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Treating Spider Phobia Using Neuro Emotional Technique™: Findings from a Pilot Study

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Abstract

Background: Specific phobia, the most common anxiety disorder, can disrupt lives, limit work efficiency, reduce self-esteem, and strain relationships. Current interventions show some degree of success, yet relapse is common. Consequently, the need for a more effective and durable intervention is evident. The purpose of this pilot study is to investigate the efficacy of a new intervention, Neuro Emotional Technique™ (NET), on individuals with spider phobia, and to determine whether further investigation is warranted.
Methods: Participants who met the inclusion criterion that spider phobia impacted their daily lives were randomized to either a control group that received no intervention ($N = 7$), or to an experimental group that received two 30-minute sessions of NET approximately 2 weeks apart ($N = 8$). The primary measure was the Subjective Units of Distress Scale, and secondary measures were the Spider Questionnaire, Behavioral Assessment Test, Beck Anxiety Inventory, and change in heart rate (HR).
Results: Compared with the no-intervention control group, statistical analysis indicates a significant advantage for the NET group in regard to state anxiety/subjective distress, reported fear, and avoidant behavior. The difference between the two groups for general anxious symptomatology (trait anxiety) and change in HR was not statistically significant. No adverse reactions were reported.
Conclusions: The findings of this pilot study suggest that NET is a promising intervention for spider phobia in adults. A larger, full-scale study is required to confirm these results.

Introduction

Phobias can disrupt lives, limit work efficiency, reduce self-esteem, and strain relationships. Also, individuals with phobia make every effort to avoid the uncomfortable and often terrifying feelings of phobic anxiety.[1,2] Specific phobia, the most common anxiety disorder, is a chronic problem with a lifetime prevalence of 2.3%–14.4% and a 12-month prevalence of 1.8%–11.1%.[3] Individuals with a specific phobia demonstrate an exaggerated fear response toward a well-defined stimulus.[4] There have been many proposed mechanisms explaining the probable causes of anxiety disorders, yet no one model seems to fit them all.[5] In the case of specific phobias, research seems to support two main models: *classical conditioning* and *evolutionary etiologies*.

Human phobias seem more irrational and more resistant to extinction than simple fear conditioning in animals.[2] In the classical conditioning model, the phobic stimulus elicits a fear response, which in turn causes physiologic changes in the body, and if perceived by the phobic, may consequently cause the fear response to escalate.[2,5] Another important component of phobias is avoidance behavior, which may be responsible for the lack of extinction of the fear response. One argument against this model maintains that many phobics lack a specific memory of a traumatic event associated with the phobic object; however, it is well established that the specificity of a fear may well diminish over time, yet the fear response remains.[2,5–7] Another argument against this model is that in simple classical conditioning, phobias would tend to develop toward anything paired with fear, yet clinical evidence suggests that phobias are only acquired on a limited collection of objects or events.[8] An explanation of this would lend itself to an evolutionary etiology, in that some individuals are more *biologically prepared* to learn fear.[2,8,9] In this case, then, phobias may represent humans' evolutionary preparation and particular predilection to learn about danger and their tenacity to retain that learned information.[2]

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The most successful interventions for spider phobia involve actual or imaginational exposure to spiders, and are considered a type of behavior therapy. However, the evidence suggests that response rates of most interventions currently used are variable, and relapse is common when the intervention is discontinued.[1] Combining exposure therapy with cognitive therapy resulted in a promising short-term cognitive behavioral therapy, which also addresses the phobic's dysfunctional beliefs about spiders.[10,11] Other psychologic therapies have been used for spider phobia with mixed results.[12] Furthermore, there is little empirical evidence for or against the use of pharmaceuticals for any small-animal phobia.[13] While current interventions have shown a degree of effectiveness, there are a significant number of sufferers who do not respond to treatment, and relapse is common when treatments are discontinued.[1] The need for a more durable intervention is evident.

