RESEARCH HYPOTHESIS & OBJECTIVES

SAMPLE SIZE CALCULATION

STUDY DESIGN

MATERIALS ND METHODS
RESEARCH HYPOTHESIS AND OBJECTIVES

**Introduction to methodology:** Previous studies on meditation indicate that, not all techniques have the same effects and in most of the studies, small sample size, suboptimal control groups, lack of long-term follow up, and problems of adherence among participants were the factors criticized. So we designed the current study with an aim to understand the effect of Integrated Amrita meditation technique on physiological and psychological stress using two control groups and of the four phases of intervention, i.e., baseline, 48 hours, 2 months, and 8 months.

**Hypothesis:** Our hypothesis is that IAM Meditation would reduce stress in normal young adults and this will be reflected as changes in physiological and psychological stress indicators.

**Research question that needs to be answered through the study:** Does IAM Meditation bring any change in the response to stress?

**Objective of the study:**

The objective of the study is to study the changes in the immediate (48 hours), short term and long term stress responses after IAM meditation technique through culturally adapted psychological questionnaires, short and long term stress coping pathways (cortisol, adrenaline) and physiological parameters like blood pressure, heart rate, respiratory rate, GABA and IGA levels.
SAMPLE SIZE CALCULATION

The sample size was calculated from the available information from published papers. Since no study was reported earlier using IAM Technique the minimum sample size was computed based on the results reported for Buddhist meditation technique. The sample size was estimated with 95% confidence and 80% power. Details of the sample size estimation are given in the Table.

(Sudsuang et al1991)

<table>
<thead>
<tr>
<th></th>
<th>Before (mean ± SD)</th>
<th>After (mean ± SD)</th>
<th>Difference (mean ± SD)</th>
<th>Sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortisol (M)</td>
<td>12.33 ± 2.82</td>
<td>9.31 ± 1.79</td>
<td>3.02 ± 3.34</td>
<td>7 ~ 10</td>
</tr>
<tr>
<td>Cortisol (C)</td>
<td>11.39 ± 1.64</td>
<td>11.43 ± 1.39</td>
<td>-0.04 ± 2.12</td>
<td></td>
</tr>
<tr>
<td>Systolic BP (M)</td>
<td>111.33 ± 8.33</td>
<td>104.66 ± 10.06</td>
<td>6.67 ± 13.06</td>
<td>21~ 25</td>
</tr>
<tr>
<td>Systolic BP (C)</td>
<td>115.11 ± 12.14</td>
<td>116.83 ± 7.93</td>
<td>1.72 ± 14.5</td>
<td>7.67~8</td>
</tr>
<tr>
<td>Diastolic BP (M)</td>
<td>73.33 ± 6.17</td>
<td>64.33 ± 6.39</td>
<td>9 ± 8.88</td>
<td>13.5~14</td>
</tr>
<tr>
<td>Diastolic BP (C)</td>
<td>75.66 ± 7.73</td>
<td>76.33 ± 6.68</td>
<td>0.67 ± 10.22</td>
<td></td>
</tr>
<tr>
<td>Heart rate (M)</td>
<td>83.69 ± 11.29</td>
<td>74.8 ± 9.15</td>
<td>8.89 ± 14.53</td>
<td></td>
</tr>
<tr>
<td>Heart rate (C)</td>
<td>80.26 ± 5.24</td>
<td>80.73 ± 7.72</td>
<td>0.47 ± 9.33</td>
<td>2</td>
</tr>
<tr>
<td>Adrenaline (M)</td>
<td>136.6 ± 13</td>
<td>119.7 ± 10.8</td>
<td>16.9 ± 16.9</td>
<td></td>
</tr>
<tr>
<td>Adrenaline (C)</td>
<td>236.8 ± 21</td>
<td>175 ± 17.4</td>
<td>61.8 ± 27.27</td>
<td></td>
</tr>
</tbody>
</table>

\[ n = \frac{(sd_1^2 + sd_2^2)}{(Z_{1-\alpha} + Z_{1-\beta})^2 / d^2} \]

(d= mean 1- mean 2)

It may be noted that maximum sample size among the various parameters was estimated for Systolic Blood Pressure which was a sample size of 25. Hence the minimum sample size was fixed as 25 for the present study for each of the three groups to obtain a characteristic difference for all the parameters which were planned to be measured.
STUDY DESIGN

The study received Institutional Ethics Committee clearance and Scientific Advisory committee clearance before the commencement.

Two pilot studies were conducted on a working adult population. The subject information sheet and informed consent were given to people working at AIMS. In the first pilot, 20 employees of AIMS were recruited and randomized into three groups (IAM, PMR, control). But out of the seven recruited for the IAM only one person came for the first visit. When the subjects were contacted further, it was learned that they were not comfortable with randomization and were not sure whether they would be able to continue for eight months in the study. In the second pilot anticipating the heavy drop out, 60 subjects were recruited and randomized but again there was a heavy dropout and the study could not be conducted. On further discussion with the drop out subjects of the pilot it was found that due to work constraints they could not find time for the practice and those who had dropped out of the control group felt that they would not benefit from learning a relaxation technique and so were no longer interested in the study. Finally it was decided to take college students for the study as they are a captive audience. (Follow up was easier as we could go to them rather than having them come to us) Ensuring compliance was also expected to be easier as the students could be contacted at regular intervals in their classes or hostels.
The original study was conducted in two campuses under the Amrita Viswavidyapeetham. The purpose of the study and the methodology was clearly explained through slides to the students of age group 18-21.

