

**EFFECTIVENESS OF SOYA PROTEIN CONSUMPTION
ON THE MENOPAUSAL SYMPTOMS AMONG WOMEN
IN SAMAYANALLUR AT MADURAI**

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**THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY,
CHENNAI - 600 032.**

In partial fulfillment of the requirement for the degree

MASTER OF SCIENCE IN NURSING

APRIL 2015

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ON THE MENOPAUSAL SYMPTOMS AMONG WOMEN
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CERTIFICATE

This is to certify that this dissertation titled, “**EFFECTIVENESS OF SOYA PROTEIN CONSUMPTION ON THE MENOPAUSAL SYMPTOMS AMONG WOMEN IN SAMAYANALLUR AT MADURAI**” is a bonafide work done by **Mrs. A. CHITRA DEVI**, College of Nursing, Madurai Medical College, Madurai-20, submitted to The Tamilnadu Dr. M.G.R MEDICAL UNIVERSITY, CHENNAI in partial fulfillment of the university rules and regulations towards the award of the degree of **MASTER OF SCIENCE IN NURSING, Branch III, Obstetrics and Gynecological Nursing** under our guidance and supervision during the academic period from 2013-2015.

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ABSTRACT

Title : Effectiveness of soya protein consumption on the menopausal symptoms among women in Samayanallur at Madurai. **Objective:** To assess the level of menopausal symptoms among women in control and experimental group in Samayanallur at Madurai, to evaluate the effectiveness of soya protein consumption on menopausal symptoms among women in Samayanallur at Madurai, to find the association between menopausal symptoms with selected demographic variables in control and experimental group in Samayanallur at Madurai. **Hypotheses :** There is a significant difference in the level of menopausal symptoms before and after soya protein consumption among women in control and experimental group, there is a significant association between level of menopausal symptoms and selected demographic variable among women in control and experimental group. **Conceptual Framework:** It was based on Kenny's outcome based theory. **Methodology :** Quasi-experimental – Non equivalent control group design. Menopausal women were selected by purposive sampling technique. This study was conducted in Samayanallur at Madurai. A total of 60 women were included in the study. 60grams soya bean given daily for 4 weeks. **Results:** Result showed that level of Menopausal symptoms among women in both groups. Experimental group post test mean was 10.6 standard deviation 3.70, Control group post test mean was 17.07 standard deviation 3.39. Experimental group post test mean was less than control group post test mean. 't' value was 7.05, 'p' value was 0.000. **Conclusion:** Menopausal women who consuming soya protein 60grams daily had a statistically significant in reducing the level of menopausal symptoms.

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Introduction

CHAPTER-I

INTRODUCTION

“Women need to devise their own rite of passage, celebration of what could be regarded as the restoration of a woman to herself.”

- German Greer

“On a planet where for thousands of years, even today, a woman’s worth has been judged exclusively by the productivity of her womb, what the hell is the point of a barren when?”

-Elissa Stein and susan

Being a woman is very special. Nature takes her through a series of transitions from her birth until death, which includes menarche, pregnancy, labor, motherhood and menopause. Each of these stages stands for different phases in her life which includes both physical and psychological changes.

A woman is a female human. The term woman is usually reserved for an adult. Women are typically capable of giving birth from puberty until menopause. Women’s health concerns including sex, pregnancy, birth control, menopause, weight control and cancer.

Countries with more gender equality have better economic growth. Companies with more women leaders perform better. Peace agreements that include women are more durable. Parliaments with more women enact more legislation on key social issues such as health education, anti-discrimination and child support.

International women’s day is celebrated on March 8 in every year. This year theme “Equality for women in progress for all” emphasizes how gender equality,

empowerment of women, women's full enjoyment of human rights and the eradication of poverty are essential to economic and social development.

The women life has three phases. The first stage is called virginity or maidenhood. The second stage is motherhood when consciousness turns outward, to the home and family. The final stage which begins at menopause is called the crone or wise women stage.

Menopause is seen more as a gateway to a second adulthood. Menopause is the permanent cessation of ovarian function. The term was originally coined to describe this reproductive age in human females, where there is an end for fertility, traditionally indicated by permanent stopping of monthly menstruation or "menses".

