FEASIBILITY STUDY OF THE SHORT TERM EFFECTS OF NEURO EMOTIONAL TECHNIQUE FOR CHRONIC LOW BACK PAIN

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ABSTRACT

Objective: To collect preliminary information on the effects of a mindfulness based stress relieving technique called Neuro Emotional Technique (NET) on pain and disability in chronic low back sufferers.

Methods: 17 participants who had chronic low back pain entered the trial were randomized to 1 of 2 groups. Participants in the intervention group received a 1-month course of Neuro Emotional technique (NET), whilst the control group underwent a sham protocol of NET. Both groups were received the intervention at a frequency of 2 sessions per week for 1 month. Subjective outcome measures were obtained at baseline and at 1 month (after 8 treatments) and again at 3 months. Outcomes included the visual analog scale (VAS) for pain and the Oswestry Disability Index (ODI) for disability level.

Results: 9 participants were enrolled in the treatment group and 8 into the control. Each of the 2 groups experienced a loss of 2 participants between month 1 and month 3. Accordingly, all remaining participants, provided data for the month 3 data collection. Significant differences were detected between the baseline and 1-month time points for the ODI scores ($P<0.001$) and the "amount of pain you have right now" rated by VAS ($P<0.001$). However, all outcomes returned to near baseline levels after 2 months without treatment.

Conclusion: Changes in VAS and ODI scores provide preliminary evidence for changes in pain, and activities of daily living after sufferers of chronic low back pain (CLBP) received a short course of Neuro Emotional Technique. Progress to a full trial on the possible role of NET in reducing pain and disability in a low-back population is feasible.

Trial registration - Australian and New Zealand Clinical Trials Registry ACTRN12608000002381. (Chiropr J Australia 2016;41:266-282)

Key Indexing Terms: Chiropractic; Low Back Pain; Disability

INTRODUCTION

Low back pain (LBP) is the most common symptomatic presentation to chiropractic practitioners. (1) A large subset of LBP is chronic in nature and has multidimensional characteristics which include psychological and social dysfunction. (2) Modern definitions of pain describe pain as "the unpleasant sensory and emotional experience associated with actual or potential damage". (3) In this context, the sensory and emotional components of pain are problematic and should be addressed in treatment. Developing effective treatments to address both these characteristics could provide substantial benefit to the population of sufferers.

The biopsychosocial model of pain acknowledges the biological, psychological and social dimensions of the pain experience. (4) The emerging importance of such a model in chiropractic has previously been discussed. (5) Disability is a function of pain and a response to it. The consequences of avoiding pain, and pain inducing activities, have been demonstrated to be deleterious. (6) The effect of pain avoidance and disability precede deconditioning and social withdrawal which may magnify the effect of the pain to further complicate the pain profile.

Adapting the biopsychosocial model of pain into treatment for chronic pain sufferers may help to progress the treatment of pain and disability. (7) Such an approach would more likely involve active therapy (with patient participation) rather than relying on passive approaches that are often employed in pharmacological medicine and surgery. (8,9) The scope of the mind-body paradigm has progressively developed due to a better appreciation of the predictors of chronicity. The literature reports that factors such as lack of exercise, prolonged rest, litigation, workers compensation and other reward systems, emotion, poor life expectations, relationship difficulties, and poor work satisfaction effect the prognosis of pain and disability in low back pain patients. (10) Mind-body treatments must be carefully managed so the most reliable and valid diagnostic approaches and effective therapies are utilised in health science disciplines.

Chiropractic is a healthcare profession that primarily manages neuromusculoskeletal conditions of the spine. Although a majority of conditions treated are spinal, musculoskeletal and chronic in nature, chiropractors also treat other non musculoskeletal conditions on a less frequent basis. (11) Recent evidence has suggested that chronic musculoskeletal conditions are frequently associated with psychosocial co-variables (12) (commonly referred to as yellow flag conditions) (13,14) and some in chiropractic have attempted to address these co-variables with various cognitive and behavioral strategies.(15,16) Neuro Emotional Technique (NET) is an attempt to provide a mindfulness based therapy in a novel manner. (5) NET may be applied as a singular therapy or as an adjunct to other “body-based” therapies including chiropractic. (16) Neuro Emotional Technique is commonly used in the chiropractic profession (17). Studies on the scope of practice of chiropractors have demonstrated that LBP is the most common complaint to the chiropractor, and that CLBP is the most common variant of LBP (18). It is therefore germane to test the usefulness of NET in this common and costly subgroup of patients. (19) In addition, CLBP is a common presenting complaint to allopathic physicians as well (20) so information derived from a pilot study would be an appropriate first step in the justification of the use of NET in a general LBP patient cohort.

