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Clinical trial: the effect of Johrei on symptoms of patients with functional chest pain

A. GASIOROWSKA, T. NAVARRO-RODRIGUEZ, R. DICKMAN, C. WENDEL, B. MOTY, J. POWERS, M. R. WILLIS, K. KOENIG, Y. IBUKI, H. THAI & R. FASS

The Neuroenteric Clinical Research Group, Section of Gastroenterology, Department of Medicine, Southern Arizona VA Health Care System and University of Arizona Health Sciences Center, Tucson, AZ, USA

Correspondence to:
Dr R. Fass, The Neuroenteric Clinical Research Group, Department of Medicine, University of Arizona, Southern Arizona VA Health Care System, GI Section (1-111G-1), 601 S. 6th Avenue, Tucson, AZ 85723-0001, USA.
E-mail: ronnie.fass@va.gov

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SUMMARY

Background
Patients with functional chest pain (FCP) represent a therapeutic challenge for practising physicians.

Aim
To determine the efficacy of Johrei as compared to wait-list in improving symptoms of FCP patients.

Methods
Patients with chest pain of noncardiac origin for at least 3 months were enrolled into the study. All patients had to have negative upper endoscopy, pH testing and oesophageal manometry prior to randomization. Subsequently, patients were randomized to either Johrei or wait-list control. Patients received 18 Johrei sessions from a Johrei practitioner for 6 weeks.

Results
A total of 21 FCP patients enrolled into the Johrei group and 18 into the wait-list group. There was no difference in symptom intensity score between Johrei group and wait-list group at baseline (20.28 vs. 23.06, P = N.S.). However, there was a significant pre- and post-treatment reduction in symptom intensity in the Johrei group (20.28 vs. 7.0, P = 0.0023). There was no significant reduction in symptom intensity score between baseline and at the end of the study in the wait-list group (23.06 vs. 20.69, P = N.S.).

Conclusion
This pilot study shows that Johrei may have a role in improving FCP symptoms; however, future studies are needed to compare Johrei treatment with sham Johrei or supportive care.

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INTRODUCTION

Noncardiac chest pain (NCCP) is defined as recurrent episodes of retrosternal pain in patients lacking cardiac abnormality after a reasonable evaluation.[1, 2] The annual prevalence of NCCP in the general population of the US ranges from 25% to 35%.[3, 4] NCCP has been shown to have a significant impact on patients' quality of life (QOL) and social well-being.[5]

The oesophageal causes of NCCP are diverse and can often overlap. They include gastro-oesophageal reflux disease (GERD), oesophageal motor dysfunction and functional chest pain (FCP).[6] The latter has been defined by Rome III as episodes of unexplained midline chest pain or discomfort that is not of burning quality in the absence of gastro-oesophageal reflux or histopathology-based oesophageal motility disorders.[7]

In general, treatment for FCP has been unsatisfactory and relied almost entirely on pain modulators. Tricyclic antidepressants, trazodone, selective serotonin reuptake inhibitors and theophylline have been shown to provide only limited efficacy in controlling FCP symptoms. This is compounded by various side effects, such as urinary retention, agitation, delirium, constipation and sinus tachycardia that clearly limit the usefulness of these medications. Consequently, nonmedical therapeutic modalities have been recently examined in NCCP patients with some success. Hypnotherapy, for example, has been shown to improve symptoms in FCP patients. It was demonstrated for the first time that hypnotherapy significantly reduced pain intensity and resulted in improvement in overall well-being of patients with FCP.[8]

The last decade saw a growing interest in complementary and alternative medicine techniques, especially among patients with chronic pain disorders.[9–11] The popularity of alternative or complementary therapeutic modalities stems primarily from dissatisfaction with conventional therapeutic approaches. Whilst not specifically studied in NCCP, a study demonstrated a significant utilization of alternative medicine among patients with GERD. In this study, alternative medicine was used primarily for pain-related disorders, weight reduction and psychological disorders such as depression or anxiety. The most common alternative therapies utilized by 11–33% of the patients were exercise, prayer, chiropractic, massage and meditation. Other alternative medicine approaches, such as acupuncture, relaxation therapy, energy healing and homeopathy, were employed by 3–5% of the study patients.[9]

Johrei, a process of transmission of healing energy, is widely practiced around the world by many practitioners, primarily as a therapeutic strategy for chronic pain syndromes.[12] Similar to Johrei is the practice of Reiki, which also involves the process of transmission of healing energy. Reiki has rapidly grown and is currently utilized in at least 100 hospitals in the US.[13, 14]

We designed a randomized, controlled pilot study to assess the value of the Johrei technique vs. wait-list in controlling FCP symptoms. The aims of our study were twofold, to determine the effect of Johrei as compared to wait-list in alleviating chest pain in subjects with FCP and to determine potential predictive factors for patients' response to Johrei treatment using a multivariate analysis.