The word "menopause" literally means the "end of monthly cycles" from the Greek words pausis (cessation) and the word root men (month)

Menopause doesn't creep up on women and hit them all of a sudden. There are Three distinct stages to menopause; Premenopausal, Perimenopause and PostMenopause. Premenopause is the word used to describe the years leading up to lastperiod, when the levels of reproductive hormones are already becoming lower. Perimenopause is defined as the period immediately prior to menopause and the firstYear after menopause and Post menopause is the period after the final menstrualPeriod. Climacteric is the phase of aging process during which a woman passes from the reproductive to the non-reproductive stage. This phase4 covers 5-10 years on each side of menopause, premenopause and post menopause. (**Alan H.DeCherney**).

Menopause is a natural phenomenon, but then it causes many symptoms which Deteriorates the health of the women and makes her in trouble for the increased chance of many complications. In the menopausal years, many women undergo noticeable and clinically observable physical changes resulting from hormonal fluctuations.

Signs and effects of the menopause transition can begin as early as age 40, although most women become aware of the transition in their mid to late 40s, often many years after the actual beginning of the perimenopausal window. The typical age range of menopause is between ages of 40 and 60 and the average for last period is 51 years in western countries. In some developing countries, the median age for natural menopause is at 44 years. In India as per the 2007 reports, the mean age at menopause ranges from 40 to 50 years.

Age at which menopause occurs is genetically predetermined. The age of menopause is not related to age at late pregnancy. It is also not related to number of pregnancy, lactation, use of oral pill, socio economic condition, race, height or weight, thinner women have early menopause. Severe malnutrition may cause early menopause. The age of menopause ranges between 45-55years, average being 50 years. **(D.C. Dutta)**.

Menopause is a significant event in most women's lives as it marks the end of a woman's natural reproductive life. The perimenopausal and early postmenopausal period is typically characterized by falling levels of endogenous oestrogen, which can give rise to vasomotor symptoms that are severe and disruptive, particularly in the

perimenopausal and early postmenopausal years. These vasomotor symptoms include hot flushes (also known as ‘hot flashes’), sweating and sleep disturbances.

Hot flushes are described as the sudden feeling of heat in the face, neck and chest (WHO 1996). Hot flushes are frequently accompanied by skin flushing and perspiration followed by a chill as core body temperature drops (Freedman 2001; Kronenberg 1990). The flushes vary in frequency, duration and severity and may be spontaneous and unpredictable (Freedman 1995). Hot flushes that occur during the night are typically referred to as night sweats. Flushes and night sweats are of concern in themselves because they can disrupt sleep patterns and alter daily activities, which can then lead to fatigue and decreased quality of life (NAMS 2004). Hot flushes are thought to result from both the brain’s response to diminished hormones and the hormonal fluctuations that occur during the menopausal transition, which then leads to instability of thermoregulatory mechanisms (that regulate temperature) in the hypothalamus (Freedman 2001; Kronenberg 1987).

The initial years of menopause are often accompanied by vasomotor symptoms such as hot flashes and night sweats, somatic symptoms such as fatigue, body aches, and vaginal dryness, and psychological symptoms such as irritability, anxiety, depression, decreased libido, and difficulty sleeping. These symptoms can begin during the menopausal transition up to 2 years before the cessation of menses.

World Menopause Day is celebrated on 18th October every year. World Menopause Day started all the way back in 1984 and was instituted by the International Menopause Society and the World Health Organization (WHO). The Menopause day is devoted to creating awareness about one of the most difficult time in a women’s life.

Many pharmacological and nonpharmacological measures are being used by perimenopausal women for centuries to overcome these devastating symptoms. Soya bean one such agent used by perimenopausal women is (glycine max) a leguminous plant containing 40% protein, minerals (like calcium, iron, phosphorus, and zinc), vitamins (like B complex, vitamin E) and phytoestrogen and lecithin. FDA(Food and Drug Administration) has recommended adding 45 to 100 mg of soya diet in a day is beneficial to alleviate menopausal symptoms.