Neuro Emotional Technique™ (NET) is a relatively new stress-reduction technique whose aim is to remove neurological abnormalities that have a specified physiopathological pattern.[14] Often, emotional trauma can cause a learned emotional response, a conditioned fear, and as a result, a related physiopathological pattern.[2,15,16] Under normal conditions, the learned response becomes extinct, and the physiopathological pattern resolves. However, occasionally this does not happen, and both persist. This especially seems to be the case in phobia. The goal of NET is to normalize the aberrant patterns through a physical correction. How NET accomplishes this extinction of a conditioned response is currently unknown. However, it is hypothesized that during an emotionally traumatic event, in the interest of self-preservation, a person adopts an avoidance behavior, thus lessening the fear or anxiety, but avoiding the full expression of emotions. During the NET procedure, the participant first becomes aware of the underlying traumatic event, and then is allowed to face it in a safe and supportive environment. As a result, he or she re-experiences the avoided emotions, and learns that the situation poses no real threat, which encourages extinction of the learned fear response. Furthermore, since the amygdala,[17] the hippocampus,[18] and the medial prefrontal cortex[19] all play important roles in either the acquisition and/or the extinction of emotional learning, it is further speculated that during the NET procedure, changes occur in these areas of the brain. Specifically how these changes occur is yet unclear, however they may involve long-term potentiation.[20,21]

A similar study also investigated the effects of NET on the intensity of emotional arousal in phobic subjects exposed to their phobic stimulus.[22] The sample size ($n = 18$) and demographics (age and sex) were comparable to this study. Peterson[22] found that NET significantly decreases the intensity of self-reported emotional arousal in the phobic subjects compared to controls. There have been no other studies published to date using NET for any other anxiety disorder.

The purpose of this pilot study is to investigate the efficacy of a new stress-reduction intervention, Neuro Emotional Technique (NET), for reducing the severity of the symptoms of spider phobia, and to determine whether further investigation is warranted.

Materials and Methods

Objectives

In the current study, we tested the hypothesis that NET would (1) reduce subjective distress, (2) reduce avoidance behavior, and (3) reduce an exaggerated psychophysiologic response toward the phobic stimulus of phobic individuals.

Participants

Adults over the age of 18 years who report a phobia of spiders were recruited in Oxford, UK via flyers, posters, and general e-mail. The respondents were screened to determine whether they met the DSM-IV-TR criterion[23] that their fear of spiders impacted their daily functioning. If they met this criterion and had no other mental health disorder, were fluent in English, and were not currently being treated for spider phobia, they were invited to participate. No payment was offered. Ethics approval (reference no. SSD/CUREC2/07-007) was granted by the Central University Research Ethics Committee of the University of Oxford, UK.

Participants were randomized to either an experimental group that received NET therapy, or to a control group that received no intervention. The participants in the experimental group were given two 30-minute sessions of NET approximately 2 weeks apart.

Intervention

NET is considered a complementary and alternative medicine modality used to diminish psychophysiologic stress. It is based on principles of a number of different health disciplines such as traditional psychology, chiropractic, and Traditional Chinese Medicine.[14] However, it is dissimilar to more traditional approaches, like cognitive behavioral therapy, in that aside from addressing a patient's cognitions, internal dialogue, and behaviors in response to a distressing experience, NET predominantly focuses on *emotions* about the experience.

The focus of the NET procedure in this study was on the participant's subjective feelings of distress about the phobic stimulus. During the NET protocol, a number of psychologic components of the experience are addressed: (1) cognitions (thoughts about the phobic stimulus and the participants' response to the phobic stimulus), (2) emotions (participants' affect in response to the phobic stimulus), and (3) behaviors (participants' behaviors in response to the phobic stimulus, for example, avoiding the phobic stimulus).[24] These various psychologic components are explored for a physiologic reaction in the participant. The manual muscle test is used throughout the NET procedure as an assessment of a participant's physiologic reactivity, which have previously been shown to be correlated.[22,25–27]

The NET procedure involves a series of well-defined steps (see Appendix 1), which address each of these components. Once a physiologic reaction is found, the practitioner helps the participant identify the specific emotion using the principle from Traditional Chinese Medicine that meridians and emotions are coupled.[28] The participant then determines how the specific emotion fits the distressing situation. Sometimes a similar distressing situation is identified earlier in life as well. While the patient *thinks* about the distressing situation and *feels* the emotion that was found to be associated, a mechanical force is applied to specific spinal levels (Appendix 2) during a full respiratory cycle.

