CHAPTER 5

METHODOLOGY

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4.1 Participants

The study included patients of essential hypertensive within age group of 30-60 years, who were on antihypertensive medication and with minimum5 years history of hypertension.

We selected 40 hypertensive subjects & two groups prepost design was followed.

IAYT group: 20 participants (with average age-46.62±9.9 years)

Non-IAYT group=20 participants (with average age-47.08±9.69 years)

Sample size: Sample size was calculated using the previous following studies:

Blood pressure: Previous master degree dissertation done by Anuj et al et al 2012 "*Effect of Integrated approach of Yoga therapy on blood pressure in subjects having hypertension*"with effect size of 2.2, at statistical significance 0.05 & power 0.97. The calculated sample size was 14.

Baroreflex sensitivity: The calculated sample size on the basis of previous study by Joceph et al, 2005 with title "Slow breathing improves arterial baroreflex sensitivity and decreases blood pressure in essential hypertension. *Hypertension"*having effect size 5.09 at statistical significance 0.05 & power 0.99 was 8.

Anxiety: The calculated sample size on the basis of previous M Sc study by Jayant et al, 2005 with title "Effect of IAYT intervention on mental health among hypertensive subjects "having effect size 1.2 at statistical significance 0.05 & power 0.99 was 18.

4.2 Source of subjects:

IAYT group: Subjects in the IAYT group were selected from, Arogyadhama, prashanti kutiram, SVYAS University campus, Vivekananda road, Kallubalu post, Hobli, Anekal Taluk, Bengaluru- 560105. Subjects in IAYT group were hypertensive patients who approached to Arogyadhama SVYASA for one week of IAYT treatment for hypertension.

Non-IAYT group: Hypertensive individual near to SVYASA University, Prashanti Kutiram, Bangalore, who visited OPD clinic of Suhas Hospital and Vijayshree Hospital were contacted durng their OPD visit.

Recruitment

Total 60 hypertenive participantsfulfilled the eligibility criteria (26 for IAYT group at SVYASA and 34 outside SYASA). Of 34 participants in non-IAYT group 9 declined for participation and 3 did not come post assessments. Further, among 26 participants in IAYT group4 participant declines, 2 quite the study in between due some some personal reason.

We kept non-diabetes as one of the selection as diabetes is also an independent casues cogntivie decline and it is also characterized by autonomic dysfunction. Non-diabetes was confirmed with fasting blood glucose reading <100 ml/dl in last two months, in case of non-avalability of reports FBS was assessed.

Forty participants completed the study (20 in IAYT group and 20 in Non-IAYT group). All the subjects were on anti-hypertensive treatment. Medication was stable throught the study for both the groups.

4.3 Inclusion and exclusion criteria

4.3.1 Inclusion criteria

- Hypertensive subjects within age range 30-60 years, with minimum 5 years history of hypertension
- Both male and female
- Willing to participate in the study