Alteration in brain–gut interaction has been suggested to have a pivotal role in symptom generation in patients with FCP.[15–17] Consequently, mind–body interventions such as Johrei, which have not been associated with adverse events, are attractive therapeutic modalities for this challenging group of patients.

MATERIALS AND METHODS

Patients

Patients with at least three episodes per week of unexplained chest pain for 3 consecutive months were invited to be screened for the study. All patients were evaluated by a cardiologist to ensure lack of cardiac cause for their chest pain. Patients had to have either insignificant coronary artery disease, normal coronary arteries on cardiac angiogram or lack of evidence of ischaemic heart disease on an exercise treadmill, stress thallium, technetium 99 m tetrofosmin or technetium 99 m sestamibi testing. To fulfil the Rome III criteria for FCP, patients had to have a normal upper endoscopy, pH testing and oesophageal manometry. Only these patients were included in this study.

Patients were excluded if they had severe underlying comorbidities, upper airway symptoms such as hoarseness, wheezing and laryngospasm, diabetes mellitus, scleroderma, gastroparesis, peptic ulcer disease, history of gastrointestinal surgery, depression, autonomic or peripheral neuropathy or neuromuscular disorder. Patients were also excluded if they were using narcotics, benzodiazepines, tricyclic antidepressants or selective serotonin reuptake inhibitors. Additionally, patients were excluded if they were unable to complete the upper endoscopy, 24-hour oesophageal pH

monitoring or oesophageal manometry. Patients demonstrating erosive oesophagitis, Barrett's oesophagus or other GERD-related complications during upper endoscopy, abnormal pH test or manometry results were also excluded.

This study was approved by the Human Subjects Committee of the University of Arizona in Tucson, Arizona.

Study design

All patients provided written informed consent before enrolment into the study. After excluding a cardiac cause for chest pain, subjects underwent an upper endoscopy to look for oesophageal mucosal injury. If the upper endoscopy was normal, patients underwent ambulatory 24-h oesophageal pH monitoring. If the pH test was normal (% total time pH < 4 less than 4.2%), then patients were further evaluated by oesophageal manometry. Only patients with a normal oesophageal manometry were considered to have FCP and thus were eligible to participate in the study.

Prior to randomization, patients underwent a 2-week baseline symptom assessment. During this period, patients documented frequency and severity of their chest pain in a daily symptoms diary. Patients who met the entry criteria of three episodes of chest pain per week were subsequently randomized to either Johrei treatment or wait-list.

Because this is a pilot study that evaluates the value of Johrei in patients with FCP, wait-list was chosen as a control. Additionally, concerns were raised about the potential for fluctuation in FCP symptoms during the study period, which may either attenuate or accentuate the effect of Johrei treatment. Because wait-list controls for several threats to internal validity such as passage of time, maturation, the effects of repeated assessments and statistical regression, it is commonly used as an initial evaluative phase prior to comparison between an intervention and sham.[18–20]

On the day of randomization, patients completed a series of questionnaires that included demographics, Short-Form 36 (SF-36), Symptom Checklist 90R (SCL-90R), Perceived Stress Scale (PSS) and Hospital Anxiety and Depression (HAD) Scale. Thereafter, and unrelated to the results of the questionnaire, patients were randomized to either the Johrei treatment or wait-list group using a stratified block randomization scheme. During the final 2 weeks of treatment or wait-list period, patients again completed a daily symptom assessment diary that evaluated the frequency and severity of their chest pain symptoms. Additionally, the SF-36 was completed again at the last day of the study. Both patient groups were clearly instructed not to use any other therapeutic modality for their chest pain during the study period. Figure 1 summarizes the study design.