The procedure is concluded when the patient no longer feels distress or discomfort associated with the cognitive statement or recollection, and as a result can resist the downward pressure of the muscle test.[24] In addition, following the

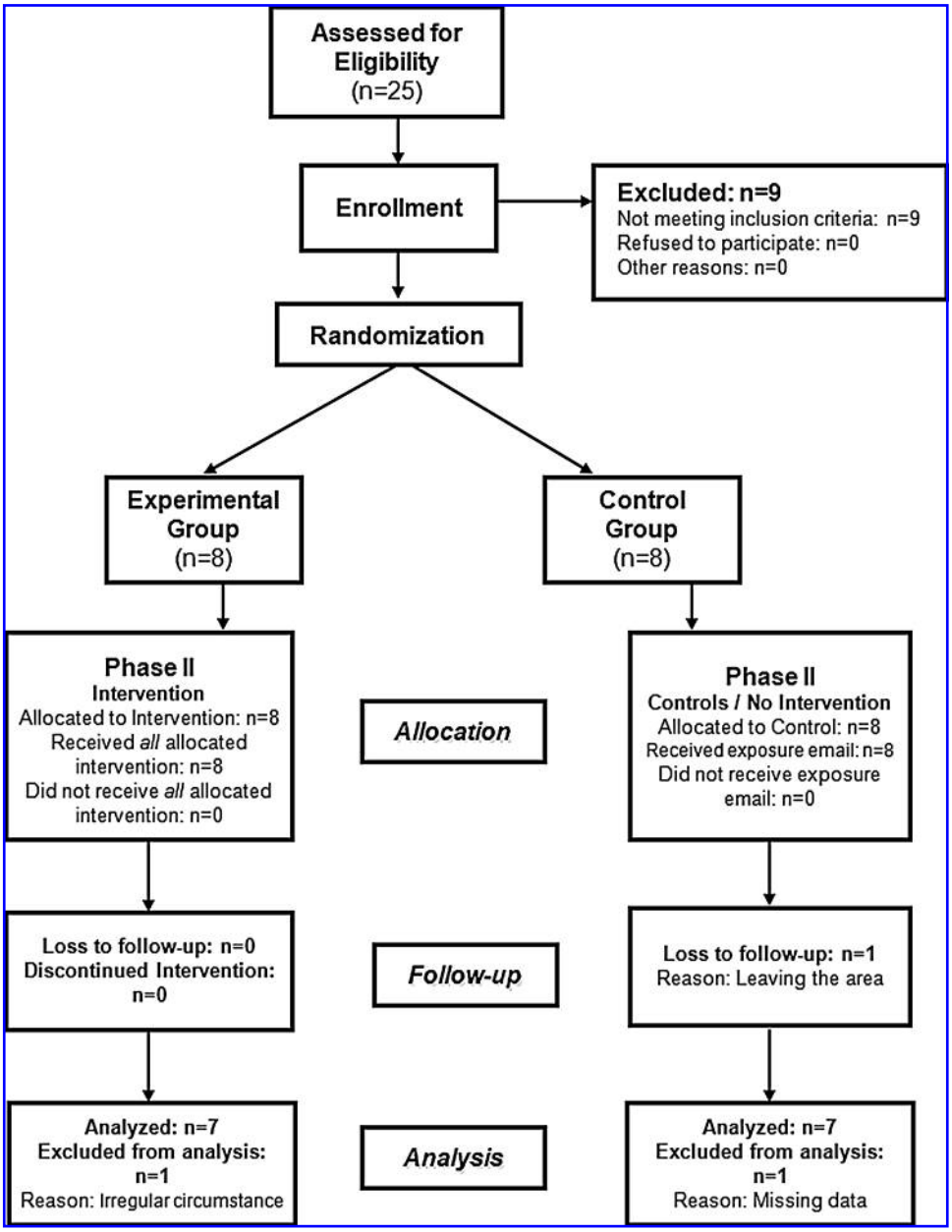

FIG. 1. Consolidated Standards of Reporting, or CONSORT, diagram (Walker, 2004[14]).

intervention, patients frequently report feeling subjective relief.[24] All intervention sessions were performed by the same certified NET practitioner (A.M.J.).

Since the participants in the experimental group were asked to think about spiders on two separate occasions between assessments, the controls were also asked to think about spiders on two occasions between assessments. This was accomplished by sending control participants two e-mails each containing a picture of a spider, and asking for their thoughts about the picture.

All assessments and interventions were performed in the same room to ensure contextual uniformity.