With very few manual therapy treatment modalities scrutinised under controlled conditions, the tenets behind mind-body treatments must be carefully managed so only reliable and valid diagnostic approaches and effective therapies are accepted in health science disciplines.

METHODS

Participants and Setting of the Study

Seventeen participants were recruited via print media. Data was collected from participants that presented to a private practice of chiropractic in the Eastern Suburbs of

Sydney Australia. They contacted the research office via a mobile telephone number and underwent a preliminary screening protocol for eligibility into the study before presenting to the practice for induction into the study. Inclusion criteria included participants suffering from low back pain ≥ than three months. Exclusion criteria included: acute low back pain (<3 months duration); < 18 years of age; currently undergoing other manual therapy or psychological intervention for depression or suicidal ideation; presence of "red flag" conditions (warning or actual evidence of serious pathological conditions); currently involved with medicolegal proceedings; pregnancy; abdominal pain; vascular disease; motor vehicle accident or falls in last 3 months; neurological signs and symptoms; organic kidney, urinary tract or reproductive disease; straight leg raise of < 30°; previous spinal surgery; and bowel, bladder or sexual dysfunction.

Lower back pain was defined as that pain occurring in the rectangle bordered by the thoracolumbar level of the spine, the lumbosacral level of the spine and the lateral margins of the body, as viewed from the posterior aspect.

Upon inclusion into the study, participants were then randomised into a treatment or control group. The participants were blinded to which group they were assigned, the assessors of data were blinded; however, the therapists were not blinded to group allocation. The trial was registered with the Australian and New Zealand Clinical Trials Registry ACTRN12608000002381.

Protocol- Participant Flow

The intervention period of the trial spanned four weeks and involved eight treatment sessions. Participants were assessed before treatment (baseline) and immediately after treatment (one month) and again at 3 months. Seventeen eligible consenting participants were recruited via print media. Nine patients were randomised to the treatment group and eight were randomised to the control group (Figure 1). A computer-based random number generator was used to allocate participants to group by producing a random sequence of numbers with no repeats. The numbers were recorded onto separate slips of paper by a research assistant and placed into opaque envelopes that were sealed and mixed. No patients were excluded according to the exclusion criteria described in the methods section.

Interventions

Neuro Emotional Technique (NET)

Participants assigned to the treatment group underwent a course of NET, which followed the protocol outlined by Walker (16). The treatment group received treatment from 1 practitioner and the control group received treatment from another practitioner. Both were experienced in the application of NET. NET is a mindfulness based stress relieving technique used to normalise unresolved physical and/or behavioral patterns in the body by combining many principles of cognitive behavioral therapies. NET attempts to access and manage aberrant emotional memories and the troubles they may cause by testing the patient response to a series of semantic statements. In this process the practitioner presents a series of statements to the patient and the emotional congruency of the statements is tested by a lightly applied muscle test after each statement. (21) The deltoid muscle test is commonly used by NET practitioners for this procedure and it has been shown to have a degree of reliability in this context. (22) The 15-step process attempts to access and allow the brain to manage aberrant emotional memories, the troubles they

cause and their associated psychological, neurological and immune system related symptoms; that is, their so-called 'psychoneuroimmunological' expression. This refers to the neurological and humoural physiological changes in the body that follow from prolonged stress. A major goal of NET is to achieve extinction of classically conditioned emotional responses to stimuli which reproduce or augment pain or disease, when the original stressors are not present. (23) A detailed description of the NET procedure and the control NET procedure is too lengthy for inclusion in this report. However, the reader is referred to a detailed description of the NET protocol (23) and the control protocols (24) used in recent randomised clinical trials. In these trials, dosage of NET was prescribed at a frequency of 2 sessions per week for 1 month.

