CHAPTER - 5

METHODS
5.0 METHODS

Part I: Prevalence of Mastalgia in Young Indian Females

The study was carried out on young women between 18 to 29 years of age from 4 residential private nursing colleges and one State Government Nursing & Degree College in south Karnataka, India. All subjects included in the survey were volunteers hailing from semi urban and rural areas. After obtaining signed informed consent from the students, they were given a lecture about the need of the study, importance of breast self examination and breast health.

They were asked to fill up the checklist for mastalgia suitable to Indian population developed as part of the study. The checklist included a numerical pain analogue scale (PAS) marked from 0 to 10, based on Cleeland’s Breast Pain Inventory (BPI), Clinical and demographic features of subjects including age, marital and educational status, history of hypothyroidism, their stress level, shifts at work, lifestyle pattern along with anthropometric and demographic data was obtained.

Weight was measured using a research grade electronic weighing scale and Height using a simple tape measure. Body Mass Index (BMI) was calculated as weight in kilograms divided by the square of height in meters.

Data analysis: Data analysis was done using ‘R’ software version=3.1.0. Mean and standard deviations are reported for continuous variables and frequencies and percentages are reported for categorical variables. Relative risk was calculated as a ratio between the proportion of cases with to cases without mastalgia for BMI and Stress categories.
Part II: Integrated Approach of Yoga Therapy for Women with Breast Pain

5.2 Design: This was a prospective, randomized, active controlled trial wherein concealed envelope procedure was followed for randomization. Participants (n=80) were randomly divided into two groups. The randomization was done using a computer generated random number table (www.randomizer.org) with a pre-labeled, sealed envelope. The intervention group (n=40) practiced yoga and the control group (n=40) did brisk walking for the same duration without any conventional treatment.

5.3 Subjects: Pre-menopausal young female participants in the age range of 18 to 25 years with breast pain (cyclical or acyclical) for more than 3 months comprised the subjects for this study. Female students of first and fourth year B.Sc. (Bachelor of Science) Nursing and GNM (General Nursing Midwifery) courses from two residential nursing colleges from Rural Bengaluru, India were recruited. Students belonged to urban, semi-urban and rural areas from 5 different states of India (Karnataka, Andhra Pradesh, Tamil Nadu, Maharashtra, and Kashmir) and Nepal.

5.4 Sample size: To ascertain the optimum sample size for the study, a pilot study including 10 women with breast pain was conducted. They went through 12 weeks of yoga therapy. Pain, quality of life (QOL), anxiety and depression were assessed for baseline as well as post-treatment. Results of 7 subjects who completed 12 weeks of yoga therapy indicated a reduction in pain (ES=3.09), anxiety (ES=1.59) and depression (ES=2.21) and an increase in mean QOL (ES=0.80) with the two tailed analyses powered at 0.95.

Taking into consideration the effect size of QOL a sample size of n=23 was obtained and anticipating a higher attrition of 70% due to the forthcoming academic year a total of 40 subjects in each arm were recruited for the study. Although the effect sizes of the
pilot study indicated the optimum sample size of 12, a sample size of 80 was chosen to ensure that the study is adequately powered (alpha=0.8) to meet its objectives.

5.5 Criteria for selection of subjects: (i) Pre-menopausal women between 18 and 25 years, (ii) those with breast pain for more than 3 months (cyclical or acyclical, uni or bilateral) requiring reassurance and/ or non drug therapy, (iii) those who had a pain score $\geq 2$ on Cleeland’s Breast Pain Inventory (BPI),(47)(iv) those with or without fibrocystic disease of the breast and (v) women not on any hormonal treatment or oral contraceptive pills (OCP), were included in the study. Post-menopausal women, women with any malignancy, pregnant women and those already practicing yoga were excluded from the study.

5.6 Consent and ethical clearance

Written informed consent from all the students was sought before the commencement of recruitment for the study. The study started after the approval from the Institutional Ethical Committee of Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA) University (RES/IEC-SVYASA/16/201). This study was registered with Clinical Trial Registry of India (CTRI/2014/08/004911).

5.7 Methodology

After giving an introductory lecture about the study, 314 students from two nursing colleges were screened for this study using a screening checklist based on the inclusion/exclusion criteria. After obtaining the signed informed consent they were asked to fill up a short symptom check list which included questions regarding their breast health and the demographic data.
A breast surgeon along with 4 female gynecologists from the state government conducted a detailed physical/clinical examination on all the 80 students who consented, in a hygienic biology lab of the college providing them the privacy and comfort. Uniformity was maintained by all the medical officers during the screening. Educating along with counseling with regard to breast care, breast self examination (BSE) and the pathology of the breast was also done during clinical examination.

Baseline clinical breast examination done on all the 80 students who consented and satisfied the selection criteria and randomised determined the necessity for further breast imaging. Breast ultrasonography was therefore done on 28 students. Of the 28, only 4 students had repeat ultrasonography at the end of study. All the 80 students underwent blood test for clinical and subclinical hypothyroidism. Students who had elevated or close to upper limit of normal thyroid stimulating hormone levels (TSH) had a repeat blood test at the end of the study.