Outcomes

The primary outcome was the *Subjective Units of Distress Scale (SUDS)*, which measures the intensity of subjective distress in response to a particular stimulus, and ranges from 0 (no anxiety) to 10 (extreme anxiety). SUDS has been shown to correlate with other measures of physiologic stress, such as heart rate and skin temperature.[29]

In addition, there were five secondary outcome measures:

1. *Spider Questionnaire (SPQ)* assesses phobic vigilance, phobic preoccupation, avoidance, and independent planning, and consists of 43 true–false questions. Scores may range up to 33, and higher scores indicate more self-reported fear.[30,31] The SPQ has demonstrated consistent psychometric properties, satisfactory reliability, and good internal consistency.[30,32] SPQ scores of 14 and above are considered phobic.
2. *Behavioral Assessment Test (BAT)* measures avoidance behavior and consists of 11 increasingly challenging tasks in approaching the phobic stimulus.[33] Two (2)

Table 1. Participant Characteristics at Baseline and Change in Scores

Variable	*Experimental group (N = 8) mean (SD)*	*Control group (N = 7) mean (SD)*	*Effect size*[a] *(95% confidence interval)*	p *value*[b]
Age (years)	28.6 (8.3)	28.6 (5.8)	—	0.803[c]
Gender (male:female)	1:7	1:6	—	1.000[c]
Baseline scores				
SUDS	7.3 (1.5)	6.3 (2.6)	—	0.415[c]
BAI	13.5 (6.9)	10.9 (6.5)	—	0.557[c]
SPQ	19.1 (5.3)	14.7 (5.5)	—	0.096[c]
BAT	13.6 (5.3)	13.6 (5.5)	—	0.876[c]
Change in HR (bpm)	33.1 (16.7)	27.1 (5.6)	—	0.445[c]
Changes in scores				
SUDS	–2.5 (1.9)	–0.1 (0.9)	-1.5 (-2.8,-0.2)	**0.005**
BAI	–1.1 (2.2)	1.3 (3.5)	-0.8 (-2.0, 0.4)	0.100
SPQ	–3.1 (3.9)	0.3 (1.8)	-1.0 (-2.3, 0.2)	**0.021**
BAT	2.7 (3.7)	–3.0 (3.2)	1.5 (0.2, 2.9)	**0.007**
Change in HR (bpm)	–0.8 (22.3)	–2.7 (10.4)	0.1 (-1.0, 1.2)	0.611

[a]Effect size is calculated using Glass' formula which gives an unbiased estimate with small sample sizes.
[b]*p* value from Mann-Whitney test statistics using exact conditional distribution of test statistics.
[c]Based on two-sided hypothesis testing. All other *p* values were calculated under one-sided hypothesis testing.
SUDS, Subjective Units of Distress; BAI, Beck Anxiety Inventory; SPQ, Spider Questionnaire; BAT, Behavioral Assessment Test; HR, heart rate; bpm, beats per minute; SD, standard deviation.

points are given for each successfully completed task, and one point, for each task attempted but not completed. Therefore, scores range from 0 to 22. The BAT has been found to be a sensitive, valid, and reliable measure of behavioral change.[33,34] Completion of step 7 (i.e., score of at least 14), which involves completely removing the lid of the container, is considered to be nonphobic.

3. *Beck Anxiety Inventory (BAI)* is an instrument to assess anxious symptoms. It is widely used and shows good reliability and validity.[35,36] Score from 0 to 21 indicate *low anxiety*, from 22 to 35, *moderate anxiety*, and over 35, *high anxiety*.
4. *Change in heart rate (HR)* from resting to exposure to the phobic stimulus has been found to correlate reliably with increased subjective anxiety.[29,37–40] Participants' HRs were measured using a Polar F4 Heart Rate Monitor, which have been shown to have good accuracy.[41] The same HR monitor was used throughout the study.
5. Satisfaction with intervention was measured using a participant satisfaction scale, which ranged from 0 (not at all) to 10 (extremely).

A reduction in SUDS, SPQ, BAI scores, or change in HR, or an increase of BAT score is indicative of a positive treatment.

Sample size

We hypothesized an effect size (difference in group means standardized by the average standard deviation) of 1.5 units of the SUDS score between the experimental and control group to be clinically important. Using the PS software,[42] the minimum sample size required for a study with 80% power, maximum tolerated type I error of 0.05, and equal allocation between two groups was 10 participants in each group. Similar sample sizes have been observed in other spider phobia intervention studies.[27,43] See Appendix 3 for details on sample size calculation.

