Amelioration of quality of life and lung function of chronic obstructive pulmonary disease by pranic healing as adjuvant therapy: A randomised double blind placebo controlled pilot study

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ABSTRACT

Aims
To study the effects of Pranic Healing (PH), as a complementary therapy to improve lung function, physiological condition and quality of life of Chronic Obstructive Pulmonary Disease (COPD) patients.

Methods
Randomised, double-blind, placebo-controlled, pilot study. 21 males with a mean age of 61.6 years and COPD stage II were randomly allocated to PH and control groups. The PH group received PH sessions thrice weekly during the study. The control group received Sham PH. Data was collected during baseline and four scheduled visits of the participants during six months. The primary outcome of the study was to access the reduction in COPD symptoms and to increase participation in physical and social activities by evaluating Spirometry, St George’s Respiratory Questionnaire (SGRQ), 6 Minute Walk Test (6MWT) and Hamilton Rating Scale for Depression (HRSD).

Results
Significant improvement for PH group in Forced Expiratory Volume in the first second (p=0.02), SGRQ domains of Activity (p=0.006), Impact (p=0.002), Total (p=0.000), and non-significant change in Symptom domain (p=0.44). PH group showed a positive tendency in 6 MWT and HRSD scores with insignificant difference between the groups. No serious adverse events occurred during the study.

Conclusion
PH as an adjunct to conventional treatment can improve lung function and quality of life of COPD subjects.

Key Words
Lung, energy healing, quality of life, complementary therapy

What this study adds:
1. What is known about this subject?
COPD is the third most life-threatening lung diseases in the world.
2. What new information is offered in this study?
Pranic Healing as complementary therapy was applied to improve outcome in COPD patients.

3. What are the implications for research, policy, or practice?
The findings in this study are of significance to complementary therapist and pulmonologist.

Background
According to WHO, Chronic Obstructive Pulmonary Disease (COPD) is a lung ailment characterized by a tenacious obstruction of airflow in the lungs. Cigarettes’ smoking is the most common cause and increases the risk of COPD and its exacerbation, clinically characterized by worsening dyspnoea, cough, sputum production, airflow obstruction and fatigue. COPD is the third highest cause of mortality in the world and its prevalence in India has significantly affected health related Quality of Life.\(^1\) Tiotropium is commonly prescribed medicine to treat COPD. However, few side effects like dry mouth, dizziness, skin allergy and high cost makes this treatment less popular. Yoga,\(^2\) pranayama,\(^3\) Tai Chi,\(^4\) breathing retraining\(^5\) and biofield therapies can be effectively used in COPD. Biofield or Bioenergy therapies include Qigong, Reiki, Pranic Healing among others. These bioenergy therapies are intended to affect energy fields surrounding the human body.\(^6,7\)

Pranic Healing (PH) is a non-touch complementary therapy which focuses on the energy fields surrounding and within the body. PH is a simple, effective healing technique, used for physical, mental, and metaphysical issues with respondents experiencing positive outcomes. It involves transference of Prana to rebalance the energy body. Prana also called vital energy or life force is essential to keep the body alive and healthy.\(^8\) Chakras or spinning energy centres absorb, digest and distribute prana to the different parts of the body and are responsible for the proper functioning of the human. Ajna, Throat, Back Heart and Solar Plexus chakra control and energise the respiratory system.\(^9\) Live objects when placed in a high electromagnetic field and photographed reveal energy body surrounding it. Pranic healing has attracted well-educated followers seeking to integrate its therapeutic practices in their working lives and personal growth.\(^10\)

In an exploratory study, 99.5 per cent of the participants felt the pranic energy and 98 per cent could see the air prana.\(^11\) By applying PH chronic pain of musculoskeletal origin was reduced.\(^12\) Lung volumes measurement after group PH on healthy adults recorded improvements.\(^13\) PH, when applied on patients, can influence their energy field.\(^14\) The energy body tends to affect the physical body, when the energy body is healed the physical body would be healed, and is called ‘Principle of Correspondence’.\(^15\) PH techniques when applied on agricultural crops can increase crop yield.\(^16\) The present study sought to find the effectiveness of PH as a complementary therapy for COPD patients by assessing changes in lung function, quality of life and increase in physical and social activities as the primary outcome.

