ABSTRACT

Background and need for the study: Previously, outpatient Yoga programs (in two of the earlier RCTs on yoga for Chronic Low Back Pain (CLBP), 12 to 16 weeks of intervention) lasting several months have been found to reduce pain, analgesic requirement and disability, and improve spinal mobility in chronic low back pain (CLBP).

Objective: (i) To compare the effect of a short-term intensive residential yoga program with physical exercise (control) on pain and spinal flexibility in subjects with Chronic Low Back Pain (CLBP).

(ii) To study the effect of a comprehensive residential yoga-based lifestyle program on pain, anxiety, depression and spinal mobility in patients with CLBP.

(iii) To study the effect of yoga on quality of life in patients with Chronic Low Back Pain.

Design: Crossover randomized control study.

Setting: A residential Integrated Health Centre in Bangalore, South India.

Subjects: A study size of 80 subjects was decided on, considerably more than the 35 required. The ES was calculated from the mean and SD of an earlier yoga study on 120 subjects. The first 80 CLBP patients admitted between April 2005 and June 2006, who satisfied the selection criteria, were recruited as subjects for the study (in all 160 CLBP patients were admitted in this time period). Inclusion criteria were history of CLBP of more than 3 months, pain in lumbar spine with or without radiation to legs, and the age range between 18 to 60 years. The exclusion criteria was organic spinal pathology such as malignancy (primary or secondary), or chronic infection confirmed by X ray, recommended surgical intervention, severe obesity and critically ill. Initial assessment
was conducted by a rheumatologist. Two experts (radiologist and orthopaedic surgeon) gave their opinion. A semi-structured interview was used to obtain both demographic and vital clinical data, including personal, family and stress history. The study was approved by both SVYASA’s review board and ethical committee. Signed informed consent was obtained from all subjects. The consent form clearly stated that subjects would be randomly allocated to one of the two active intervention groups. The study was a randomized control trial. Two different one week interventions, yoga and physical exercise, were administered. Two groups of 40 numbers the spanning integers 1 to 80 were created by a computer generated random number table. As CLBP patients were admitted to the health centre week by week, they were sequentially assigned to one of the two groups so generated. Numbered containers were used to implement the random allocation. The following were blind to the subjects’ intervention group: the statistician who generated the randomization sequence and subsequently analysed the data; the clinical psychologist who administered and scored the psychological questionnaires; and the researcher who carried out allocation and assessments. The questionnaires’ coded answer sheets were analysed only after completion of the study.

**Intervention:** The intervention consisted of a two week-long intensive residential yoga program comprising of āsanas (physical postures) designed for back pain, prāṇāyāma (breathing practices), and meditation apart from didactic and interactive sessions on philosophical concepts of yoga. The control group practiced physical exercises under a trained physiatrist and also had didactic and interactive sessions on lifestyle change. Both the groups were matched for time on intervention and attention.

**Outcome Measures:** (i) Pain-related outcomes were assessed by Oswestry Disability Index (ODI), Numerical Rating Scale (NRS), (ii) spinal flexibility assessed using
goniometer, Sit and Reach and Straight Leg Raising test, (iii) Psychological variables like State and Trait Anxiety for anxiety, Becks Depression Inventory for depression, baseline stress scores using Perceived Stress Scale (iv) Quality of Life using WHO QOL Bref, at 1<sup>st</sup> day, 7<sup>th</sup> day and 14<sup>th</sup> day after intervention. Data were analyzed using Repeated Measures analysis of variance (Repeated Measures ANOVA).

Results: Data conformed to a Gaussian distribution. There was a significant reduction in ODI scores in the yoga group compared to control (p=0.01, effect size 1.26). Spinal flexibility measures improved significantly in both the groups but yoga group showed greater improvement as compared to controls on spinal flexion (p=0.008, effect size 0.146), spinal extension (p=0.002, effect size 0.25), right lateral (p=0.059, effect size 0.006) and left lateral flexion (p=0.006, effect size 0.17). There was better reduction (p=0.001, Repeated Measures ANOVA) in pain in yoga (p=0.01, effect size 1.26) than control group on PAS, in State (p=0.001, effect size in yoga 0.73) and Trait anxiety (p=0.001, effect size in yoga 1.092) on STAI, and in depression (p=0.001, effect size for yoga group 0.96) on Beck’s depression inventory. Spinal mobility assessed by ‘Sit and Reach’ (SAR) instrument improved in both yoga (Repeated Measures ANOVA, p= 0.001, 49.9% effect size 2.99) and control (p=0.001, 3.6 %, effect size 0.81) groups. There was positive correlation of change score between BDI and PAS (p=0.01). There were significant negative correlations (Pearson’s, p<0.001) between baseline stress scores and all 4 (physical, psychological, social and environmental) domains of WHOQOL Bref. After the intervention, the quality of life increased on all 4 domains in yoga group (Repeated Measures ANOVA p=0.001) with significant differences between groups (p<0.01). Spinal flexibility increased in both groups (p=0.001) with significantly higher increase in yoga group for SLR (right leg only) at p=0.044 (Repeated Measures ANOVA). In the group which started with yoga in the 1<sup>st</sup> week and went on to control in the 2<sup>nd</sup> week (YC) there
was significant improvement in the 1\textsuperscript{st} week followed further by a reasonable improvement in most of the variables in the 2\textsuperscript{nd} week. In the group which started with control intervention and went on to yoga in the 2\textsuperscript{nd} week (CY) there was an improvement in the 1\textsuperscript{st} week followed by a significant improvement in the 2\textsuperscript{nd} week. The overall change at the end of 2 weeks within groups was significant in most variables in the yoga group but did not differ between groups indicating the spillover effect of yoga.

\textit{Conclusion:} A short-term intensive residential yoga-based lifestyle program improves pain-related disability and spinal flexibility. Yoga reduces pain, anxiety and depression, in patients with CLBP better than physical exercise. There was a negative correlation between stress and quality of life at baseline in patients with CLBP. Yoga was better than physical exercises in increasing quality of life.