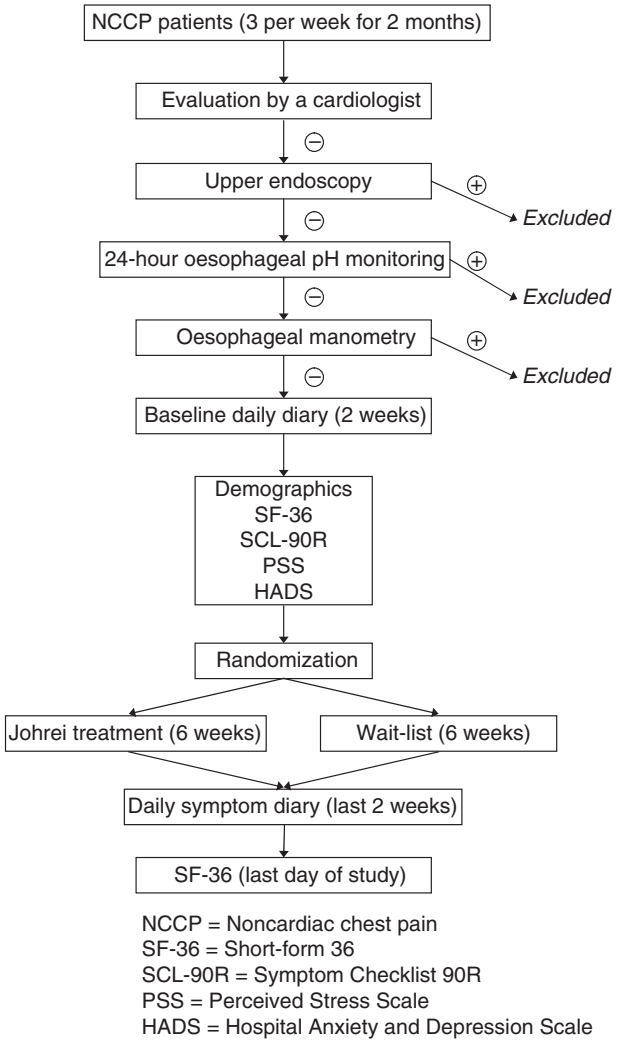

Figure 1. Algorithm of the study design.

Procedures

Upper endoscopy. All patients who signed informed consent underwent a diagnostic evaluation with an upper endoscopy. After an overnight fast, patients were placed in the left lateral position and sedated

with a combination of midazolam (Roche, Nutley, NJ, USA) and fentanyl (Baxter, Deerfield, IL, USA).

An Olympus GIF 100 endoscope (Olympus, Tokyo, Japan) was inserted through the mouth and into the oesophagus to assess for any mucosal abnormalities in the oesophagus, stomach and first portion of the duodenum.

Ambulatory 24-h oesophageal pH monitoring. After an overnight fast, a pH probe with lower oesophageal sphincter (LOS) identifier (Digitrapper MK III; Medtronics, Minneapolis, MN, USA) was inserted through the nostril and into the stomach. The probe was positioned 5 cm above the proximal margin of the LOS and connected to a digital portable recorder.

Patients were instructed to keep a diary recording meal times, position changes and the time and type of their symptoms. Patients were encouraged to pursue their normal daily activities and maintain their usual diet. At the beginning of the study, the electrode and the system were calibrated in standard solutions of pHs 1 and 7.

Reflux was defined as pH <4 and reflux time as the interval until pH is >4. The 24-h pH test was considered positive when the % total time pH <4 was >4.2%.[21] Abnormal oesophageal acid exposure in the upright and supine positions was defined as pH < 4 of more than 6% and 1.2%, respectively. Analysis of the recorded data was performed using standard, commercially available computer software (Medtronics).

Oesophageal manometry. Oesophageal manometry was performed in the supine position, using a calibrated four-channel, air-charged balloon catheter (Latitude; Clinical Innovations, Inc., Murray, UT, USA). The catheter was inserted through the nostril and into the stomach. Using the station pull-through technique (0.5 cm increments), the LOS was identified. Subsequently, LOS basal pressure and relaxation were assessed by all four balloons (5 cm apart). Thereafter, the tip of the probe was placed 3 cm above the proximal margin of the LOS, and oesophageal body amplitude contractions were recorded at levels 3, 8, 13 and 18 cm above the proximal margin of the LOS. Each subject underwent 10 swallows of 5–10 cc water at 30-s intervals.