Method
Randomized control trial was chosen as the study design. Allocation to PH and Control groups was made by computer generated equal randomisation of 1:1. Participants and outcome assessors were blinded during randomisation. Investigators involved in the assessment were blinded to the treatment allocation of the subjects to avoid bias. 410 people gave written consent to take part in the study. Inclusion criteria for the study were the ability to give informed consent, current smokers with a minimum of 10 pack years, male patients diagnosed with COPD stage 2 in accordance with GOLD criteria, within age of 40 to 75 years, and able to perform all study related procedures. Exclusion criteria from the study during recruitment were those having other chronic pulmonary diseases such as congenital bronchiectasis/ILD/tuberculosis, and having other major comorbidity such as liver or renal failure or cardiac diseases or vital organ failure. Those who quit smoking during the study period, who showed significant reversibility in the FEV1 as compared to baseline (more than 12 per cent and 200ml) suggestive of asthma were excluded from the trial during clinic visits two and three.

As this study is the first of its kind sample size was not calculated. Against a sample size of 30 we could recruit only 29 participants and provided medication of Tiotropium and inhaled Salbutamol during visit two. The participants were asked to take medicines regularly and come for visit three after one month for medical assessment. PFT results showed that six were asthmatic and had poor PFT, while one stopped smoking and another declined to participate. Considering the above inclusion and exclusion criteria, 21 participants were randomly allocated to Pranic Group and Control group with 20 of them completing the study as per protocol (Table 1).

The effect of PH was evaluated along with baseline treatment as per international (GOLD) guidelines. Tiotropium, once daily 18 mcg as an inhaled medication and inhaled Salbutamol, as rescue medicine was provided. The study participants were divided into Pranic Healing (PH) and
control group receiving Sham Pranic Healing (SPH). Trained Pranic Healers from Master Choa Kok Sui courses with experience of more than 10 years were recruited for this study. PH participants were asked to be comfortably seated with eyes closed and palms facing upwards. The Pranic Healer thoroughly sweeps the participants energy field by cleansing technique. To strengthen the energy field of the participant, the healer applies energising technique using different hand gestures without touching the participant. For control group, the same PH gesture without pranic energy transfer was applied, thus having a Placebo effect. One to one PH and SPH sessions were administered thrice a week for 27 weeks by the same healers at participants’ convenience.

The treatment allocation was performed by computer-generated randomization. Sequentially numbered, sealed, opaque envelopes were used to prevent foreknowledge of group assignment. Participant & Investigator were blinded in the current study. The process followed is outlined in Figure 1. Medication, PH, SPH was administered to the participants along with physical and breathing exercises. PH procedure was applied as detailed in supplementary file. The recruitment of participants started during visit one, on 16 December 2012 and continued until 7 July 2013. The last participant completed his fifth visit on 6 February 2014 (supplementary file). As recruitment of participants got extended beyond planned period, the interim analysis could not be performed. However, all participants received Pranic Healing during the final six months of the study. To compare baseline, intermediate and post-test characteristics of Pranic and Control groups, frequency distributions of the collected data variables were analysed using descriptive statistics, repeated measure ANOVA and independent sample t-test. SGRQ scores were assessed and evaluated by Excel-Based Scoring System. As the outcomes were not binary in nature, variables are shown as continuous; the absolute and relative values of the variables were not calculated.