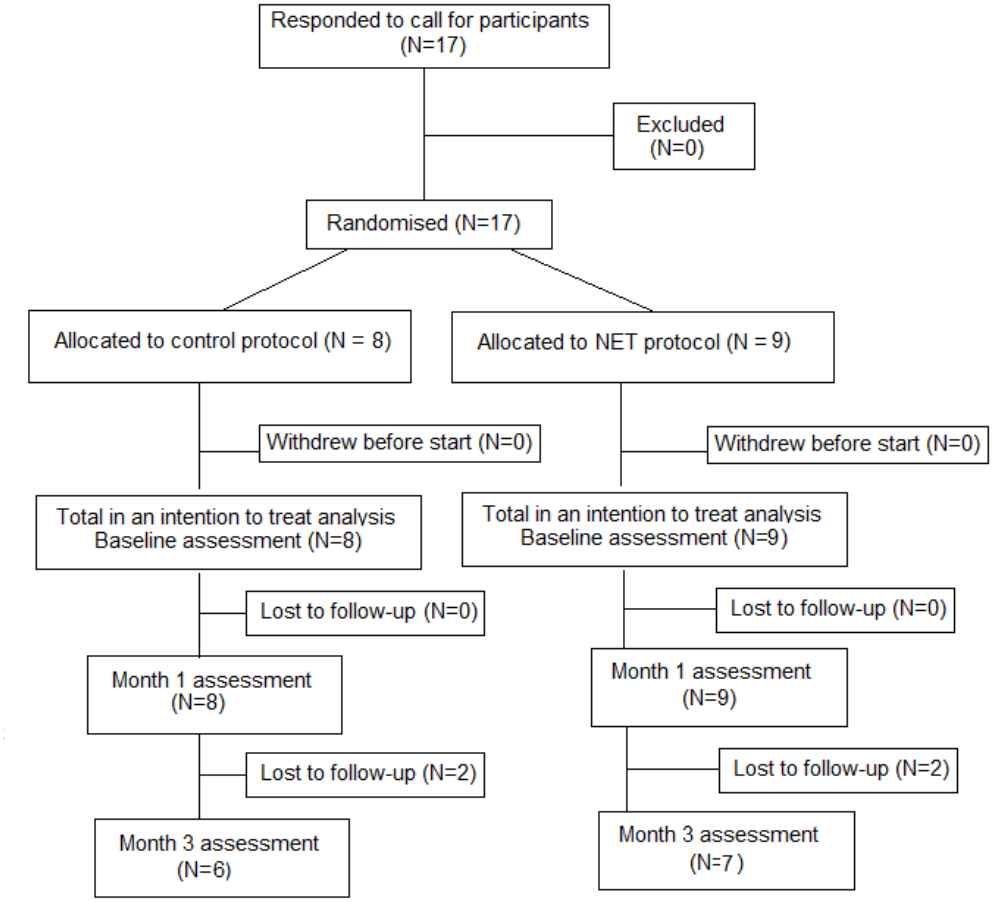

Figure 1. Modified Consolidated Standard for Reporting Clinical Trials (CONSORT) protocol at 1 and 3 months.

Control Group

Participants who were assigned to the control group underwent a sham protocol of NET by a different practitioner to that providing the treatment in the experimental group. The participants were administered a realistic treatment of muscle testing in an identical manner to the treatment participants. The same muscle was utilised but irrelevant contact points were used. Further, the control participants were challenged with semantic

statements which were innocuous and therefore unlikely to trigger any emotional response. Based on our feedback from participants and test subjects used in training programs, the control protocol was perceived as being similar to the experimental protocol. Treatment was prescribed at a frequency similar to the experimental group, 2 sessions per week for 1 month. The participants were unaware of their allocation to either treatment or control group to help maintain the impression of a normal treatment interaction.

Masking

A blinded examiner carried out all outcome assessments. Participant blinding was optimised by using a realistic placebo intervention and by ensuring participants did not attend for treatments or assessment concurrently. The statistician was unaware of treatment allocation until the completion of analyses.

Outcome measures

An assessment of outcome measures which related to pain, function and disability were obtained at baseline and immediately after treatment (one month) and again at 3 months. Outcome measures included: Visual analog scale for pain (VAS) is a commonly used ratings scale with good reliability, validity and utility (24). The scale consists of a 10-mm line with 2 extremes: no pain (0) and worst possible pain (10), Patients indicate a location on the line corresponding to the intensity of pain experienced. In this study we utilised a VAS scale for the following statements: “amount of pain you have right now”, “your average pain right now”, “your pain level at its best” and “your pain level at its worst” in order to describe the pain experience of the participants at the time of assessment.

Oswestry Disability Index (ODI) (25) a commonly recommended condition-specific outcome measures for spinal disorders. The ODI is designed to assess limitations of various activities of daily living. The ODI is a valid and reliable measure of condition-specific disability

Statistics and Sample Size

Participants’ scores at months 0, 1 and 3 were analysed using a repeated measures analysis with a power model for the correlation over time. This model is preferable to a model that assumes that the correlation between a participant’s scores at 2 times is the same irrespective of the time interval. A power model assumes that if the correlation between the scores 1 month apart is (say) *corr*, the correlation between scores 3 months apart is *corr*3 (26). We used P values from F tests in the repeated measures analysis rather than from x2-based Wald tests, as the latter P values are known to underestimate the probabilities in small sample designs (26). These F tests allow us to compare any improvement in LBP of the NET treatment group with that of the control group after the first month of treatment, and again 2 months later during which no treatment was given.