Digital information was transferred into a computer and processed with a commercial software program (POLYGRAM software, version 6.40; Irving, TX, USA). Diagnosis of oesophageal motility abnormality was verified, according to accepted published criteria.[22]

Questionnaires

Demographics. All subjects completed a demographic questionnaire that evaluated age, gender, ethnicity, level of education, residence area population and annual household income. Additionally, data about current smoking and drinking habits were collected. Body mass index (BMI) was calculated using an individual's weight and height.

Daily symptoms assessment diary. Patients kept a daily record of the frequency and severity of chest pain for 2 weeks at the beginning and the end of the study period.[2] The following scale was used to determine the severity of each symptom: mild, symptom easily tolerated and not long lasting; moderate, symptom caused some discomfort but did not interfere with usual activities; severe, symptom caused much discomfort and interfered with usual activities; and disabling, symptom unbearable and interfered considerably with usual activities.

Symptom intensity score was calculated by adding the reported daily severity (1 – mild, 2 – moderate, 3 – severe, 4 – disabling) multiplied by the reported daily frequency values.[2]

Short-Form 36. Quality of life was assessed at baseline (prior to treatment or wait-list condition assignment) and at the last day of treatment period. The SF-36, a self-report, was constructed to evaluate health-related QOL (HRQOL). This questionnaire includes a multi-item scale that assesses eight health-related domains: physical functioning, role physical, bodily pain, general health, mental health, vitality, social functioning and role-emotional. Each SF-36 domain is measured on a scale from 0 (worst) to 100 (best) and a five-point difference in SF-36 score represents a 5% difference in health status.[23, 24]

HAD Scale. The HAD Scale is a well-validated, brief inventory for assessment of symptoms of anxiety and depression.[25, 26] There are seven items each for anxiety and depression. It uses a four-point Likert response format (0–3) and a maximum score of 21 per scale. A score of ≤7 on each scale denotes a normal range,

8–10 a 'likely case' and ≥11 a 'case' of anxiety or depression disorder.

Perceived Stress Scale. The PSS is a 10-item self-report that measures perceived stress. PSS assesses the different components of perceived stress and measures the presence of negative responses to stressors as well as the perception of the degree of coping ability in relation to existing stressors as well as the degree to which situations in one's life over the past month are appraised as stressful. Items were designed to detect how unpredictable, uncontrollable and overloaded respondents find their lives.[27, 28]

Subjects were queried about feelings and thoughts during the month prior to their first visit. Subjects rated items on a five-point Likert scale ranging from 0 (never) to 4 (very often). PSS scores are obtained by calculating the sum of all 10 items. The higher score reflects greater and longer self-perceived stress.[27, 28]

Symptom Checklist 90 Revised. Patients' psychological profile was obtained by using the validated SCL-90R questionnaire.[29] The SCL-90R is a 90-item self-report symptom inventory reflecting the psychological symptom pattern of an individual. Each of the items is rated on a five-point scale of distress (0–4) ranging from 'not at all' to 'extremely'. SCL-90R is scored and interpreted in terms of nine primary symptom dimensions and three global indices of distress. The primary symptom constructs are somatization, obsessive–compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic, anxiety, paranoid ideation and psychoticism.

The raw scores were converted to standard *T*-scores based on normal adult male and female nonpatients. The gender differences were accounted for by converting the raw psychological scores to *T*-scores based on gender-specific norms. In addition, three global indices provided measures of overall psychological distress: the Global Severity Index (GSI), the Positive Symptom Distress Index and the Positive Symptom Total.

Johrei treatment

Johrei is a spiritual practice based on the belief that spiritually oriented actions reflect in the physical realm. Trained Johrei practitioners provide energy healing through the open, raised hand to a receiving person. The giver sends Johrei to the receiver's body without touching the subject.