5.8 Breast examination (clinical/physical) procedure

Breast examination involved inspection of the breasts with the subject in a seated position and then with both arms raised above the head, to see the abnormalities in terms of the shape, difference in the skin color, rashes, visible lumps or swelling, inverted nipple. With the subject in the seated and supine position, all quadrants of the breast were palpated using the flat of the hand. The nipples were examined to check any abnormal discharge. The axillae were examined.

5.9 Blinding and masking: Double blinding was not possible as this was an interventional study. The research medical officer, the breast surgeon, 4 gynecologists, Ultrasonologists and the laboratory staff were blind to the groups. Also, the statistician
who did the randomization and the final analysis was blind to the source of the data. The coded answer sheets were analyzed only after completion of the study.

5.10 Intervention: All the 80 students were allocated to one of the two arms: yoga or brisk walk. The interventional group underwent Integrated Approach of Yoga Therapy (IAYT) module. IAYT included breathing practices, warm up stretches, Surya namaskara (Sun Salutation), asanas (postures), prāṇa yama practices (altered breathing), and dhyana(meditation). It also included lectures on the conceptual basis of yoga from the traditional scriptures of yoga (Patanjali Yoga Sutras, Upanishads, and Yoga Vasishthha) which helps in overall development of a personality (physical, vital, mental, emotional, intellectual and spiritual) and yogic counseling for emotion culture, deep relaxation practices for stress management. Control group subjects did brisk walking for half an hour followed by warm up stretches and supine rest. Both the groups practiced for six days a week up to twelve weeks under supervision by the therapist. Both the groups were given conventional lecture classes about breast disease, its causes and the role of stress etc. Attendance was taken for both the groups. The duration of practice along with lecture was one hour and fifteen minutes/day for both the groups.

5.11 Assessments

Demographic and anthropometric details including age, height, weight, BMI, hometown were obtained. A check list included the age of menarche, menstrual history, breast pain (mild, moderate or severe), breast pain before/during/after menstrual cycle (cyclical), breast pain throughout the month (acyclical), breast pain duration, history of fibroadenoma, fibrocystic disease, previous history of breast cancer, history of other previous illnesses, treatment, scanning or surgery, Secondary Variables: Pre menstrual
symptom checklist was obtained which included menstrual history, back pain, migraine headache, anger, mood swings, stress levels etc., lifestyle details like shifts in work, sleep and appetite, diet pattern, alcohol and smoking, happiness scores were collected. Clinical examination of the breast was documented in all cases.

5.11.1 Cleeland brief pain inventory (BPI): Cleeland’s BPI (Cleeland CS, 1994) was used after obtaining written permission from the author. Numerical Pain Analogue Scale (PAS) is a valid and reliable measure of pain intensity. BPI is a validated tool (Keller, 2004) with a Cronbach’s alpha between 0.77 to 0.91. The 5th question of BPI is a numerical PAS from 0 (no pain) to 10 (pain as bad as you imagine) to measure the pain intensity. The PAS from Cleeland’s BPI has been vastly used for mastalgia studies.

5.11.2 Ultra sound scanning (US scanning): US Scanning was done to look for fibroadenoma/cysts and blood test for thyroid profile was done in cases recommended by the clinician. Post data were collected after 12 weeks of intervention.

5.11.3 Psychological assessments: QOL and BDI questionnaires were administered at baseline, after 3 months and 6 months after the intervention.

Beck depression inventory: BDI, developed by Dr Beck in 1961, (BECK, WARD, MENDELSON, MOCK, & ERBAUGH, 1961) aims to evaluate the risk of depression and level of depressive symptoms objectively. The inventory consists of 21 questions, each with 4 possible answers scored between 0 and 3, with the total score ranging from 0 to 63. The total score demonstrates the level of depression. The score for each item ranges from 0-3 and the range of total score is 0-63. A score between; 0 ≤ 9: No depression, 10-19: Mild depression, 20-25: Moderate depression, 26 and above: Severe depression. BDI has been used widely and has Cronbach’s alpha coefficient of
This instrument has a reliability of 0.48–0.86 and validity of 0.67 with the Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnostic criteria for depression. (Hisli N, 1988)

BDI questionnaire attempts to measure the intensity, severity and depth of depression. It is commonly used in clinical setting as a novel way of diagnosing and categorizing depression in psychiatric settings.

**WHOQOL-BREF questionnaire**

Quality of Life reflects the psychological imbalances that result from amplified responses to incorrectly perceived environmental situations. The WHO QOL-Bref which is the short version of the WHOQOL-100 is widely used. WHO QOL-Bref consists of 26 items assessing the QOL in four domains (Physical health, Psychological health, Social relationships and Environment) and a general evaluative facet (Overall QOL and general health). The psychometric properties of the WHOQOL-Bref is considered good for assessment of QOL in women with benign breast disease. (Lotje Van Esch ., 2011) Higher the scores in WHO QOL-Bref, higher is the quality of life. Cronbach’s alpha being >0.70.

**5.12 Statistical analysis:** Data was analyzed using ‘R’ software (ver. 3.1.0). The data was analyzed using a repeated measures ANOVA to investigate changes in mean scores over three time points (baseline, 3rd month & 6th month). Post-hoc tests were done using Bonferroni correction for changes at different time points between groups. Chi-square test was done for secondary variables. Statistical significance was set at Alpha =0.05.