There is some evidence that the variance of the score data was not constant in this study – in clinical trials, it is often the case that the variance for a control group differs from that for a treatment group. Unfortunately, the small numbers prevented an in-depth analysis of this potential problem. Also, while the assumption of normality does not hold for score data, the measures used were converted to percentages, and hence the P value from the repeated measures analysis is a fairly reliable indicator of the significance between the 2 groups for pain. For measures using a 0 to 5 scoring system the P values we obtain are

used with caution. All analyses were performed in Microsoft Excel or in GenStat (Version 11).

Objectives of the Study

The purpose of this study was to collect preliminary information on the effects of NET on the pain profile of chronic low back sufferers, as assessed by the Oswestry Disability Index (ODI). It was the additional aim to test the protocols and procedures of a larger clinical study utilising the same inclusion and exclusion criteria. This information is necessary to develop a line of investigation into the role of the NET stress relief technique on the reduction pain and disability in chronic low back sufferers.

RESULTS

Baseline Data

Baseline information for the control and treatment participants is provided in Table 1.

Table 1: Baseline characteristics for control and treatment participants

Characteristics	**Control**		**Treatment**	
	Male	Female	Male	Female
N	4	4	5	4
Age, mean (s.d.)	45.5(11.6)	41.0 (4.7)	41.4 (5.2)	44.8 (5.9)
Duration of pain				
3-6 months, n (%)	1 (12.5)	0 (0.0)	1 (11.1)	0 (0.0)
6-12 months, n (%)	0 (0.0)	2 (25.0)	2 (22.2)	0 (0.0)
12-36 months, n (%)	1 (12.5)	2 (25.0)	2 (22.2)	2 (22.2)
36-120 months, n (%)	2 (25.0)	0 (0.0)	0 (0.0)	2 (22.2)
Oswestry mean	28.5		32.2	
QVAS Q1 mean	4.9		5.2	
QVAS Q2 mean	5.5		5.2	
QVAS Q3 mean	3.4		3.1	
QVAS Q4 mean	8.0		7.3	
Total mean QVAS	21.8		20.8	

Changes in Pain and Disability Assessment over Time

We found a significant change between the treatment and control groups in disability and pain over time. There were significant improvements in ODI scores ($P<0.001$) and the "amount of pain you have right now" rated by VAS ($P<0.001$) with NET treatment. See Figures 2 and 3.

There was a significant decline in LBP at the end of the first month following treatment for the above measures, but in all cases LBP then returned to baseline after 2 months of no additional treatment. At the 1 and 3-month assessment points there were no differences in mean scores between treatment and control groups in all measured outcomes of pain or disability as measured by the VAS and ODI.

The QVAS pain score improved with NET treatment (P<0.001) and (P= 0.014) for QVAS 1 and QVAS 4 respectively. It's noted that QVAS 3 showed relatively the same improvement for both groups rendering it not statistically significant in evaluating NET therapy. Improved performance of the Treatment group over the Control group was noted at the Month 3 assessment but in this small cohort, the level of improvement did not reach statistical significance.