Table 1. The protocol for Johrei treatment administration

Front		Back	
Forehead	1 min	Back of head	1 min
Point between eyebrows	30 s	Base of skull	1 min
Front of the neck	30 s	Scruff of the neck	30 s
Left side of the neck	30 s	Left shoulder	1.5 min
Right side of the neck	30 s	Right shoulder	1.5 min
Heart area	3 min	Back of the heart	1 min
Solar plexus	1 min	Left lung	1 min
Abdomen	1 min	Right lung	1 min
(below the navel)		Back of stomach	1 min
		Left kidney	1 min
		Right kidney	1 min
		Tail bone	30 s
Total time	8 min	Total time	12 min

All treatment sessions were delivered by an experienced and certified Johrei practitioner in a hospital clinic with minimal interaction with the patient beyond delivery of Johrei treatment. The same practitioner provided all Johrei sessions to the same patient and also to all patients. When providing Johrei treatment, the practitioner starts by facing the front of the patient for a total of 8 min and thereafter the back of the patient for additional 12 min. Each Johrei treatment session usually lasts 20 min. Table 1 provides the protocol used for administering Johrei treatment.

Adverse events were recorded based on observations, volunteered information or in response to open-ended questions.

Wait-list group

Subjects in the wait-list group recorded their symptoms daily during the first and last 2 weeks of the study and were also required to repeat the SF-36 questionnaire at their final study visit.

Statistical analysis

Summary of continuous variables are reported as mean ± standard deviation (s.d.). Group differences in nominal variables were tested by chi-squared analysis. Differences in continuous variables were tested using the Student's *t*-test or the Mann–Whitney *U*-test if distributions were skewed considerably (abnormal).

Postintervention chest pain score between treated and control subjects was compared after adjusting for baseline chest pain score using a linear regression model. The effect can be interpreted as the difference in mean score comparing treatment and control subjects who are equal in their baseline score.

Chest pain score was adjusted for baseline score as well as other potential confounders. Potential confounding factors included demographic variables, smoking status, BMI, alcohol consumption, HAD scales, PSS score, SCL-90R scales and SF-36 subscales. Confounding factors, included in final regression models, were chosen via a mixed process of backward-stepwise selection (which tests all removed variables for re-entry after each elimination) and specific testing of variables known and assumed to be associated with chest pain score.

Interactions between treatment group and demographic variables were also tested to determine whether the effect of Johrei treatment varied by certain characteristics. Findings were considered statistically significant if $P < 0.05$ for group differences and regression coefficients and if $P < 0.10$ for interaction terms. Analysis was performed using STATA version 10.0 (Copyright 1984–2007; Stata Corp., College Station, TX, USA).

RESULTS

Baseline characteristics

Of the 53 patients with FCP who were enrolled initially into the study, 14 had to be excluded because of abnormal upper endoscopy (eight), or 24-h oesophageal pH monitoring (six) results. Of the 39 patients who completed the study, 21 were randomized to the Johrei treatment group and 18 to the wait-list control group.

Demographics

There were no significant differences in any of the demographic characteristics between the Johrei and wait-list groups (P = N.S.). Table 2 compares the different demographic characteristics between the two patient groups.

Table 2. Demographic characteristic of the study patients (P = N.S.)

	Johrei group	Wait-list control
Total (n)	21	18
Gender (M/F)	11/10	15/3
Age (±s.d.)	54 ± 11.03	55 ± 12.96
Range (year)	32–74	32–70
Ethnicity (%)		
Caucasian	84.62	66.67
African-American	15.38	33.33
Educational status (%)		
Less than high school	12.5	37.5
High school and college	75	37.5
Professional training	12.5	25
Body mass index (kg/m^2)	31.88 ± 5.75	32.02 ± 7.83
Alcohol user (%)	28	19
Current smoker (%)	11	25

HRQOL assessment

Patients' QOL was analysed at baseline and at the end of the study. There were no statistically significant differences between the two patient groups in all eight SF-36 domains that were obtained at baseline. Patients who received Johrei treatment had a numerically higher increase in the SF-36 domains compared to those who were in the wait-list group at the end of the study. However, this higher rate of improvement in SF-36 did not reach statistical significance.

Psychological assessment

At baseline, the mean PSS score for the Johrei treatment group was 12.55 (s.d. = 10.75, range: 7.2–17.9) and for wait-list control 17.94 (s.d. = 9.77, range: 12.73–23.14). There were no statistical differences in PSS score between the two groups at baseline. There was no gender predilection. Male and female subjects from the Johrei and wait-list control groups were not significantly different in total PSS score at baseline.

