pain was less after the second period than the first period regardless of treatment order (-0.9, 95% CI: -0.3 to -1.5, $p = 0.008$) and therefore treatment effects were estimated adjusted for this period effect. The average pain intensity after participants had received acupuncture with sensory discrimination training (2.8±2.5) was less than when they received acupuncture without sensory discrimination training (3.6±2.0). This difference was statistically significant (after adjustment; mean difference = -0.8, 95% CI: -1.4 to -0.3; $p = 0.011$).

Post-treatment measures for each individual by group are displayed in Figure 2. There was no significant period/treatment interaction detected, indicating that the effect of sensory discrimination training was unlikely to have differed according to whether it was administered in the first or second period. ($p = 0.182$).

DISCUSSION

The aim of this study was to determine if acupuncture delivered in a way in which sensory discrimination is optimised is superior to acupuncture delivered when it is not. We hypothesised that CLBP patients would have greater pain relief from acupuncture used as a sensory discrimination training tool than they would with acupuncture applied in a way in which sensory discrimination is less. In both conditions we used the same number of needles, in the same points, inserted to the same depth and with an identical type and amount of needle manipulation. In the control condition, participants were asked to relax and not focus on the needles. In the experimental condition, participants responded to each needle manipulation by trying to localise the position of the needle that was being manipulated. In

keeping with our hypothesis, participants reported significantly less movement-related pain immediately after the sensory discrimination condition than they did after the control condition. Although there was a period effect, the significant difference in pain intensity remained after adjusting for this and the advantage of the sensory discrimination condition was not affected by whether it was undertaken first or second.

Our results are consistent with the idea that 'sham' acupuncture may offer some mode of action beyond placebo and that a discrimination-like effect may contribute. The plausibility of this perspective is supported by the ample data suggesting body-perception is disturbed in people with CLBP. Neuroimaging studies demonstrate significant alterations in brain structure and function in the CLBP population [14], including degeneration [31-35] reorganisation [36-38] and biochemical abnormalities [39 40] in cortical areas that are thought to subserve the perception of the back [41]. Furthermore, psychophysiological findings consistent with disruption of the mechanisms that underpin body-perception are also apparent, such as decreased lumbar tactile acuity [42-44], impaired graphaesthesia performance over the back [43], difficulties localising tactile stimuli delivered to the back [45], neglect like dysfunction to stimulation of the lumbar spine as well as the space around the painful area [46], deficits in proprioception [47-52], poor performance on a trunk movement tracking task [53], back-specific impairment in the visual recognition of actions [54] and reduced trunk motor-imagery performance [55]. CLBP patients also seem to have difficulty delineating the outline of their back [42] and frequently endorse questionnaire items associated with altered self-perception of the lumbar spine [56].

Although it seems clear that self-perception is altered in CLBP, the role altered self-perception plays in the condition is less apparent, though there are several hypotheses as to

why distorted self-perception may negatively impact on clinical outcome. Poor bodily awareness may adversely influence lumbar spine control, leading to abnormal loading of the spine and thence peripheral nociceptive input [57]. Peripheral tissue health may also be adversely affected by a distorted body image, for example a body part specific drop in temperature [58], increased histamine reactivity [59] and increased pain and swelling on movement [60], have all been observed within minutes of body-awareness disruption. Finally, disruption of bodily awareness may be associated with incongruence between predicted and actual proprioceptive feedback and this incongruence may give rise to pain [61 62].

There is also some evidence from randomised controlled trials that improved perception of the back may improve outcome. While Barker et al. [63] found no difference between TENS and a device designed to deliver sensory discrimination training, other researchers have noted significant improvements in clinical status with other sensory stimulation protocols. Morone et al. [64] developed what they called a '*surface for perceptive rehabilitation'* comprised of a series of rubber cones of different heights and rigidity. Patients lay on this surface and underwent training, requiring them to discriminate tactile, proprioceptive, pressure, and kinesthetic information. This approach was superior to an intensive educational and general exercise approach in reducing LBP in the short-term and superior to medical care at both short and long-term evaluation. Hohmann et al. [65] asked CLBP patients to lie on a needle stimulation pad, a plastic mat consisting of a large number of sharp but non-penetrating plastic spikes. After a two-week period of daily treatment, patients reported significant and clinically meaningful improvements in pain in comparison to a waiting list control. In addition, sensory discrimination training protocols have been shown to improve outcome in people with phantom limb pain [18] and complex regional pain syndrome [19 20], and

improvements in pain strongly relate to improvements in tactile acuity [18-20]. Moreover, representational changes within the primary somatosensory cortex also relate to improvements in tactile acuity and pain [18]. Relevant to this line of thought, Napadow et al. [66] reported that treatment with acupuncture was associated with correlated changes in cortical reorganisation and pain in people with carpal tunnel syndrome.