Randomization and allocation concealment

Participants were initially assessed by a blind assessor, and then randomly allocated into either the experimental or control group by means of a set of sealed opaque envelopes containing group allocation. The contents of the envelopes were previously unknown to the assessor and participants. Because only the experimental group received active intervention, allocation concealment, while not explicitly addressed, was obvious to participants and to the practitioner.

Statistical methods

We use the nonparametric Mann-Whitney *U* test statistics[44,45] to test whether the difference in medians of the two groups is statistically significant.

When a difference in the direction of the test statistics is *a priori* anticipated, a one-tailed procedure is implemented. Otherwise a two-tailed procedure is indicated.

Results

Participant flow

As shown in Figure 1 (Consolidated Standards of Reporting, or CONSORT, diagram), 25 people were screened, 16 were randomized, and 15 were included in the analysis. The most frequent reason for exclusion was failure to meet the entry criteria that the phobia interfered with daily functioning (36%).

Recruitment

Eligible participants were assessed at baseline and again within 2 weeks.

Baseline data

Table 1 shows that the differences between the groups at baseline were not statistically significant. Both groups scored in the phobic range in the SPQ and BAT, and reported

moderate distress about spiders (SUDS). In addition, both groups were found to have low general anxiety (BAI).

Numbers analyzed

The primary analysis was intention-to-treat and involved all participants who were randomly assigned to both groups. One (1) participant in the control group was lost to follow-up. In addition, the data from 1 participant in the experimental group was omitted from the secondary analysis because they were exceptionally irregular. The reason for this irregularity is attributed to her high levels of stress on the day of the secondary assessment. Thus, data from 14 participants were available for the secondary analyses.

Efficacy outcomes

Table 1 also summarizes the changes in scores from baseline to second assessment. Secondary analyses identified a statistically significant advantage for the NET group relative to the control group in subjective distress about spiders (SUDS, $p = 0.005$), self-reported fear (SPQ, $p = 0.021$), and avoidance behavior (BAT, $p = 0.007$). There were no significant differences between the groups with regard to general anxious symptomatology (BAI) and change in HR. When we repeat the analysis with Last Observation Carried Forward (LOCF) assumptions, we obtain similar results with the exception of changes in BAT scores which show no significant differences. The raw data are given in the Appendix 4.

The satisfaction scores in the intervention group were 3, 5, 8, 8, 9, 10, 10, 10 (mean value is 7.88).

Adverse events

There were no adverse events reported by any participant.

Discussion

The results of this randomized controlled pilot study indicate that NET, administered for a short duration, may be helpful in treating adults with spider phobia. NET, a noninvasive technique, appears to be a safe and efficacious intervention.

The main limitations of this study are the small sample size and the lack of allocation concealment to the practitioner and to the participants. The small sample size may have caused the study to be underpowered, and the lack of allocation concealment may have led to expectation bias, which may have favorably affected outcomes in the experimental group.[46]

There was one deviation from protocol in that the targeted sample size of 10 in each arm was not achieved in the planned timeframe of this study. As a result, the NET practitioner was no longer available. This may have resulted in the study being underpowered, increasing the likelihood of a type II error.[47]

Additionally, the high mobility of the participants (who were mostly international students completing a 1-year course) did not allow for a long-term follow-up. Since relapse is common when interventions for a specific phobia are discontinued,[1] long-term follow-up assessments would strengthen future research.

As expected, when exposed to a live spider, HR did increase in all participants; however, the change was not predictive of group. The lack of effect in change in HR and also in BAI scores may be indicative of the lack of power or the short duration of the study. Nevertheless, it appears that NET is efficacious at reducing *state* anxiety (SUDS, BAT, and SPQ), but not *trait* anxiety (BAI) and its resultant physiology (change in HR).

It might be argued that the NET intervention was a form of systematic desensitization, which is a type of exposure therapy. However, the evidence suggests that for exposure therapy to be effective, it must have a duration of at least 3 hours.[13] In this study, no actual spiders were present during any intervention session, and imaginational exposure did not exceed 30 minutes per session, or 1 hour in total. It is unlikely that this length of exposure alone had any therapeutic effect.

During the final assessment, experimental subjects were asked to rate their satisfaction with the NET intervention and to comment on their impressions of the intervention. Satisfaction scores indicate a high rate of satisfaction.

It has been previously reported that phobics often describe feelings of loss of control, unpredictability/uncertainty, and helplessness.[5] These themes were also noted in the participants of this study. In addition, it has been found that the age of onset of specific phobia is usually in childhood or early adolescence,[3] which was similar to reports in this study.