Soya beans are very rich in nutritive components. Besides the very high protein content. It contains a lot of fiber and is rich in calcium, magnesium. 100g soya bean contains 36.5gm of protein and 200 mg of is flavones. 60gm soya bean contains 21.9 gm. Daily recommended protein for women and is 46gm per day. Green soybeans are called Edam me. It is sweet taste. According to an article published in a 2007 edition of the **“Journal of the International Society of sports Nutrition”** physically active women require protein 1.4 to 2.0 gram per kilogram of body weight. According to the Institute of medicine 0.8gram of protein per kilogram of body weight.

It is high in phytoestrogen which is a plant chemical that acts like estrogen which is produced naturally in the body. These plant estrogens are thousands of times weaker than natural estrogen. But they also circulate in the blood at levels thousands of times higher than natural estrogen. Soya bean contains Genistein, one of the phytochemicals. It blocks cancer development by preventing tumors from creating blood vessels that would provide nourishment for growth. One serving a day (1cup of

soya bean) has shown to be effective for cancer prevention. It contains synthetic estrogen to protect women from bone weakness and maintain a healthy heart.

For many women menopause has been a worrying and difficult time of life. She needs to be conscious of her own self-worth, strength, and wisdom. It is the Rites of Passage were women should go for natural remedies.

1.1 NEED FOR THE STUDY

“From birth to age 18 a girls need good parents, from 18 to 35 she needs good looks, from 35 to 55 she needs a good personality, and from 55 on she needs good cash.”

- **Sophia Tucker**

“Women don’t realize how powerful they are”

- **Judith light**

Women experience various turning points in their life cycle, which may be developmental or transitional. Midlife is one such transitional period which brings about important changes in women. Menopause is a unique stage of female reproductive life cycle, a transition from reproductive to non reproductive stage.

Menopause is said to be a universal reproductive phenomenon, which can be perceived as unpleasant. This period is generally associated with unavoidable manifestation of aging process in women. Menopause may be smooth experience for some women with only symptom of cessation of menstrual flow while others face one or more of post menopausal symptom. In present era with increased life expectancy, women are likely to face long periods of menopause accounting to approximately a third of her life.

In the developed world, mean life expectancy for women since 1990 has increased from 50 to 81 years. The life expectancy of the population around the world

is estimated to be 75-80 years. Today, there are over 200 million postmenopausal women worldwide and 40 million in India. According to the **World Health Organization** they estimated that by 2025 there will be 1.1 billion women above the age of 50 years experiencing menopause and the average age of experiencing the symptoms of menopause is 47.5 years.

According to **Indian Menopause Society Research** there are about 65 million Indian women over the age of 45 and estimated that in the year 2026, the population in India will be 1.4 billion, people over 60 years will be 173 million and the menopausal population will be 103 million. The average age of Indian menopausal women is 47.5 years:

A study was conducted to establish the age at onset of menopause and the prevalence of menopause and menopausal symptoms in South Indian women. 352 postmenopausal women attending the outpatient clinics of obstetrics and gynecology department of Dr TMA Pai Hospital, a tertiary care Hospital in South India, were included in the study. The Menopause-Specific Quality of Life (MENQOL) questionnaire was used for analysis and data were presented as percentages for qualitative variable. The study results revealed that the mean age at menopause was 48.7 years. Most frequent menopausal symptoms were aching in muscle and joints, feeling tired, poor memory, lower backache and difficulty in sleeping. The vasomotor and sexual domains were less frequently complained when compared to physical and psychological domains. The study concluded that the age at onset of menopause in southern Karnataka (India) is 48.7 years which is four years more than the mean menopause age for Indian women.

Menopause is a natural process, almost all women during and after the menopause suffer from typical symptoms with approximately 40% seeking a medical help for various symptoms like vasomotor, psychological, urogenital, musculoskeletal symptoms. Recent studies failed to show the protective effect of hormone replacement therapy in reducing the risk of coronary artery disease and have revealed an increased risk of heart disease, stroke and invasive breast cancer. So there is a need of natural approaches to relieve menopausal discomfort and soya is considered as “super food” for relieving menopausal symptoms.