Any student who had practiced any relaxation technique at anytime was asked not to participate in the study.

The volunteers were selected through a screening questionnaire i.e., Life styles questionnaire. The exclusion criteria were alcoholics, chronic smokers and psychiatric patients. There was only one student who had reported that she was taking psychiatric medicine and was excluded. Subjects signed informed consent forms prior to participation in the study.

Since we anticipated a heavy dropout of subjects after randomization, double the required sample size was selected for the first visit. Thus one hundred and fifty college students were randomly assigned three groups by the lottery method. Subjects were numbered and tokens were prepared with these numbers written on it. From this the tokens were drawn and assigned to three different groups. The first group was trained to practice the meditation technique called Integrated Amrita Meditation (IAM) Technique. The subjects randomized to the second group were given training on Progressive Muscle Relaxation (PMR) technique. The subjects randomized to the third group served as controls and did not practice any meditation technique or do any relaxation exercises.

IAM technique was taught to the IAM group by trained instructor from the MA Math. PMR technique was taught by a trained physiotherapist. The control
group was not given any special training. All the psychological, physiological and biochemical parameters were collected after 48 hours to study the immediate changes and again after two months of continuous practice to see the short term effect and after eight months of regular IAM or PMR practice to study the long term effects.

A self-maintained diary assessed compliance in both the groups. All the subjects in the IAM and PMR groups continued regular practice of these techniques throughout the eight month period. Apart from assessing the diaries, compliance was also assured by frequently visiting the students at their college and hostel.

Baseline values for all the parameters were collected at 0 hours, i.e. before any training was given to the IAM & PMR groups. (Throughout the entire study all data were collected in the morning by 8 am). Blood was collected for all the visits and plasma was separated and stored at minus 20 degree Celsius in the deep freezer. The tests were conducted for all the parameters in AIMS.

The data was entered in SPPSS statistical package. All subjects were followed up for a total duration of eight months. Regular refresher courses were arranged for IAM and PMR groups.
MATERIALS AND METHODS

IAM TECHNIQUE

Like any other form of meditation, IAM has its roots in the Indian Tantric practices. It is a method for experiencing the energy of the macrocosm within the microcosm through mastering a technique of energy movement called Prana Sanchara. It consists of energizing exercises (yogic postures) for up to 8 minutes, a brief period of relaxation for 2 minutes and 13 minutes of meditation. At the end of the technique the subjects are asked to remain in silence for 5 minutes.

The components of the technique are:

Relaxation exercises/yogic postures: These exercises progressively relax the muscles and joints and so the mind too. It also has an energizing, holistic effect.

Breathing exercises (focused breathing): These breathing exercises draw attention to the way one breathes, prompts a more complete breathing.

Awareness: Throughout the process awareness is the main component. One is encouraged to be aware of all the subtleties of each of the steps. One part in particular focuses on the flow of breath.

Visualization: This is a key component of this technique as mind is focused on an internal point, rather than on a physical object outside.

Only the first class is guided. The later practice is without the help of any external means.

Criteria for successful practice: Belief in a spiritual master and chanting the mantra given by the master is recommended.
The relaxation of the mind by this technique is expected to reduce stress and expand thinking in general, making the subject more creative on his work or studies.

This is the first study on the IAM Technique

PROGRESSIVE MUSCLE RELAXATION TECHNIQUE

Progressive Muscle Relaxation (or PMR) is a technique for reducing anxiety by alternately tensing and relaxing the muscles. It was developed by American physician Edmund in the early 1920s (Jacobson, E. 1924). Jacobson argued that since muscular tension accompanies anxiety, one can reduce anxiety by learning how to reduce the muscular tension. PMR has a physical and mental component.

The physical component involves the tensing and relaxing of muscle groups over the arms, legs, face, abdomen and chest. With the eyes closed and in a sequential pattern, a tension in a given muscle group is purposefully done for approximately 10 seconds and then released for 20 seconds before continuing with the next muscle group.

The mental component focuses on the difference between the feelings of the tension and relaxation. Jacobson found that the relaxation procedure is effective against ulcers, insomnia, and hypertension. The technique has also proven effective in reducing acute anxiety in people with Schizophrenia. (Chen WC 2009). Jacobson's Progressive Relaxation has remained popular with modern physiotherapists. This is a standardized relaxation technique. We have taken this as one of the control group because IAM technique is a combination of few
relaxation exercises and deep meditation and we wanted to see if the effects of the mediation are due to the muscle relaxation part of the technique or due to the deep meditation.

**PSYCHOLOGICAL INSTRUMENTS**

**A. Life changes stress scale**

In 1967, psychiatrists Thomas Holmes and Richard Rahe examined the medical records of over 5,000 medical patients as a way to determine whether stressful events might cause illnesses. Patients were asked to tally a list of 43 life events based on a relative score (Holmes TH 1967). A positive correlation of 0.118 was found between their life events and their illnesses. Their results were published as the Social Readjustment Rating Scale (SRRS) known commonly as the Holmes and Rahe Stress Scale. M A Miller and Rahe Recent life changes questionnaire in scaling for the 1990 containing 73 items which is a modified version of Holmes and Rahe scale was used in the study. M A Miller and Rahe Recent life changes questionnaire was initially given to the adults and college students in Kochi in South India where the study was conducted. As the subjects reported that many items given in the scale were irrelevant for the Indian population and many stress precipitating factors were missing, the questionnaire was modified. The new questionnaire contained 74 items.