Conclusions

NET intervention appears to be a promising alternative treatment for spider phobia. However, the small sample size, lack of active controls, and lack of long-term follow-up means that further testing is required with a larger number of participants and more rigorous design. It would also be worthwhile investigating the effectiveness of the NET intervention in other phobias as well. For example, most small-animal phobias (e.g., snakes, mice, insects) and most other specific phobias (e.g., heights, flying, water) share a similar clinical and symptomatic presentation and are thought to be caused by fear conditioning.

In conclusion, NET can offer clinicians a promising alternative for the treatment of spider phobia and is worthy of further investigation.

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Clinical Trials Registration: This trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR)—ACTRN12608000276358. The URL is http://www.ANZCTR.org.au/ACTRN12608000276358.aspx

Disclosure Statement

No competing financial interests exist.

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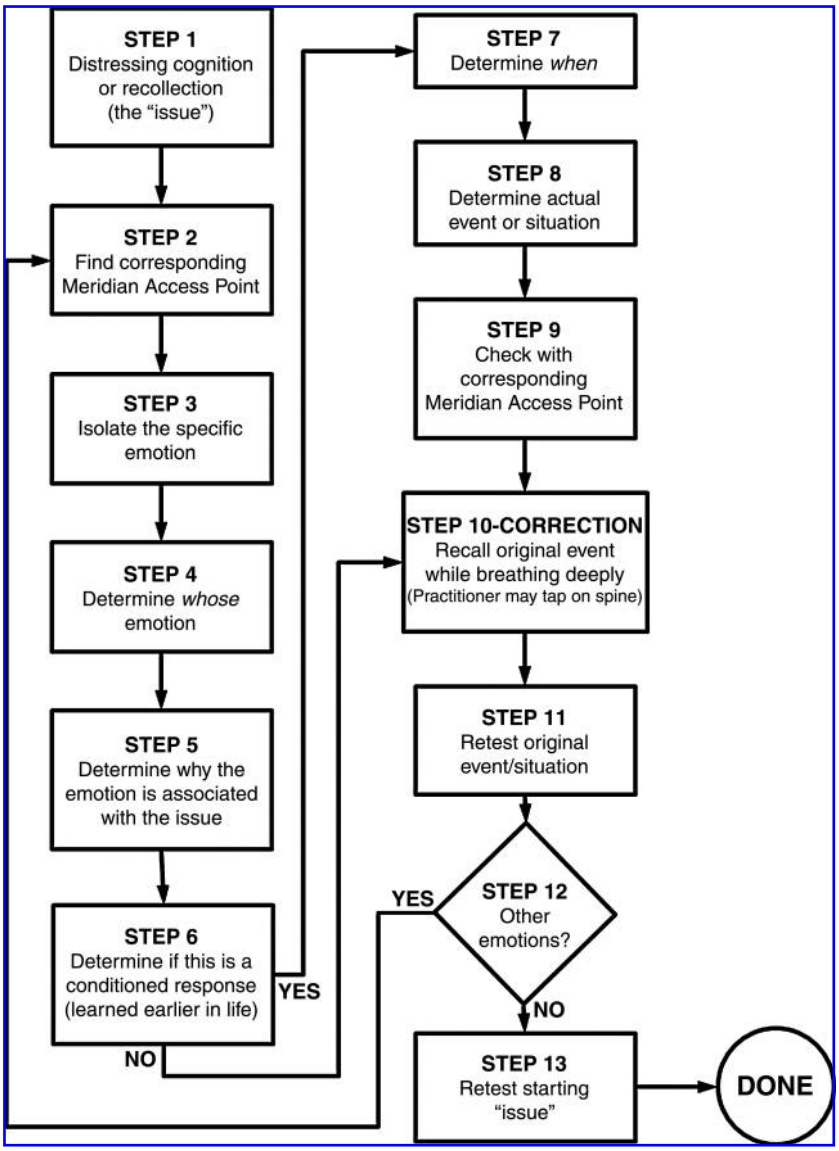
Appendix 1:
Neuro Emotional Technique™ Protocol Flowchart (Walker, 2004).[14]



Appendix 2. Meridian/Organ Spinal Levels (from Walker, 2004[14])