The HAD scores at baseline were not statistically different between Johrei patients and the wait-list group for anxiety (6.85 ± 5.59 vs. 8.62 ± 5.64 respectively, P = 0.36) and for depression (4.72 ± 4.14 vs. 7.31 ± 4.87 respectively, P = 0.10).

Figure 2 summarizes the SCL-90R T-scores for each group. At baseline, there were no significant differences in all domains of SCL-90R except paranoid ideation between patients from the Johrei group and those

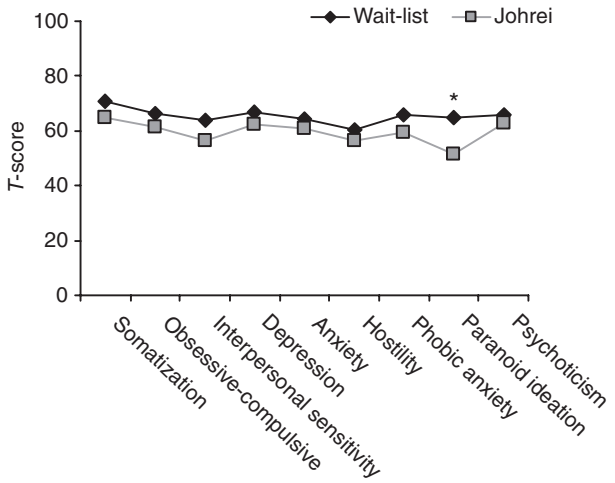

Figure 2. Baseline *T*-scores derived from the Symptom Checklist 90R subscales for Johrei treatment group and wait-list control (* $P < 0.5$).

Table 3. Comparative assessment of the psychological profile of both patient groups using the SCL-90R

Primary symptom dimensions	Johrei treatment (mean ± s.d.)	Wait-list (mean ± s.d.)	*P*-value
Global Severity Index	0.67 ± 0.6	1.04 ± 0.84	0.14
Positive Symptom Total	31.33 ± 21.73	45.44 ± 25.63	0.1
Positive Symptom Distress Index	1.82 ± 0.4	1.82 ± 0.62	0.98

from the wait-list group. However, the GSI indicated that there was no overall difference in symptoms between the patient groups (Table 3).

Symptom assessment

There was no difference in the symptom intensity score between Johrei group and wait-list group at baseline (20.28 vs. 23.06 respectively, P = N.S.). However, there was a significant improvement in symptom intensity score between baseline and post-treatment period in the Johrei group (20.28 vs. 7.0, $P = 0.0023$). In contrast, there was no significant improvement in symptom intensity score in the wait-list group between baseline and at the end of the study (23.06 vs. 20.69 respectively, P = N.S.; Figure 3).

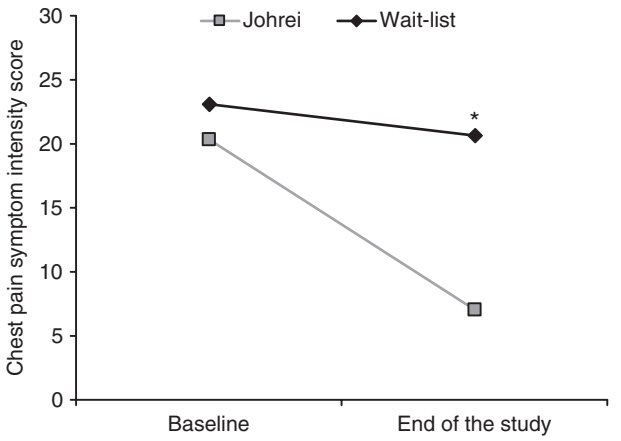

Figure 3. Comparison of symptom intensity score for chest pain between Johrei and wait-list at the end of the study (* $P < 0.0023$).

Predictive factors for treatment response

Caucasian subjects were more likely to experience a significant (13-point) decrease in chest pain at the end of treatment compared with African-American subjects ($P = 0.049$).

For each additional year of age, chest pain score at the end of Johrei treatment decreased by 33%.

Tolerability and safety assessment

Johrei treatment was well tolerated and no side effects were reported by treated subjects. Subjects experienced Johrei treatment differently. Some reported a sense of tingling or warmth, relaxation, feeling sleepy, calm or peaceful, while others reported no specific sensations.