Soya bean is commonly called wonder bean since it is an excellent source of nutrients such as proteins, fats, carbohydrates, vitamins and minerals. It contains 43gm of protein per 100 gm of soya which is the highest among the pulses. It also contains 19.5gm of fat, 21gm of carbohydrate and provides 432 kcal per 100gm. Soya bean also contains a family of chemical compounds called phytoestrogens. Phytoestrogens have chemical structures similar to the estrogens produced in the body and it is believed that eating foods rich in phytoestrogens can help alleviate low estrogen production in the body. Isoflavones are the active ingredients in soya beans which have estrogen-like properties. Isoflavones reduce menopausal symptoms, blood cholesterol level, incidence of cancer and osteoporosis. Eating 100gm of soya protein per day provides 200 mg of soya isoflavones. A target range of 80-160 mg of isoflavones per day is needed for adequate relief of menopausal symptoms. Soya bean is used extensively as human food, animal feed and for industrial purposes. All the products of soya bean are of dietary importance such as soya bean cheese, soya bean milk, soya bean oil, soya bean meal.

Some types of soya protein content foods are yellow split peas, black turtle bean, Red Kidney beans, Red lentils, soya beans, sesame seeds, sunflower seeds, pumpkin seeds, and broccoli parsley, Raspberries, Apple, Pears and Plums. Some complementary therapies are available. Such as yoga programmed Acupuncture, Acupressure, Hypnotherapy, Aromatherapy, Reflexology and homeotherapy. Many women like the use of herbal remedies as a more natural way of managing their menopausal symptoms than conventional medicines. Some herbs may have estrogenic properties. Its phytoestrogens (Isoflavones) are naturally occurring, for relief of menopausal symptoms. Oestrogen like compounds derived from plants for more than 20 years. Isoflavones are found in beans and pulses particularly soya beans and soya products. So I provided the Red color Kidney shaped bean. 100 gram Red Kidney beans with salt, cooked and boiled beans nutritional value is 225 calories, fat 0.88gram, carbohydrate 40.36gram, protein 15.35gram, calcium 5%, iron 29%, and vitamin c 4%. (Ralph).

Atmaca (2008) conducted a double randomized study in tertiary care centre united states to assess the effect of soya protein containing isoflavones on quality of life in post menopausal women. A sample of 93 healthy, ambulatory women were randomly assigned to receive 20 gm of soya protein containing 160 mg of isoflavones versus matched placebo (20gm whole protein milk) and quality of life was assessed by menopause-specific quality of life questionnaire. The study results revealed that there was a significant improvement in all 4 quality of life scales (vasomotor, psychosexual, physical and sexual) among the women taking soya protein and no changes were seen in placebo, the study concluded that use of soya isoflavones as an alternative to estrogen therapy may be potentially safe and seeming safe in women who are looking for relief from menopausal symptoms.

Soya also helps to promote better health and has gain health benefits in preventing metabolic disorders, cancer and cardiovascular conditions. This motivated the investigator to assess the effect of soya protein on menopausal symptoms.

1.2 STATEMENT OF THE PROBLEM

“A study to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women inSamayanallur at Madurai.”

1.3 OBJECTIVES OF THE STUDY

1. To assess level menopausal symptoms among women in control and experimental group in Samayanallur at Madurai.
2. To evaluate the effectiveness of soya protein consumption on menopausal symptoms among women inSamayanallur at Madurai.
3. To find the association between menopausal symptoms with selected demographic variables in control and experimental group in Samayanallur at Madurai.

1.4 HYPOTHESES

H₁: There is a significant difference in the level of menopausal symptoms before and after soya protein consumption among women incontrol and experimental group.

H₂: There is a significant association between level of menopausal symptoms and selecteddemographic variable among womenincontrol and experimental group.

1.5 OPERATIONAL DEFINITIONS

Effectiveness

In this study effectiveness refers to outcome of soya protein consumption on reducing the menopausal symptoms among women as measured by Menopausal Rating Scale developed by Heinemann (2003).

Soya protein

In this study it refers to soya protein is one of the plant protein. It contains genistein and isoflavones. It acts like estrogen which is produced naturally in the body. These plant estrogens are thousands of time higher than natural estrogen. It helps to reduce the menopausal symptoms. 60gm cooked soyabean given daily for 4weeks.