Earth Element	
Stomach	T8-T10-T12
Spleen	T1-T5-T9
Pancreas	T5
Metal Element	
Large Intestine	L5
Left Lung	T1-T8-L2
Right Lung	T2-T9-L3
Water Element	
Bladder	L5
Kidney	T1-T5-T8
Wood Element	
Gall Bladder	T4
Liver	T2-T5-T8
Fire Element	
Small Intestine	L5
Heart	T2-T8-T12
Thyroid	C1-C4-C7
Adrenals	T7-T9-T11
Prostate	L5
Testes/Ovaries/Uterus	Bilateral S.I. Joints-L3-L5-Coccyx
Pituitary	C2-C5-T1
Other	
Governing Vessel	T3-T6
Conception Vessel	T3-T6

Appendix 3. Sample Size Calculation

For sample size estimation, we used PS software (freely available from http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize) using the following settings under the *t*-test tab: design = independent, $\alpha = 0.025$ (one-sided testing), power = 0.80, $\delta = 1.5$, $\sigma = 1$, m = 1 and obtained the sample size of 10 for each group.

One can also obtain similar results using the R software (freely available from http://www.r-project.org/) using the following command:

>power.t.test(delta = 1.5, sd = 1, sig.level = 0.025, power = 0.80)

Two-sample *t*-test power calculation

n = 9.821082
delta = 1.5
sd = 1
sig.level = 0.025
power = 0.8
alternative = two-sided

NOTE: n is number in ***each*** group

We are not aware of any software to calculate sample size for Mann-Whitney *U* test, which we planned to use for analysis. Therefore, we used the independent design instead of paired design to inflate the sample sizes. The sample size in each group would have been only seven had we used the design = paired in PS software or in R. Therefore, we use and report the higher sample size of 10 per group in the main text.

Appendix 4A. Raw Data

	Gender	*Age*	*SUDS*	*BAI*	*BAT*	*SPQ*	*HR_Change*
Case 1	1	37	4	6	22	7	33
Case 2	2	21	8	20	12	19	37
Case 3	2	21	9	9	12	22	16
Case 4	2	23	7	19	20	25	25
Case 5	2	43	7	11	11	19	6
Case 6	2	22	7	24	8	21	52
Case 7	2	31	8	14	21	21	53
Case 8	2	31	8	5	10	19	43
Control 1	2	28	10	1	18	12	28
Control 2	2	25	7	20	18	19	34
Control 3	2	34	8	8	6	20	21
Control 4	2	35	5	18	21	6	20
Control 5	2	23	2	11	10	16	34
Control 6	1	34	7	11	10	20	27
Control 7	2	21	5	7	12	10	26
Control 8	2	28	7	22	20	25	31

SUDS, Subjective Units of Distress Scale; BAI, Beck Anxiety Inventory; BAT, Behavioral Assessment Test; SPQ, Spider Questionnaire; HR, heart rate.

(*Continued*)

Appendix 4B. Baseline Measurements for Cases (i.e., Received Neuro Emotional Technique™ Intervention) and Controls

ID	Primary measure	Secondary measures				
	SUDS_change	*BAI_change*	*BAT_change*	*SPQ_change*	*HR_change_change*	*Satisfaction*
Case 1	0	2	0	−1	24	8
Case 2	−1	−1	4	0	−12	3
Case 3	−3	−2	−2	0	19	5
Case 4	−2	−3	0	−4	−1	8
Case 5	−4	2	9	−10	27	10
Case 6	−2	−2	4	−1	−28	9
Case 7	−2	−4	−18[a]	−1	−6	10
Case 8	−6	−1	4	−8	−29	10
Control 1	−2	4	−6	1	−14	Null
Control 2	0	5	2	−2	10	Null
Control 3	0	−2	0	−2	−4	Null
Control 4	0	−4	−7	0	4	Null
Control 5	0	0	−4	1	8	Null
Control 6	0	5	−4	1	−16	Null
Control 7	1	1	−2	3	−7	Null
Control 8[b]	NA	NA	NA	NA	NA	Null

[a]The postintervention BAT measurement for case 7 is an outlier because of its exceptional irregularity. The reason for this irregularity is attributed to her high levels of stress on the day of the secondary assessment and thus was omitted from the analysis.

[b]Subject 8 was lost to follow-up.

SUDS, Subjective Units of Distress Scale; BAI, Beck Anxiety Inventory; BAT, Behavioral Assessment Test; SPQ, Spider Questionnaire; HR, heart rate.