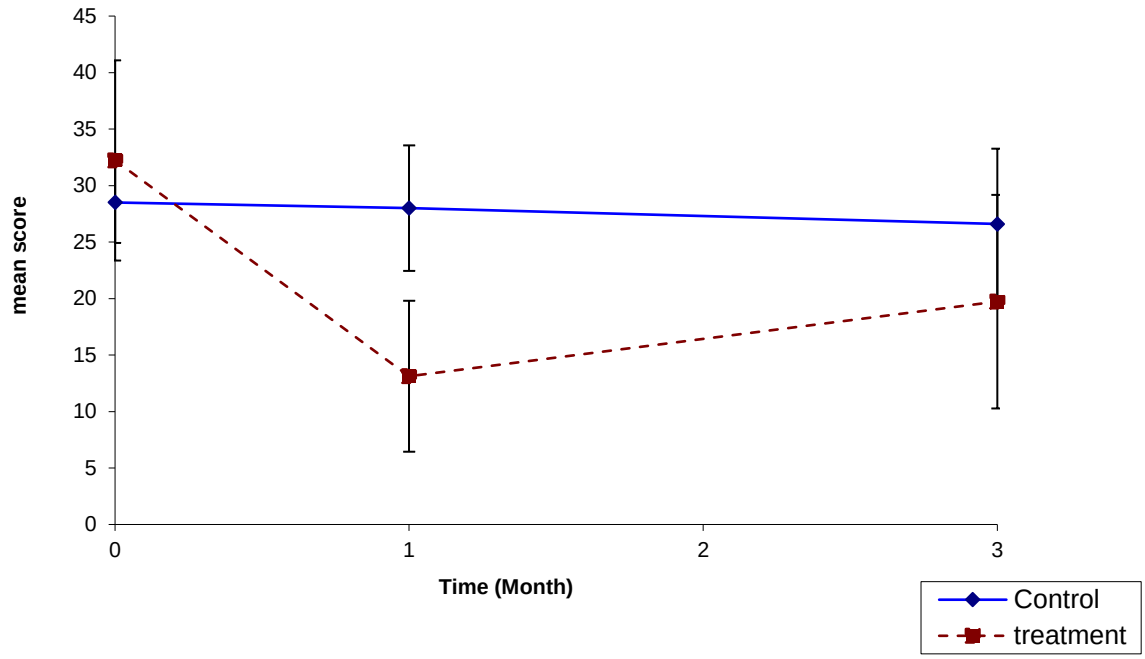

Figure 2. Changes in Oswestry Scores within Groups over Time. Oswestry Disability Index was obtained at Baseline, 1 Month and 3 Months. At 1 Month the NET treatment group improved versus the control (P< 0.001). Each point represents the estimated mean at the time point ± SEM of data analyzed**.**

Control

Treatment

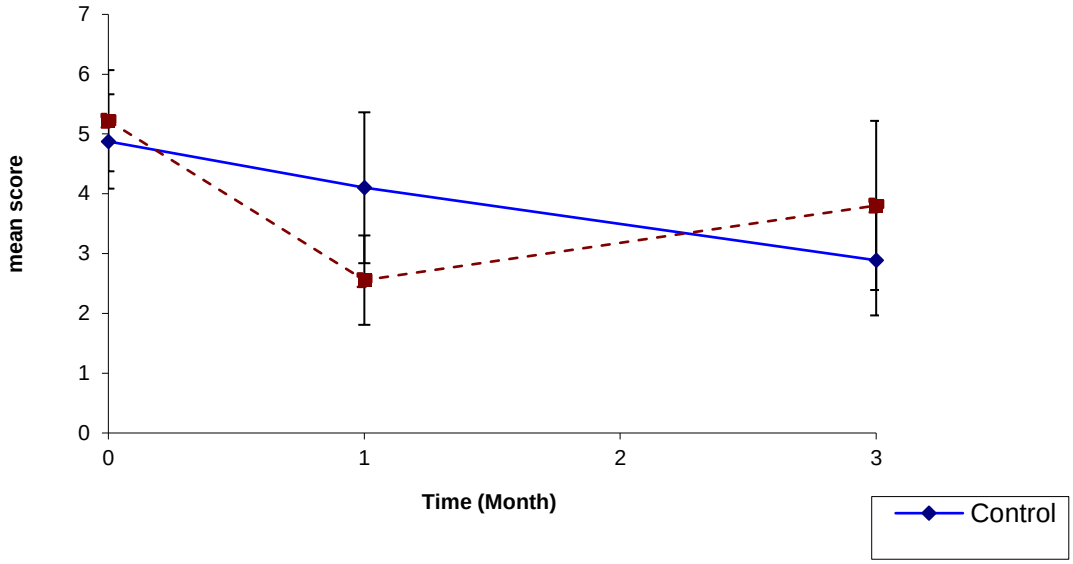

Figure 3. Changes in QVAS Q1 Scores within Groups over Time. QVAS Q1 asked respondents "Identify the amount of pain you have right now?" was obtained at Baseline, 1 Month and 3 Months. At 1 Month the NET treatment group improved versus the control (P< 0.001).This was not maintained at Month 3. Each point represents the estimated mean at the time point ± SEM of data analyzed.

On the basis of the repeated measures analysis, estimates of the means and standard deviations of the scores, and of the correlations between scores taken a month apart, are given in Table 2.

Table 2. Means and standard deviations (s.d.) of the scores, and correlations between the scores taken a month apart (*corr*), from the repeated measures analyses. Four component pain VAS scores are shown.