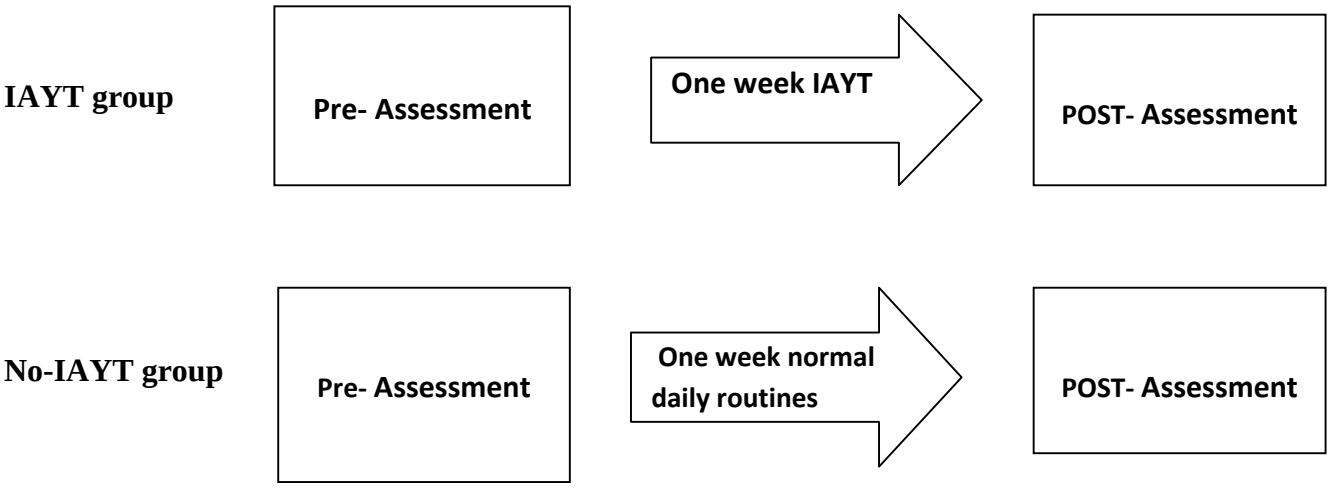
4.3.2 Exclusion criteria

- Subjects with history of diabetes mellitus
- Subjects with any form of psychiatric problem
- Patients taking anti-psychotic medication
- Severe heart problems
- Those who cannot follow the practice of IAYT itnervention
- Past history of major depression episodes
- Known case of any form of anxiety disorder
- Known case of Cerebrovascular disorder or sever neurodegenerative disorder

4.4 Design of the study

We followed convenient sampling method and two group prepost designs.

Figure 5 Design of the study



4.5 Ethical considerations

The study was approved by Institutional Ethical Committee of SVYASA University, and Bangalore, India. (IEC rapproval number RES/IEC-SVYASA/68/2015)

Duly signed written informed consent was obtained from all the participants before the commencement of study. Subjects were informed about study in detail in their respective mother tongue.

4.6 Intervention

4.6.1 IAYT group intervention

All the subjects in IAYT underwent one week of residential yoga based lifestyle intervention Integrated Approach of Yoga Therapy.

Table 8: Daily routines of IAYT intervention

Daily activities	Time (Hrs)	Daily activities	Time (Hrs)
Ablution	5:00	Cyclic meditation	15:00
Om Meditation	5:30	HTN Special techniques	16:00
HTN Special technique	6:00	Tuning to nature	17:00
Spiritual discourse	7:15	Devotional session	18:00
Breast fast	8:00	MSRT	18:45
Yogic counseling	9:30	Dinner	19:30
Pranyama (Breathing techniques)	10:30	Happy assembly	20:30
Milk or herbal tea	11:30	Group discussion/Self-study	21:15
HTN Special technique	12:05	Lights off	22:00
Lunch & rest	13:00		

HTN Special techniques: Includes special yoga practices designed for hypertension; Om Meditation: A Meditative technique; MSRT-Mind Sound Resonance Technique: It is a kind of Yoga based relaxation techniques includes chanting of mantra in supine posture; Happy Assembly- Playing indoor games, laughter, singing etc.

Table 9: Hypertension special techniques

Type of activity	List of practices
Loosening practices	⁾ Sukshmavyayama ⁾ Slow jogging ⁾ Side bending
Breathing Practices	⁾ Hands in and out breathing ⁾ Ankle stretch breathing ⁾ Straight leg raising breathing ⁾ Lumbar stretch breathing
Asanas	**Standing:** ⁾ Ardhakati chakrasana ⁾ Ardhachakrasana ⁾ Trikonasana ⁾ Rikshasana **Sitting** ⁾ Vakrasana ⁾ Ardhashirshanasa ⁾ Ustrasana ⁾ Vajasana **Supine** ⁾ Setubandhasana ⁾ Folded leg lumbar stretch ⁾ Shavasana ⁾ Pavanamuktasana **Prone** ⁾ Bhujangasana ⁾ Shalabhasana ⁾ Dhanurasana ⁾ Makarasan
Relaxation techniques	⁾ Quick relaxation technique ⁾ Deep relaxation technique ⁾ Guided relaxation
Pranayama	⁾ Nadi Shodhana ⁾ Ujjayi ⁾ Sukha pranayama ⁾ Anuloma Viloma ⁾ Brahmari ⁾ Left nostril breathing
Meditation	⁾ OM meditation ⁾ Nadanusandha

Non-IAYT group:

Subjects in Non-IAYT intervention followed their daily routines.All the subjects in non-IAYT group were on regular anti-hypertensive medication and they followed their dialy routines such as job, family environment and diet. Most of the subjects were not following any kind of physical activity.

4.7 Outcome measures

4.7.1 Cardiac variables

- Heart rate
- Systolic blood pressure
- Diastolic blood pressure
- Mean arterial blood pressure
- Baroreflex sensitivity
- Total peripheral vascular resistance

4.7.2 Psychological variables

- Anxiety
- Depression

4.7.3 Cognitive variables

- Selective attention
- Concentration
- Scanning memory
- Psychomotor speed
- Short term memory
- Working memory

4.8 Assessment tools:

4.8.1 Cardiac parameters

All cardiac assessments were done at the baseline and after one week for both groups. FinaPress-non-invasive BP monitoring system was used for all cardiac assessemnts. Assessments were done in morning hours, between 10 am-12 pm, in a silent room.