Menopausal symptoms

In this study it refers to symptoms associated with menopause (hot flashes, heart discomfort, sleep problems, depressive mood, irritability, anxiety, physical and mental exhaustion, sexual problems, bladder problems, dryness of vagina, joint and muscular discomfort) as listed in Menopausal Rating Scale developed by Heinemann (2003).

Women

In this study it refers to women who were in the age group of 45-56 years in Samayanallur at Madurai.

1.6 ASSUMPTIONS

The study assumes that

- women will suffer from menopausal symptoms.
- women are not aware that soya protein will reduce the menopausal symptoms
- reduction of menopausal symptoms may improve the quality of life of menopausal women.

1.7 DELIMITATION

1. The study is limited to menopausal women of Samayanallur only
2. This study is limited to 4 weeks only.

1.8 PROJECTED OUT COME:

The results of the study will give strong evidence that soya protein consumption will reduce the menopausal symptoms among the women. This type of non-invasive alternative and complementary therapy will be useful for the menopausal women to reduce the menopausal symptom. Hence this study will motivate the health care professionals to implement this soya protein consumption.

Review of Literature

CHAPTER - II

REVIEW OF LITERATURE

Review of literature involves systematic identification, location, scrutiny and summary of written materials that contain information on research problem. The literature review is based on an extensive survey of books, journals and international nursing index. Research and non-research literature were reviewed to broaden the understanding and gain insight into the problem under study.

The literature relevant to this study was reviewed and arranged in the following

- 1. Literature related to Menopause.**
- 2. Literature related to soya protein consumption.**
- 3. Literature related to effect of soya protein consumption on menopausal symptoms.**

1. LITERATURE RELATED TO MENOPAUSE

Most women can expect to live into their ninth decade with changes that accompany aging. Especially those associated with the menopause can be a source of anxiety. Menopause is a natural event in the course of every woman's life it is a time of last period but symptoms can begin several years before that these symptoms can last for months or years. Sometimes around 40 years, the women notice that her menstruation is different in its duration, frequency and amount of bleeding. Changing levels of estrogen and progesterone which are the two female hormone produced in the ovaries, might lead to these symptoms (**National Institute of Aging, 2006**).

According to North American Menopause Society (2000), the average age for the onset of perimenopause is 47.5 years and natural menopause occurs at the age of 51.4 years in western women. In rural North India, **Singh and Arora (2005)** found that the average age at menopause is 44.1 years. There were many studies reported the mean age of menopause between 45 to 55 years. **Quazi (2006)** reported it as 50 years. **Dhillon Singh, Hamid and Mahmood (2001)** document it as 49.4 + 3.4 years. **Chim, Tan, Ang, Chew, Chowg and saw (2002)**, in their study mentioned as average range of **40 to 59 years** with the mean of 49 years.

Marcio L. Griebeler. (2010), conducted a cross sectional study in China to investigate the factors associated with hot flashes in perimenopausal (N= 817), and postmenopausal (N=582) women 40-60 years old. Among postmenopausal women, an omnivorous diet decreased the prevalence of hot flashes OR=0.38; 95% CI=0.07-0.85.

C.Nagata, (2010) conducted a study to evaluate the cross-sectional relationships of diet and other lifestyle variables to menopause. A total of 4186 female residents aged 45-55 in Takayama City, Japan, responded to a self-administered questionnaire (the response rate was 89.3%). Diet in the past year was assessed by semi quantitative food frequency questionnaire. Using the logistic regression model, associations between study variables and menopausal status were estimated in terms of odds ratio (OR). The study result shows that Nulliparity and lower relative weight were significantly associated with menopause after controlling for age ($P < 0.05$). The association of smoking with menopause was marginally significant after controlling for age ($P = 0.06$). Higher intakes of fat, cholesterol, and coffee were inversely and significantly associated with later menopause after controlling for age, total energy,

parity, menarche age, and relative weight (ORs for the highest tertiles of fat, cholesterol and coffee intakes were 0.78, 0.79, and 0.70, respectively, $P < 0.05$). The highest tertiles of calcium and soy product intakes were significantly associated with menopause after controlling for the covariates (ORs = 1.25 and 1.42, respectively, $P < 0.05$). The study concluded that dietary factors appear to be associated with onset of menopause.