	Control			**Treatment**				
	Mean			Mean			SED	*corr*
Month	0	1	3	0	1	3		
Oswestry (total %)	28.5	28.0	26.6	32.2	13.1	19.7	19.98	0.89
VAS Q1	4.9	4.1	2.9	5.2	2.6	3.8	2.73	0.80
VAS Q2	5.5	5.2	3.9	5.2	4.3	4.4	2.56	0.79
VAS Q3	3.4	2.0	2.1	3.1	1.4	2.1	1.79	0.75
VAS Q4	8.0	7.8	6.3	7.3	5.9	6.7	2.30	0.75

In Table 3 and 4 we present the changes in mean scores over the first month for the 4 measures whose time profiles were plotted in Figures 3 to 6. Also given are the standard errors of each of the differences. It is clear that during the first month when the treatment was applied, there is a significant improvement in pain levels (as opposed to no improvement for the control group). After a further 2 months, pain levels for the treated group approached those for the control group. This suggests that the treatment effects in this cohort for the measures of pain (VAS) and disability (ODI) were short-term in nature.

Table 3. The change (decrease) in mean scores over the first month, with estimated standard errors of differences, s.e.d. and 95% confidence intervals (C.I.) for the four outcome measures.

	Treatment			Control		
Measure	change in mean score	s.e.d.	95% C.I.	change in mean score	s.e.d.	95% C.I.
Oswestry	19.1	3.27	(12.4, 25.8)	0.5	3.33	(-6.3, 7.3)
VAS Q1	2.7	0.57	(1.5, 3.8)	0.8	0.64	(-0.5, 2.1)

Table 4. Change over Time within Groups for Mean QVAS Pain scores; M0 =Baseline, M1=Month 1 and M3=Month 3.

Outcome Measure	**Change in mean score M0– M1**	**95% C.I.**	**P value**	**Change in mean score M1 –M3**	**95% C.I.**	**P value**
			CONTROL GROUP			
VAS Q1	0.8	(-0.6, 2.1)	0.241	1.21	(-0.98 to 3.40)	0.261
VAS Q2	0.3	(-1, 1.6)	0.6	1.29	(-0.81 to 3.39)	0.214
VAS Q3	1.4	(0.4, 2.4)	0.008	-0.10	(-1.66 to 1.47)	0.900
VAS Q4	0.3	(-1, 1.5)	0.688	1.49	(-0.53 to 3.51)	0.140
			TREATMENT GROUP			
VAS Q1	2.7	(1.5, 3.8)	<0.001	-1.25	(-3.27 to 0.77)	0.212
VAS Q2	0.9	(-0.2, 2.0)	0.12	-0.04	(-1.98 to 1.90)	0.970
VAS Q3	1.7	(0.8, 2.5)	0.001	-0.70	(-2.15 to 0.75)	0.327
VAS Q4	1.4	(0.3, 2.6)	0.014	-0.76	(-2.63 to 1.11)	0.405

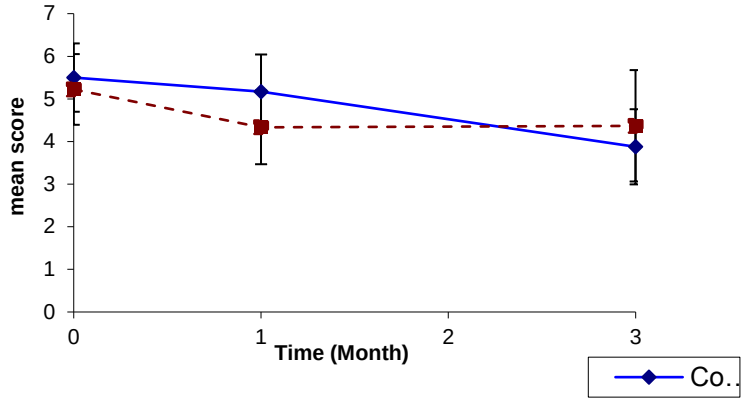

Figure 4 Changes in QVAS Q2 Scores within Groups over Time. QVAS Q2 asked respondents “What is your TYPICAL or AVERAGE level of pain?” was obtained at Baseline, 1 Month and 3 Months. At every time interval the control and NET treatment groups did not demonstrate statistical significance. Each point represents the estimated mean at the time point ± SEM of data analysed.

