

# CHAPTER 5

## METHODS

## **5.0 METHODS**

### **5.1 PARTICIPANTS**

In the present study, subjects were recruited from Pyramid Valley International, Bengaluru, which is a non-profit organization and it has a mega pyramid in which 5000 people can meditate at a time sitting inside the pyramid. We have screened 140 individuals for the study and recruited them in the first week of February 2017 under the supervision of experienced supervisors.

#### **5.1.1 SELECTION AND SOURCE OF PARTICIPANTS**

The participants for the study were selected from the visitors of Pyramid Valley International situated on Kanakapura Road, Ramanagaram District, Bengaluru.

#### **5.1.2 INCLUSION CRITERIA**

Both male and female participants in the age group of 20 to 65 were included in the study.

#### **5.1.3 EXCLUSION CRITERIA**

The subjects were informed about their health position specifically on chronic diseases, cancer, diabetes and hypertension before they are enrolled. We excluded people with diabetes, cancer, and hypertension from the study based on their self-reports. We considered only chronic diseases for exclusion since the study period was 6 months.

#### **5.1.4 ETHICAL CLEARANCE**

The Institutional Ethics Committee (IEC) of S-VYASA, Bengaluru had approved the project proposal (approval RES/IEC/SVYASA/24/2014).

All the participants of the study have submitted approved and informed consent. The purpose of the study, the benefits of the study, and the procedure of *Ānāpānasati* Meditation were explained to the participants. The informed consent with all details printed in English was given

to the participants and they were asked to sign the consent form, with an understanding that they can withdraw from the study at any point in time if they do not wish to participate. We did not give informed consent in regional languages (like Kannada) as all participants were knowing English. The signed informed consent is appended in Appendix-2.

## **5.2 DESIGN OF THE STUDY**

The study is a prospective randomized controlled design to compare the effect of the *Ānāpānasati* Meditation technique between practicing and non-practicing participants. The sample size of 140 was computed based on previous studies that had an effect size of 0.4 and the power was set to 0.8 with a 5% level of significance. The GPower was used for sample size computation. Initially, 140 participants provided consent to participate in the study, but at the end of the screening period of 7 days, 10 participants withdrew as they were not interested. Ultimately, 130 participants were enrolled. The participants were randomly divided into the experimental and the control groups consisting of 65 participants each. Identification numbers (ID) were assigned to Participants and assigned IDs were randomly picked from the set of IDs and allocated to both the groups in such a way that the first ID was allocated to the experimental group and the next ID is allocated to the control group. The procedure was repeated until all the IDs are allocated. The participants were informed about their group through a sealed envelope. The identities of the participants of both groups were not disclosed, i.e., participants in the experimental group did not know the participants of the control group. Similarly, participants in the control group did not know the participants of the experimental group.

The study aimed to investigate the effect of *Ānāpānasati* meditation on levels of anxiety as assessed by the State-Trait Anxiety Inventory (STAI), verbal aggression as assessed by the verbal aggressiveness scale (VAS), and depression as assessed by the Beck Depression Inventory-II (BDI-II).

### **5.2.1. QUESTIONNAIRES USED FOR THE STUDY:**

**We employed the following questionnaires for collecting the data of parameters.**

1. State-Trait Anxiety Inventory (STAI)
2. Verbal Aggressiveness Scale (VAS)
3. Beck Depression Inventory-II (BDI-II)

The collection of parameters was completed immediately after the screening period of 7 days at the commencement of the practice as well as at the end of the intervention under the supervision of the supervisors. We had interaction with the participants when we screened the questionnaires and requested to complete the forms as far as possible.

#### **5.2.1.1 STATE TRAIT ANXIETY INVENTORY**

We used the State-Trait Anxiety Inventory (STAI), a self-report questionnaire as the scale to study the effect of the intervention on anxiety. The questionnaire is appended in Appendix-3. The STAI consists of two parts state anxiety and trait anxiety each consisting of 20 questions which take values from 1 to 4. The researcher has considered the state anxiety part (STAI-S) of the questionnaire for the study which shows the current state of anxiety in a specific situation when compared to trait anxiety that is a general tendency of the individual.

#### **5.2.1.2 VERBAL AGGRESSIVENESS SCALE (VAS)**

We used the Verbal Aggressiveness Scale developed by Infante and Wigley (Infante & Wigley, 1986) as the scale to study the effect of the intervention on verbal aggression and assessed the VAS score as part of the study. The Verbal Aggressiveness Scale is available in the Appendix-4. The VAS contains 20 items scored on a 5-point linear rating format with reverse scoring on 10 out of 20 items (questions 1, 3, 5, 8, 10, 12, 14, 15, 17, 20). These scores can range from 20 to 100. The participants read each statement and selected the appropriate response to indicate how often each statement was true for him/her when he/she tried to influence other persons. They chose their responses from:

- (1) Almost never true,
- (2) Rarely true,
- (3) Occasionally true,
- (4) Often true and
- (5) Almost always true.