Results
Lung Function: The means and standard deviation of Pre- and Post-bronchodilator FVC per cent Predicted values of pulmonary function test, from visits two to five are shown in Figure 2. In Pre-bronchodilator, the FVC values in Pranic group showed a decrease of 1.4 per cent predicted when compared to a decrease of 7.7 per cent predicted for control group. In Post-bronchodilator the noted changes of FVC values between visit 2 and 5 were 1.6 per cent predicted increase for Pranic group and 6.8 per cent predicted decrease for control group respectively which were not significant (p=0.09). Thus, over a period of six months, a slight increase in Post-bronchodilator FVC per cent predicted in the PH group and a nearly 7 per cent decrease of FVC per cent predicted in the control group was observed. In Pre-bronchodilator spirometry test, the observed changes were -0.3 and -5.9 in FEV₁ per cent predicted values for PH and control groups respectively between visits two to five. In Post-bronchodilator spirometry, the noted changes in FEV₁ values between visits two and five were 3 and -5.5 for PH and Control groups respectively. The FEV₁ values indicated an intergroup significance of (p=0.02) between visits two to five. Post-bronchodilator FEV₁ per cent predicted showed an improvement of 3 per cent over six months in the PH group against more than 5 per cent fall of FEV₁ per cent predicted in the control group (Figure 3). In view of adverse events, four COPD exacerbations were recorded with three subjects from control group and one from PH group.

Quality of Life: Figure 4 shows the means and standard deviation of Symptoms, Activity, Impact and Total domains scores of SGRQ questionnaire for PH and Control groups from visit two to five. In Symptoms domain, the mean score improvements for PH and Control groups were 19.46 and 8.73 units respectively. In Activity domain, the mean score improvements for PH and control groups were 20.42 and 4.28 units respectively which was significant (p=0.006). In Impact domain, the mean score improvements for PH and control groups were 26.65 and 6.94 units respectively with a significance of (p=0.002). Finally, in Total, the mean score improvements for PH and control groups were 23.67 and 6.33 units respectively with a significance of (p=0.00).

The mean and standard deviation of 6 MWT from visit two to visit five is provided in Figure 5. PH group showed a mean improvement of 9.16 units compared to 3.58 units in Control group. This corresponded to 15.64 per cent improvement in PH group compared to 5.95 per cent improvement in Control group (p=0.19). The HRSD showed an insignificant difference between the groups (p=0.48). Though results showed statistical insignificance between the groups, a tendency for improvement in blood pressure, heart rate and respiratory rate for PH Group was indicated. The results can be referred in the supplementary file.

Discussion
This study was the most rigorous to date in the evaluation of PH as an adjunct to the standard of care for COPD patients. None of the participants had previous experience of PH. The study proposal was to include 30 participants, based on inclusion and exclusion criteria. Twenty nine were identified and eight were later excluded for reason as mentioned in Table 1. Only, 21 participants were
randomized and one from PH group withdrew the consent and dropped out of the study. Hence, analysis was conducted on 20 participants. After PH experiences like feeling warmth in the body, pranic energy perception in hands, lightness in the body, participants became interested, enthusiastic, and started looking forward and being regular in attending the healing sessions. Control group participants practised breathing and physical exercises along with PH group, without reporting any PH experiences.

PH, pranayama, Qigong, Tai Chi use Prana/Ki/Chi to balance and harmonise the vital energy. They promote circulation of prana in the body by facilitating the drawing in of fresh prana and expelling of used-up prana. In the current study, we found a significant improvement in participants’ activity, impact and total domain scores of SGRQ. SGRQ is a valid, repeatable and sensitive measure of impaired health in chronic airflow limitation diseases. Health related QOL along with lung function should be measured in patients with COPD to reach the health management goals and are complimentary to each other. International Primary Care Respiratory Group has stressed that QoL is an important goal in COPD management and a future research requirement. The reason being that spirometry is weakly associated with various health status questionnaires and does not provide a real picture of COPD patients’ wellbeing. In any SGRQ domain, the threshold for a clinically significant difference between groups of patients and for changes within a group of patients is four units. More PH participants showed improvement in Activity, Impact and Total domains of SGRQ indicating improvement in QoL. The reason behind such improvement might be due to normalising of ajna, heart and solar plexus chakras in the energy field of the participants. Green and orange prana have cleansing effects. Orange facilitates expelling of the old air in the lung. The interaction of red prana with green and orange prana has a regenerating effect.