Shalin Yadega, (2009) conducted a cross sectional study on 500 postmenopausal women from rural areas attending OBG clinic at Government Medical College, Jammu India. This study showed that the mean age of menopause was 49.35 years and the predominant symptoms were fatigue and lack of energy 70%, rheumatology related symptoms 60%, Cold sweats, Weight gain, Irritability and nervousness 50%. Dyslipidemia was seen in 39% and metabolic syndrome in 13%. In this study group 10% had a hectic lifestyle, 55% sedentary and 35% had moderate lifestyle. Only 5% of women received Hormonal Replacement therapy. Among these women 2.4% were hypertensive, 9% diabetic and 8% of them had dyslipidemia. The study concluded that there is an alarmingly high prevalence of cardiovascular risk factors especially diabetes, hypertension, dyslipidemia and obesity in postmenopausal women from rural areas.

Jones G L, Sutton A (2009) conducted a study to assess the quality of life in obese postmenopausal women. The aim of this review was to identify the ways in which obesity affects the health-related quality of life of postmenopausal women. This was considered important because a growing body of literature has identified obesity as a significant predictor for a poor psychological wellbeing and negative HRQoL, particularly in women, and because during the transition through the

menopause women tend to accumulate more body weight. After searching eight electronic databases, only nine papers appeared meaningful. Although a meta-analysis was not possible, we found that a body mass index >30 kg/m² was associated with a poor HRQoL in postmenopausal women; particularly in the areas associated with physical functioning, energy and vitality, and health perceptions. Thus, clinical management of obese postmenopausal women should focus on weight reduction and exercise in an attempt to improve wellbeing in these areas.

Kevan Richard (2009) conducted a study to assess the quality of sexual life and menopause. The importance of female sexual fulfillment is increasingly recognized in today's society. Women's sexual lives continue well into the menopausal years and beyond; however, the impact of menopause on the quality of that sexual life has not been comprehensively studied in the medical literature. This review attempts to clarify the impact of the physiological, psychological and psychosocial changes occurring at midlife that may affect women's quality of sexual life. Pharmaceutical and psychological interventions that may assist in improving the quality of sexual life of menopausal women are discussed. Contrary to popular expectation, there is a substantial prevalence of sexual activity among middle-aged women, and the majority of middle-aged women express satisfaction with the quality of their sexual lives.

Avis N E, Colvin (2009) did a study to assess the changes in health related quality of life during the time of menopausal transition. The study was done with the sample of 3302 who were between the age group of 42 to 52 years. The findings of the study revealed the little impact of menopausal transition on health related quality of life.

Suzanne (2009) published a study on postmenopausal women's loss of sexual desire effects health, quality of life. The study was done through telephone interview with 1189 postmenopausal women by using quality of life surveys. The study result shown between 9% and 26% of women suffer with the loss of sexual desire and it is mainly depends on the age and the menopausal stage.

Amanda J Welton (2008) conducted a cross sectional study among postmenopausal women aged 50 to 69 to assess the effect of combined hormone replacement therapy (HRT) on health related quality of life. Health related quality of life and psychological wellbeing as measured by the women's health questionnaire. After one year small but significant improvements were observed in three of nine components of the women's health questionnaire for those taking combined HRT compared with those taking placebo. Hot flushes were experienced in the combined HRT and placebo groups by 30% and 29% at trial entry and 9% and 25% at one year, respectively. No significant differences in other menopausal symptoms, depression, or overall quality of life were observed at one year. Combined HRT started many years after the menopause can improve health related quality of life.

Mary C, Mark D (2008) has conducted a cross sectional study to assess the quality of life and related factors to impairment of quality of life among postmenopausal women. Cluster sampling technique was used and the data was collected from 480 postmenopausal women by using MENQOL scale. The study revealed that the menopause causes poor quality of life which is dependent to the work of the women and socio demographic variables.