The VAS gives a single overall score that describes the disposition of an individual toward low, moderate, or high verbal aggressiveness. Scores from 20-46 suggest low verbal aggressiveness, 47-73 suggest moderate verbal aggressiveness and 74-100 suggest high verbal aggressiveness.

The psychometric properties of the VAS were as follows:

The coefficient alpha was 0.81. And test-retest correlation was 0.82 ( $P < 0.001$ ).

### **5.2.1.3 BECK DEPRESSION INVENTORY II (BDI-II)**

Beck Depression Inventory-II (Beck, 1966, 1996) was used as the scale for measuring the effectiveness of the intervention. The scale is appended in the Appendix-5.

The BDI-II scale is more useful in research studies. It can monitor and provide an objective measure of finding improvement and effectiveness or otherwise of interventions given. It contains 21 questions, with each answer being scored on a scale value of 0 to 3. Higher scores indicate more severe depressive symptoms. The standardized cut-offs used is:

0-13: minimal depression,

14-19: mild depression,

20-28: moderate depression and

29-63: severe depression.

We assessed the BDI-II score as part of the study.

### **5.3 INTERVENTION**

We undertook to recruit the participants in the first week of February 2017 under the supervision of experienced supervisors. We have explained in detail how to fill in the questionnaires. While administering the questionnaires, we provided them with an “Instructions Leaflet” individually, containing the detailed procedure of *Ānāpānasati* Meditation practice. We have made it clear about the practice and the procedure they need to follow for the duration of 6 six months. We ensured monthly recorded verification in their status by the supervisors for the period of intervention. We took the analysis of data in the second week of August 2017 at the end of the period of practice i.e., 7-8-2017. The “Instructions Leaflet” issued in this regard is available in the appendix-6. The *Ānāpānasati* Meditation technique was the intervention for the experimental group. The duration of the intervention was 6 months. The participants had to practice this meditation for one hour every day. *Ānāpānasati* is essentially quietening the mind by being aware of inhaling and exhaling. In this practice, mindfulness of breathing is the object of observation as it is not a physical object that arouses any distraction in the mind. It is quite a natural and non-fluctuating effortless process.

#### **5.3.1. PROCEDURE FOR ADMINISTRATION**

First, the participant has to sit comfortably, keeping both hands together. A moment of silence has to be observed by the participant. Awareness of the breathing in and the breathing out is the prime part of the practice. Gradually all thoughts disappear. One will experience, knowledge, vision, awareness and joy for himself in this state of mindful breathing.

The duration of the practice has been one hour at one go daily from 6 a.m. to 7 a.m. for 6 months. A detailed text of the intervention is available in Annexure-6.

##### **5.3.1.1 DEMONSTRATION OF THE MEDITATION**

Steps included in the demonstration are given below:

1. Sit comfortably in any posture convenient to them and clasp hands together.
2. Close the eyes and begin witnessing inhaling and exhaling normally.
3. Keep the breathing process uniform with no fluctuations.
4. Be aware of their natural process of breathing in and breathing out for one hour every day.
5. They are to restart if they happen to lose awareness of breathing during the course of the practice.

The experimental group was practicing *Ānāpānasati* Meditation, for an hour every day along with their routine duties and the control group did not practice meditation but were performing their daily routines. The participants of the experimental group practiced *Ānāpānasati* Meditation under the supervision of trainers for one week in Pyramid Valley International and later, they continued the practice at their residences. They also attended meditation classes once a week. The trainers were seniors practicing *Ānāpānasati* Meditation for the past 15 years. It was ensured that there was no interaction between the groups during the entire period of six months from 8-2-2017.

We had taken up the assessment in the second week of August 2017. The participants had a quiet environment free from distractions to fill in the questionnaires. The participants filled in the questionnaires with the assistance of the experts present there for rendering any clarification and checking consulting others while filling the questionnaire.

#### **5.4 DATA EXTRACTION**

Experienced meditator supervisors have undertaken the assignment with the prescribed questionnaires administered for the collection of data. They carried out the scoring of the questionnaires as per the instructions in the manual. A person not involved in the group formation evaluated the coded response sheets. A person who was not involved in the study decoded the response sheets only after noting the scores before and after data were completed.

## 5.5 STATISTICAL ANALYSIS

We analyzed the data using SPSS Statistics Version 10. The data were presented as mean  $\pm$  of standard deviation. We assessed the data for normality using the Kolmogorov-Smirnov test. The BDI, STAI and VAS scores were normal in both the experimental and control groups. The pre-post comparison in the groups was performed using repeated-measures ANOVA, with a  $p$ -value  $<0.05$ , which is considered statistically significant for all comparisons. In the tables, the data (mean  $\pm$  standard deviation) show two significant figures after the decimal.