Subjects were asked to sit on a comfortable soft chair and were asked to relax for 5 minutes before assessment in a silent room.

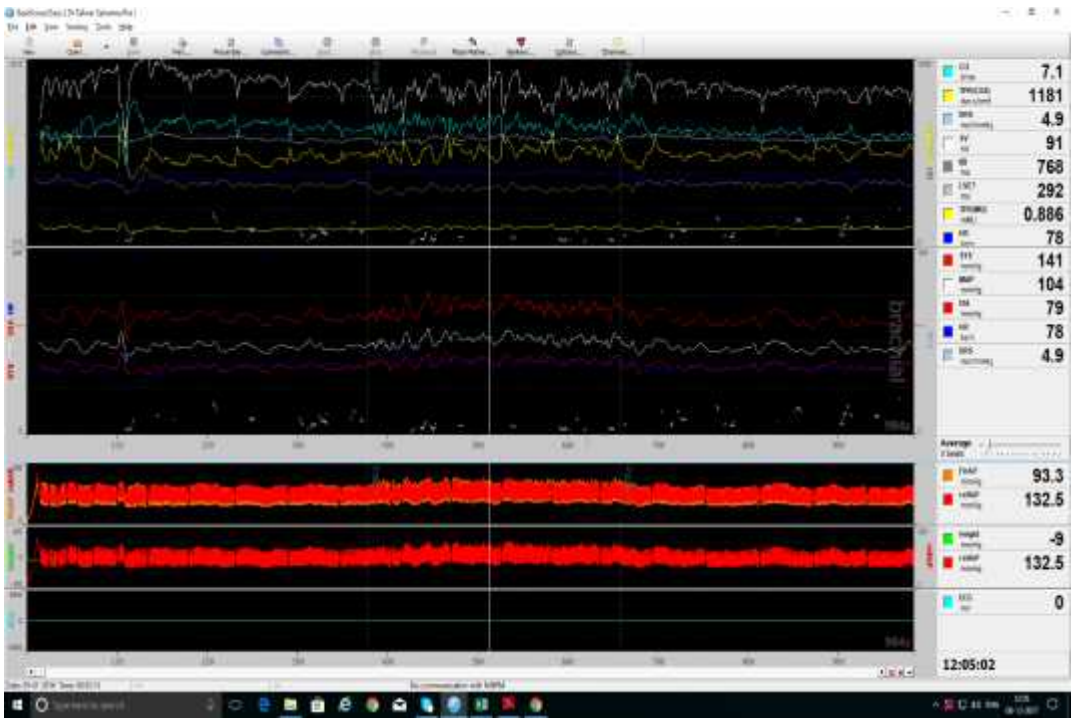
FinaPress: Non-invasive continuous blood pressure monitors (Finapres MedicalSystems B.V., 184 Netherlands). It delivers continuous finger blood pressure waveform (Imholz, 1998). This device appears to offer a reliable alternative to intra-arterial blood pressure monitoring. It is widely used instrument in many clinical studies (Imholz, 1998).It is a reliable tool to assess baroreflex sensitivity, cardiac output (Janson, 2001).

Finapres is based on the volumeclamp method (Wesseling, 1995), and reflects changes in systolic, mean and diastolic arterial pressure under variableconditions (Fridmen, 1990). The cuffed finger was fixed in theanterior axillary line at heart level.Beat-to-beat changes in stroke volume (SV) werecomputed by modelling flow from arterial pressure, simulating a non-linear, time-varying model of the aorticinput impedance. The SV was obtained as theintegral of the flow waveform for one beat (Harms, 1999).

Total peripheral vascular resistance: was calculated from themean arterial pressure (MAP) and the CO.Cardiac output (CO) was the product of the SVand the heart rate (HR).