Appendix 4C. Raw Measurement Data

ID	*SUDS_pre*	*SUDS_post*	*SUDS_change*
Case 1	4	4	0
Case 2	8	7	−1
Case 3	9	6	−3
Case 4	7	5	−2
Case 5	7	3	−4
Case 6	7	5	−2
Case 7	8	6	−2
Case 8	8	2	−6
Control 1	10	8	−2
Control 2	7	7	0
Control 3	8	8	0
Control 4	5	5	0
Control 5	2	2	0
Control 6	7	7	0
Control 7	5	6	1
Control 8	7	7	0

ID	*BAI_pre*	*BAI_post*	*BAI_change*
Case 1	6	8	2
Case 2	20	19	−1
Case 3	9	7	−2
Case 4	19	16	−3
Case 5	11	13	2
Case 6	24	22	−2
Case 7	14	10	−4
Case 8	5	4	−1
Control 1	1	5	4
Control 2	20	25	5
Control 3	8	6	−2
Control 4	18	14	−4
Control 5	11	11	0
Control 6	11	16	5
Control 7	7	8	1
Control 8	22	22	0

Appendix 4C. (Continued)

ID	*BAT_pre*	*BAT_post*	*BAT_change*
Case 1	22	22	0
Case 2	12	16	4
Case 3	12	10	−2
Case 4	20	20	0
Case 5	11	20	9
Case 6	8	12	4
Case 7	21	3	−18
Case 8	10	14	4
Control 1	18	12	−6
Control 2	18	20	2
Control 3	6	6	0
Control 4	21	14	−7
Control 5	10	6	−4
Control 6	10	6	−4
Control 7	12	10	−2
Control 8	20	20	0

ID	*SPQ_pre*	*SPQ_post*	*SPQ_change*
Case 1	7	6	−1
Case 2	19	19	0
Case 3	22	22	0
Case 4	25	21	−4
Case 5	19	9	−10
Case 6	21	20	−1
Case 7	21	20	−1
Case 8	19	11	−8
Control 1	12	13	1
Control 2	19	17	−2
Control 3	20	18	−2
Control 4	6	6	0
Control 5	16	17	1
Control 6	20	21	1
Control 7	10	13	3
Control 8	25	25	0

ID	*HRi_pre*	*HRmax_pre*	*HR_change_pre*	*HRi_post*	*HRmax_post*	*HR_change_post*	*HR_change_change*
Case 1	78	111	33	77	134	57	24
Case 2	82	119	37	88	113	25	−12
Case 3	84	100	16	81	116	35	19
Case 4	81	106	25	86	110	24	−1
Case 5	60	66	6	47	80	33	27
Case 6	72	124	52	86	110	24	−28
Case 7	72	125	53	77	124	47	−6
Case 8	82	125	43	83	97	14	−29
Control 1	86	114	28	89	103	14	−14
Control 2	65	99	34	64	108	44	10
Control 3	65	86	21	68	85	17	−4
Control 4	66	86	20	84	108	24	4
Control 5	81	115	34	72	114	42	8
Control 6	81	108	27	71	82	11	−16
Control 7	78	104	26	73	92	19	−7
Control 8	82	113	31	82	113	31	0

BAT, Behavioral Assessment Test; SPQ, Spider Questionnaire; HRi, heart rate (Initial).

Appendix 5. CONSORT Statement 2001—Checklist ✓ (Items to Include When Reporting a Randomized Trial)

PAPER SECTION and topic	*Item*	*Descriptor*	*Reported on page #*
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation," "randomized," or "randomly assigned").	1
INTRODUCTION Background	2	Scientific background and explanation of rationale.	2–3
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	3
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	3
Objectives	5	Specific objectives and hypotheses.	3
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	4
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	4
Randomization—sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	5
Randomization—allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	5
Randomization—implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	5
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	5
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.	5
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	5–6
Recruitment	14	Dates defining the periods of recruitment and follow-up.	5
Baseline data	15	Baseline demographic and clinical characteristics of each group.	5
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	5
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).	5–6
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	N/A
Adverse events	19	All important adverse events or side-effects in each intervention group.	6
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes.	6–7
Generalizability	21	Generalizability (external validity) of the trial findings.	7
Overall evidence	22	General interpretation of the results in the context of current evidence.	7

www.consort-statement.org and, Moher D, Schulz KF, Altman D. The CONSORT Statement and Checklist: Revised recommendations for improving the quality of reports of parallel-group randomized trials. JAMA 2001;285:1987–1991.