Despite some suggestions that Johrei treatment may also trigger physical response such as coughing, sneezing, diarrhoea, vomiting, fever or a temporary exacerbation of existing conditions, none of these symptoms was observed or reported by study patients.

DISCUSSION

This study was designed as a pilot study to assess the therapeutic value of Johrei. Our data show that in reference to a wait-list control group, Johrei treatment significantly improved FCP-related symptoms, whilst wait-list was associated with no change in FCP symptom intensity. The results obtained from this study clearly support moving forward with a sham-controlled trial or comparison with a support group.

We chose to compare the Johrei treatment arm with wait-list to control for various threats to internal validity such as passage of time, maturation, the effects of repeated assessments and statistical regression.[18, 19] The purpose of the wait-list group in this study was to ensure a better design of future comparative trials using Johrei treatment. We recognize that our study did not control for the influence of nonspecific treatment factors such as therapist-patient relationship, therapist's technique, suggestion and patient expectations.[8, 30–33]

For the future sham-controlled trial, it would be also beneficial to add an evaluative tool that determines patients' expectations of improvement from Johrei treatment. It will allow us to determine if FCP subjects with higher expectations from such therapeutic intervention are more likely to report symptomatic response than those with lower expectations.

Both patient groups were matched by age, ethnicity, educational status, psychological and stress profile and perceived HRQOL. However, 48% of the Johrei treatment group patients were females compared to 20% of the subjects in the wait-list group. Thus far, there is no evidence in the literature that female subjects with FCP are more or less likely to respond to complementary medicine intervention. Studies assessing the value of hypnotherapy, cognitive behavioural therapy and others in patients with either NCCP or FCP did not report gender-related differential therapeutic effect.[8, 30–32] Consequently, we do not believe that the different gender ratio between the two patient groups significantly impacted the study results.

All SF-36 domains improved at the end of Johrei treatment compared with baseline, but the difference did not reach statistical significance. It is likely that the SF-36, which is a more general HRQOL tool and is not specific for FCP, is not sensitive enough to detect the Johrei treatment effect on the patient's reported QOL. A more specific HRQOL tool for FCP, which is currently unavailable, would be more helpful.

The mechanism by which Johrei treatment improves FCP-related symptoms remains to be elucidated. Hypnotherapy has been shown to reduce oesophageal sensitivity, stress and negative cognitions.[8] It is possible that Johrei treatment has similar clinical and physiological effects, but future studies are needed. Furthermore, it is also possible that Johrei treatment confers its effect through the anterior cingulate cortex, an area in the brain responsible for processing emotions related to painful stimuli.[8]

There are a growing number of studies demonstrating the efficacy of Johrei in treating various psychosocial disorders. In one study, a 10-min Johrei treatment reduced negative mood and increased positive mood states after the acute effects of a laboratory-induced stressor in comparison to a resting control condition in 33 medical students.[34] Johrei treatment has also been shown to decrease a negative emotional state and improve well-being,[35] decrease stress and depression as well as physical pain in subjects undergoing treatment for substance abuse[36] and stress reduction associated with concomitant reduction in certain lymphocyte subpopulations.[37]

The number of participants in each arm was relatively small. However, recruitment into this study was relatively difficult because patients had to undergo multiple invasive tests. Additionally, patients were excluded if they had a positive upper endoscopy, abnormal pH test or oesophageal dysmotility. Our study provides only a short duration of treatment (6 weeks) and lacks a post-treatment follow-up to assess the durability of Johrei treatment. However, the purpose of the current study was to demonstrate the feasibility of Johrei treatment as a viable option for treating patients with FCP. Future studies should embark on longer duration of Johrei treatment followed by up to 1 year of monthly assessments to determine the durability of the Johrei treatment effect. The exact mechanisms by which Johrei confers its effect were not explored by this study; this was not the purpose of this study. As the role of Johrei in treating FCP patients is further established, then future mechanistic studies will be needed.

In conclusion, Johrei may have a promising therapeutic role in FCP. Presently, these patients remain a therapeutic challenge and our current therapeutic approaches have mostly proven unsatisfactory. Because in this pilot study, we compared Johrei treatment with wait-list, future studies comparing Johrei with sham intervention or support treatment are needed to substantiate further the role of Johrei treatment in FCP.

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