Images showing assessments of cardiac parameter and Finapress

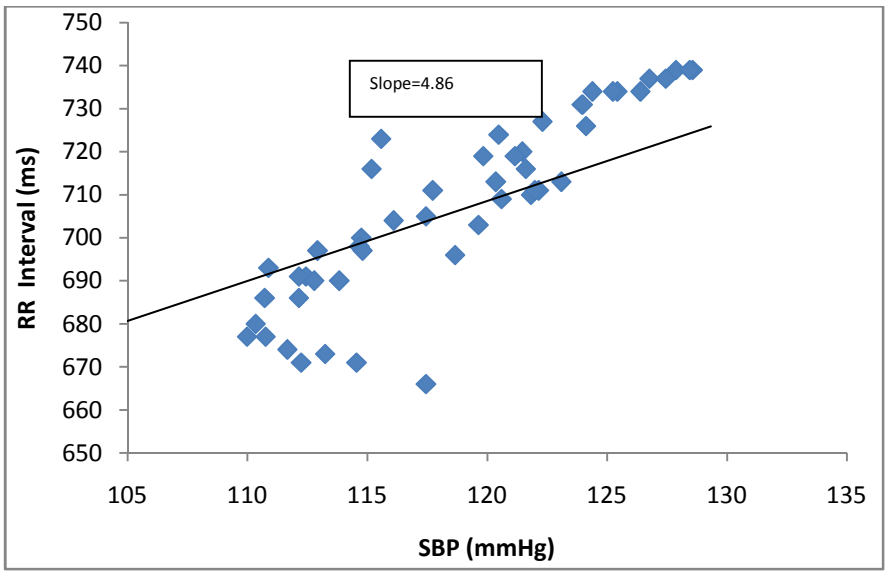
Image showing the data recording in Finapres



Baroreflex sensitivity:

Baroreflex sensitivity was assessed using FinaPress NIBP system. Sponteneous baroreflex sensitivity was evaluated from systolic blood pressre and heart rate changes. Data was extracted using beat-scope softeware and exported into excel sheet.

Graph 1: An example of the data obtained during the cardiovagal baroreflex test from 1 subject is displayed.



4.8.2 Digit Letter Substitution Test (DLST)

The digit letter substitution task (DLST) was developedfrom the Digit Symbol Substitution Test (DSST) as one of thesubsets of the Wechsler intelligence scale. Substitutiontests are essentially speed-dependent tasks that requirethe subject to match particular signs and symbols, digits or letters to other signs within a specified time period (90 sec).Substitution tasks involve visual scanning, mentalflexibility, sustained attention, psychomotor speed andspeed of information processing. DLST is a valid toolfor assessing neuro-psychiatric illnesses and has beenstandardized for the Indian population (Pradhan B, 2009).

4.8.3 Memory

Short term and working memory were assessed using digit forward and backward memory scale. Digit span forward and backward: Digit Span (DS) is a sub-test in the Wechsler Adult Intelligence Scale, 3rd ed (WAIS-III). It includes two sub-sections (DS-Forward and DS-Backward), and is considered a good tool to evaluate short-term memory and working memory. DS-F evaluates short-term memory by simply requiring participants to repeat numbers. DS-B assesses working memory by requiring participants to memorize numbers and to repeat the numbers in the opposite order (Wechsler, 1997).

4.8.4 Hospital Anxiety and Depression Scale (HADS):

Anxiety and depression were assessed using Hospital anxiety and depression scale (HADS). HADS is considered as a valid tool to assess symptom severity and cases of anxiety disorders and depression in both somatic, psychiatric, and primary care patients and in the general population. The HADS scale consists of two components, HADS-A & HADS-D. HADS-A component consists of 7 measures subjective anxiety and HADS-D consists of 7 items which measures subjective depression symptoms (Zigmond, 1983). Depresion or anxiety score more more than 11 is considered to be clinical caseness for depression and anxiety respectively.

5 Data extraction and analysis

5.1 Data extraction

Cardiac variables Systolic BP, diastolic BP and mean arterial BP were extrapolated from finger arterial pressure through the use of a height correction unit and waveform filtering and level correction methods, supplied by the BeatScope software package (Finapres Medical Systems B.V., 184 Netherlands).

Mean arterial pressure (MAP), SBP and DBP were expressed in mmHg. Stroke volume (SV), cardiac output (CO), Total Peripheral resistance (TPR) and Baroreflex Sensitivity (BRS) were also extrapolated from the standard formulae using BitScope Easy 2.0 computer based program.

Digit Memory Test Raw score of digit forward backward test was calculated manually and entered in excel sheet.

Hospital anxiety and depression scale Raw score of anxiety and depression were calculated as per the instructions mentioned the manual of Hospital Anxiety Depression Scale (HADS) Hospital anxiety and depression (Snaith, 2003).

Data of vvariables was transformed in excel formate for statistical calculation.

Data analysis

Descriptive statistics: Mean and standard deviation were calculated in Microsoft Excel.

Prepost data of all the variables were presented as mean and standard deviation.

Data was subjected to normality test, data for all variables except baroreflex sensitivity & total peripheral vascular resistance was found to be normally distributed.

Paired sample t test was used to assess within group changes for normal distributed data and independent sample t test was used for assessment of between group changes.

Similarly Wilcocson's signed rank test and Mann-Whetney's test was used assess within group and between group changes for non-normal distributed data respectively.

SPSS version 16 software was used for statistical analysis.