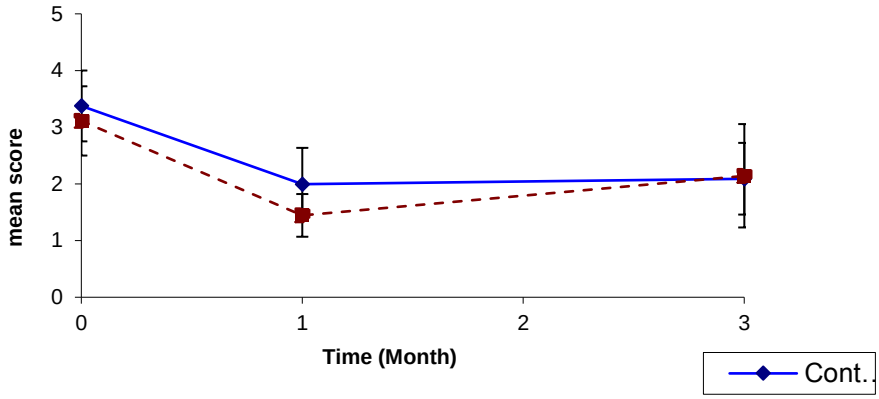

Figure 5 Changes in QVAS Q3 Scores within Groups over Time.QVAS Q3 asked respondents “What is your pain level AT ITS BEST (How close to '0' does your pain get at its best)?”was obtained at Baseline, 1 Month and 3 Months. At every time interval the control and NET treatment groups were essentially identical rendering no statistical significances for the evaluation of NET therapy. Each point represents the estimated mean at the time point ± SEM of data analysed.

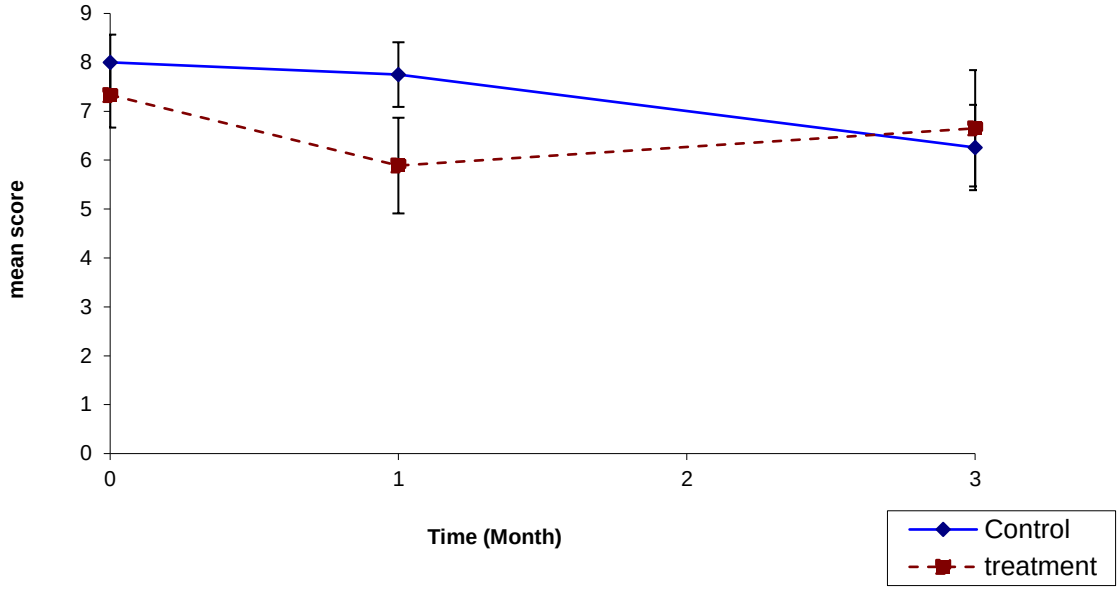

Figure 6 Changes in QVAS Q4 Scores within Groups over Time. QVAS Q4 asked respondents "What is your pain level at its worst?" was obtained at Baseline, 1 Month and 3 Months. At 1 Month the NET treatment group improved versus the control (P< 0.014).This was not maintained in Month 3. Each point represents the estimated mean at the time point ± SEM of data analysed.

DISCUSSION

We conducted a small randomised controlled trial of a new biopsychosocial multimodal stress relieving treatment in a small cohort of low back pain sufferers with chronic low back pain. This pilot study demonstrates the feasibility of providing Neuro Emotional Technique to a cohort of sufferers of chronic low back pain. It is an important first step in evaluating the potential utility of NET in the treatment and management of chiropractic conditions. Whilst previous case based studies have been reported (27-31), this is the first published randomised controlled trial for this therapy in those with low back pain.

We found significant changes in participant scores for the question “Amount of pain you have right now,” “Your pain level at its best,” and “Your pain level at its worst” of the VAS after a 1-month trial of NET. After the treatment ceased the pain levels began to approach the non-treated control values at the three month assessment point. This implies, based on this small sample, that the NET treatment was effective in reducing chronic low back pain whilst it was being delivered but not for a prolonged period afterwards. However, some of the measures (Oswestry Disability Index) at 3 months suggested that a treatment effect may have continued until the 3-month assessment point since the disability score did not return to its pre-treatment level. This preliminary result may be an important finding that should be tested with a larger study.