Thirty per cent of participants experienced COPD exacerbations in control group compared to 10 per cent in PH group during study indicating a reduction in overall health care cost and improved QoL. As per recent GOLD guidelines, health status, dyspnoea measurement and a number of exacerbations are set to be key elements to the existing spirometry, for management and treatment of COPD. A meta-analysis of eight RCTs using Tai Chi indicated a significant improvement in SGRQ scores except impact domain. Effects of short-term yoga training with breathing exercises, meditation, and yoga postures for six weeks on the QoL, recorded using SGRQ showed significant improvements (p<0.05). These two studies indicate the effectiveness of complementary therapies in improving the QOL of patients with COPD. In a controlled study, PH was found to significantly reduce chronic pain in patients. The current study recorded significant improvement for participants using Pranic Healing in SGRQ scores except for symptoms domain. Acupuncture and Acupressure showed similar improvements in exercise tolerance of COPD patients with comparable disease severity. Acupuncture points are gates through which prana flows.

As many symptoms of COPD and depression are similar in nature, it is difficult to distinguish them. Depressive symptoms are common in elderly patients with COPD, with greater severity of depression in most disabled and sick older people. A comprehensive yoga program to address mood has reduced symptoms of depression and associated physical or mood states. In the current study, both groups improved their HRSD scores, however, control group improved from mild depression to normal and PH group improved from moderate depression to mild depression, which is relatively noteworthy change. In a randomized controlled trial, PH helps in alleviating mild to moderate depression.

PH group recorded a bigger systolic pressure drop before 6 MWT between visits two and five, and even after walking additional distances in six minutes recorded drop in systolic blood pressure. This clearly indicates the effectiveness of PH in lowering the blood pressure. PH group had a significant improvement in Oxygen saturation. 6MWT distance, Blood Pressure and Oxygen saturation levels indicate that physical condition of PH group recorded an improvement compared to Control group. Physical exercises in the form of Hatha Yoga or Tai Chi promote circulation of Prana in the body and facilitate the drawing in of fresh Prana and the expelling of used-up Prana. This is seen clairvoyantly as white fresh Prana being drawn in and used up Prana being expelled. Our findings are in line with research on Qigong and Tai Chi. Qigong is traditionally viewed as a practice to cultivate and balance qi (chi), translated as "life energy". Studies on Yoga, pranayama, breathing retraining have also indicated the positive change in the exercise capacity in COPD subjects. The main limitation of this study is the low numbers of COPD patients. There were variables showing a
tendency of significance but were not found to be significant, this would have changed if a larger number of subjects were included in the study.

Conclusion
The study indicates that PH is a useful adjunct treatment for the patients with early stage COPD. PH improves the lung function and quality of life of the patients as demonstrated by the Pulmonary Function Tests and SGRQ resulting in the reduction in overall health care costs. PH group showed a positive trend in 6MWT.

References
ETHICS COMMITTEE APPROVAL
Ethics committee, Allergy Asthma Associates, Mysuru functioning as per the requirement of the ICH-GCP, schedule Y and their SOP's approved the study as a proof of concept study on 28th September 2012. Written informed consent was obtained from all participants before screening.

Figure 1: Flow chart

CONSORT 2010 Flow Diagram
Figure 2: Pre- and Post-bronchodilator values of Pulmonary Function Test

![Graphs showing FVC% Predicted (Pre) and FVC% Predicted (Post) with Pranic and Control groups.]

Figure 3: FEV1 (%) predicted values of pranic and control groups

![Graph showing FEV1 % Predicted (Post) with Pranic and Control groups.]

**p = .027**
Figure 4: SGRQ values of pranic and control groups

Figure 5: 6 MWD and HRSD values of pranic and control groups
Table 1: Demographic and Clinical Characteristics of study participants

<table>
<thead>
<tr>
<th>Demographic and Clinical characteristics</th>
<th>Pranic Group (N=10)</th>
<th>Control Group (N=10)</th>
<th>Total (N=20)</th>
<th>Significance</th>
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<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
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<tr>
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<td>FVC-Pre (% predicted)</td>
<td>75</td>
<td>8.86</td>
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<td>74.9</td>
<td>9.99</td>
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<td>14.304</td>
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<td>54.483</td>
<td>8.869</td>
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<td>8.287</td>
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BMI – Body Mass Index, SD – Standard Deviation, p – Significance, cm – centimetre, kg – kilogram