In most acupuncture trials, the site of needle insertion is dictated by principles of traditional Chinese medicine (TCM) that are at odds with modern sciences understanding of anatomy and physiology. The equivalence in outcome seen between randomly placed needles and needles placed according to the principles of TCM further highlights the implausibility of this model. While our data are only preliminary, they suggest that an alternative but evidence-informed approach that may be taken towards determining the site of stimulation. That is, tactile acuity over the back is worse in areas of pain, and this corresponds to areas of altered body awareness [42]. If our current results are corroborated by further research, it would seem reasonable to focus needling on the areas of pain/altered awareness, rather than choosing the site for needling based on the system advocated in TCM. Further, progression might be better based on the individual's level of sensory acuity (see for example [67]), rather than on the principles of TCM. In addition, using penetrating needles is not without risk [68] and the mechanism suggested here certainly does not mandate that the stimulation be penetrative needling. It is plausible that a safer and equally effective treatment might be discrimination training using non penetrative stimulation, but clearly further research is needed in this area.

There are some limitations to this research that need to be considered. The two treatments were not indistinguishable so participants were not strictly blinded to condition, although

they were naïve to our hypothesis. In addition, we used patient self-report as the outcome measure, so assessor blinding was also suboptimal. However, we do not think that these methodological weaknesses introduce a high risk of bias because both interventions were plausible, active treatments and we informed patients of this. In addition, both conditions were delivered by the same clinician who was not blinded. Importantly however, that clinician has post-graduate qualifications in the use of acupuncture based on TCM principles, and has used this approach in the management of LBP for some years. One might predict that an advocate of TCM-based acupuncture would introduce a bias against our hypothesis, but we did not measure this. We also did not assess potential indicators of disturbed body-perception such as tactile acuity or cortical reorganisation. The addition of this information may have provided data to further support (or refute) the proposition that the greater effect seen in the experimental condition was due to changes in self-perception. At this stage, we can only conclude that the sensory-discrimination condition was better than the other condition, and speculate as to why. Finally, these findings are based on a preliminary, experimental study and the design we used only enabled evaluation of very short term outcomes. Furthermore, although there was no statistical evidence for carry-over of effects from one treatment period to another, the power to detect this was limited with the numbers available. Before these ideas are adopted clinically there is need for replication of these findings on larger samples of patients, using more intensive treatment approaches with the evaluation of clinically meaningful outcomes over longer periods of time. Our findings clearly lay the platform for further research that could account for these limitations.

In summary, our results support the hypothesis that CLBP patients would have greater pain relief from acupuncture used as a sensory discrimination training tool than they would with acupuncture applied in a way in which sensory discrimination is less. Our findings are

consistent with the idea that acupuncture may offer specific benefit that is not dependent on precisely where the needles are inserted so much as that the patient attends to where they are inserted. If so, the location of the needles might be better focussed on the painful area and the need for penetration of the skin may be mitigated.

What are the new findings?

- Patients with CLBP reported less pain after acupuncture used as a sensory-discrimination training tool than they did after acupuncture applied in a way in which sensory-discrimination was less.
- Acupuncture may favourably influence pain by improving self-perception.

How might it impact on clinical practice in the near future?

- These results add some support to the idea that altered self-perception might be a target for treatment in the management of CLBP
- If supported by further research, these findings might prompt clinicians who use acupuncture in the management of CLBP to consider the principles of sensory discrimination training when applying this intervention
- These findings are preliminary and replications on larger samples using more intensive treatment regimens are needed before they are adopted into clinical practice

Acknowledgements: GLM is supported by the National Health & Medical Research Council of Australia (ID 579010)

Competing Interest: There are no conflicts of interest related to this manuscript. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subjects of this manuscript.

Funding: No funds were received in support of this work.

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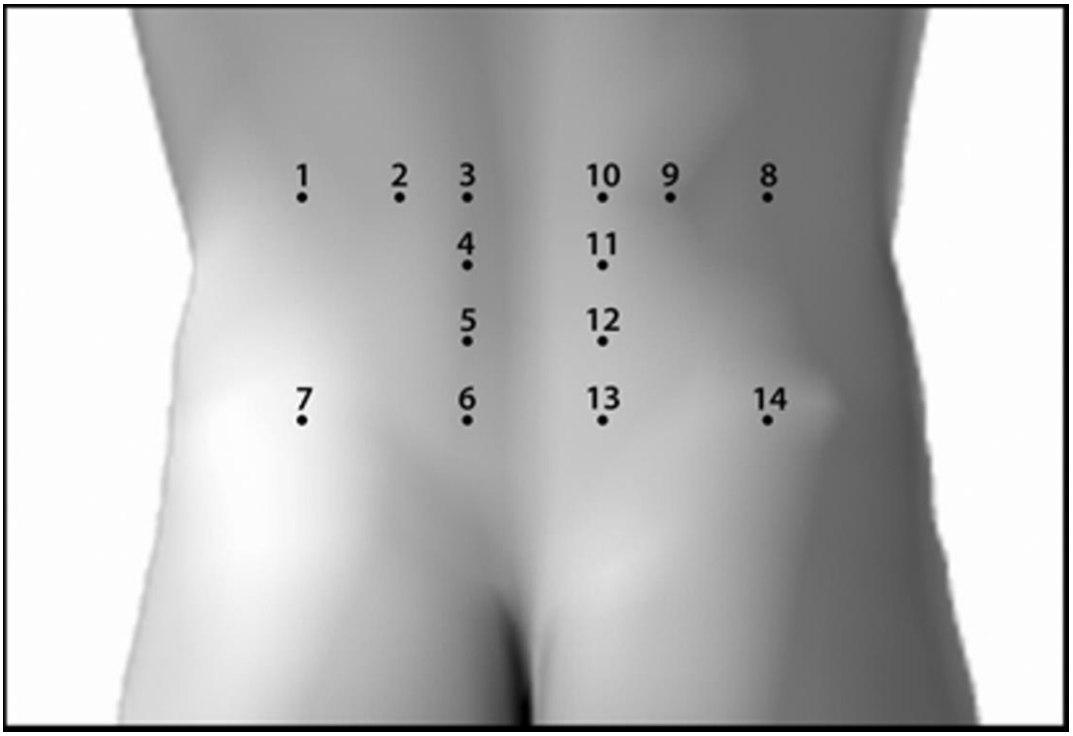
FIGURE LEGENDS