In the calculation of the power we found significant interactions for all outcomes measures. Based on the improvement noted in this small group, it is highly recommended that a long-term, large-scale, randomised controlled trial be undertaken to investigate NET for managing CLBP.

No drop outs were recorded for this data set. One patient in the control group did not properly complete the VAS at the 1-month assessment point. Whilst this did not have an effect on this study, it is important that subsequent trials have no missing data, and all questionnaires should be checked for completeness.

It is premature to conclude from this study that NET works best for CLBP sufferers with mild to moderate pain scores. However, a possible important limitation that warrants comment is the initial baseline value of pain and potential regression to the mean. The low initial pain score may have affected treatment outcome potential. It is assumed, that when scores at base-line are low, that they can only improve slightly i.e. a VAS score of 4 can only improve towards 0, with little significance detected. Scores of 8 or 9 have the room to improve considerably, and give statistically significant changes. With an average VAS of 5.4 (control) and 5.2 (treatment) groups, a floor effect may be in operation muting the results of this study in lower score values. We therefore recommend that inclusion criteria consider a baseline VAS score equal or greater than 4 for inclusion in subsequent studies to avoid possible “floor” effects in data analysis.

Generalisability

The results of this study are preliminary in nature and need to be confirmed by additional work. The results of small studies are known to be limited for a variety of reasons. Small studies can produce false-positive results, and they may over-estimate the magnitude of an association amongst other statistical issues. (32) The results of this study should not be extrapolated to individual patients or other sub populations of LBP sufferers not examined in this cohort. (33) Also, patient selection, insufficient patient numbers, and a short time frame in therapy and follow up may render it difficult (or impossible) to document the efficacy of the therapy. (34) More specifically, the small sample population was drawn from a specific geographical location with an above average socioeconomic status. This status may not be consistent with outcomes from those in different socioeconomic groups. Future investigations should endeavour to more broadly represent the population of LBP sufferers participating in the study. (35) Future study would be strengthened if more objective assessment of LBP, anxiety and depression could be ascertained. For example, analysis of inflammatory markers in blood such as C-reactive protein, cortisol, Interleukin 1, 6, 10 and TNF-alpha would be appropriate measures to detect inflammation associated with the low back pain. (36-40) Additionally, the treating doctors were not blinded to the intervention they were providing. Whilst this is a significant limitation of the study, we attempted to minimise this bias by having an independent assessor complete all assessments in the study. A further limitation was that experimental and control participants were treated by different doctors, creating the possibility for a variance of doctor confounding effect.

Limitations

The main weakness of this study consisted of its size and duration. While all effort was made to broaden the pool of potential participants, most patients were drawn from the Eastern Suburbs of Sydney, an inner city region. As patients were drawn from a relatively small region, it is possible that this outcome may be somewhat specific to its cohort. The main study had 17 participants after drops outs, which is a small-sized RCT for therapy. Additionally, the participants were followed for only 3 months, which constitutes a short term follow-up. As a first study this is reasonable but future studies should attempt to follow patients for at least 1 year and preferably 2 or more years to elucidate the ultimate effect of the therapy on CLBP, especially since this condition is known to be recurrent or episodic in nature. (41)

It is an inherent weakness of any physical therapy based RCT that practitioners cannot be blinded to the treatment they are rendering. In order to minimise the bias possible with this intervention independent assessors were used for all assessments made in this study. This action reduced potential bias as the assessors were not aware of subject allocation status.

Finally, the profile of conditions that made up the CLBP cohort was not known. Although red flag conditions and lumbar radiculopathies were excluded, beyond this it was not known what the cause of the LBP was, and therefore which category or subset of symptoms the LBP patients were distributed in. Future studies should ascertain the sub-types of CLBP such as those with degeneration, spinal stenosis, spondylolythesis, as some of these conditions might have very different natural histories and respond differently to this form of management.

CONCLUSION

The feasibility trial demonstrated that the basic trial protocol could be followed and administered successfully. Data gathering and analysis procedures were refined for the purpose of administrative ease and integrity. The feasibility trial was successful in terms of showing that participants were able to complete the trial without discomfort or adverse incident. The feasibility trial showed promise in confirming a need to investigate the effect of NET treatment on a larger cohort of LBP sufferers by revealing administrative proficiency and potential efficacy with respect to change over time in the short term. As there were no adverse events noted in the conduct of the feasibility trial the main randomised controlled trial was commenced.

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