FIGURE 1. Site of needle insertion

FIGURE 2: Pain intensity (NRS) post-treatment for individual subjects with and without sensory discrimination training, by group (A: No discrimination training followed by discrimination training, B: discrimination training followed by No discrimination training)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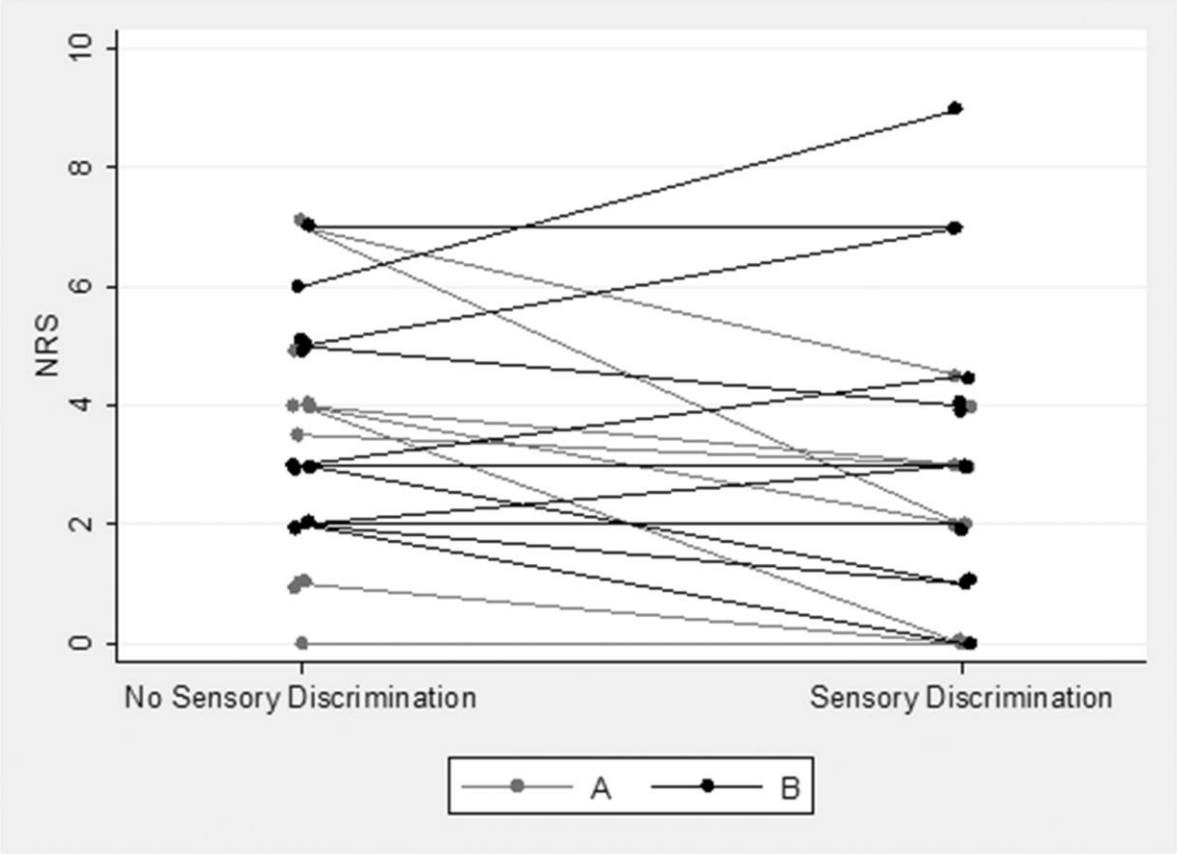
NRS
0
2
4
6
8
10
No Sensory Discrimination
Sensory Discrimination
A
B