Mahadeen A.I. (2008) did a study to describe the perceptions of Jordanian midlife women about making the menopausal transition. Audio taped interviews were

conducted with 25 peri-menopausal Jordanian women. Interviews were analyzed as appropriate for descriptive qualitative inquiry. The major theme generated was 'A Life Transition', which included: a time of no more reproductive obligations, changing from the burdens and obligations of reproductive roles and responsibilities to freedom, relief and rest; a time for managing peri-menopausal symptoms; and a time for growing into a wise woman and accepting aging as a part of life.

Young, Rabago, (2007) objectively measured the sleep quality among 589 premenopausal, perimenopausal, postmenopausal women. Sleep quality was measured by polysomnography and self reported sleep problems. Results revealed that the quality of sleep was not worse in perimenopausal compared with premenopausal women.

Jeremy (2007) done a study to determine the age of attaining menopause among Indian women and they found that 3.1 percent about 17 million of Indian women are attaining menopause between the ages of 30 and 34, 8 percent are in the age of 39 and 19 percent have attained in the age of 41 years. Medical experts say that natural menopause occurs in between the ages of 45 and 55 and the mean age is 51.

Sharma S. (2007) conducted a cross-sectional study on perceptions regarding menopause, prevalence of menopausal symptoms and association of family environmental factors with menopausal symptoms among 100 postmenopausal and 100 perimenopausal rural women in south India. 57% of postmenopausal women perceived menopause as convenient. The study findings revealed that 69% of them complained of diminishing abilities after menopause 23% felt that sexual life ends with the onset of menopause, 16% reported that their husbands had become disinterested in them after menopause and 11% were apprehensive about the loss of

femininity. A higher proportion of menopausal women reported hot flushes, night sweats, urge incontinence and other somatic symptoms. They concluded that there was significant associations between multiple somatic symptoms, vasomotor symptoms, urge incontinence, loss of sexual desire, and menopause.

Tandon.RV. (2007) conducted a cross-sectional study on factors associated with menopausal symptoms and their relationship with the quality of life. Data was collected from 886 women of mean age 48.62 years with a questionnaire including demographic variables, quality of life and menopause symptom checklist. The study revealed statistically significant variables like health problems, recent life stresses, absence of relaxation methods, number of pregnancies, inadequate and unbalanced nutrition, age and dissatisfaction in marriage. There was negative relation between menopausal symptom scores and quality of life scores. Study recommended that stress management and health-promoting practices should be incorporated into menopausal care programmes to improve health and quality of life of middle aged women.

Kakkar V, Kaur D et al. (2007) conducted a cohort study to find out the variation in menopausal symptoms with age, education and working/non working status in North-Indian sub population. The MRS scale, a self administered standardized questionnaire was applied with additional patients related information for analysis. The results were evaluated for psychological, somatic and urogenital symptoms. Average age at which menopause set in the cohort was found to be 48.7 ± 2.3 yrs. The cohort was divided into peri (35-45) menopausal, early menopause (46-51) and the postmenopausal (52-65). A significantly higher % of perimenopause women (36%) showed a psychological score ≥ 7 while a higher % of postmenopausal women showed somatic score and urogenital score ≥ 7 . Working women suffer more from

psychological symptoms whereas nonworking women showed a greater incidence of somatic symptoms. Educated women showed a lower incidence of psychological and somatic symptoms. Thus, the study concludes that age; level of education and working/non working status may also contribute to significant variation of menopausal symptoms.

Peter Chedrauiab (2006) evaluated the quality of life and determined the factors related to its impairment among postmenopausal Ecuadorian women. Postmenopausal women that participated in a metabolic syndrome screening and educational program at the Institute of Biomedicine of the Universidad Católica of Guayaquil, Ecuador were interviewed using the Menopause-Specific Quality of Life Questionnaire. Mean domain scores as well as factors associated to higher scores within each of the domains of the questionnaire (vasomotor, psycho-social, physical and sexual) were determined. Three hundred twenty-five postmenopausal women were surveyed. More than 50% of women had scores above the median for each domain of the questionnaire. In this postmenopausal Ecuadorian population, impairment of quality of life was found to be associated to age and related conditions such as abdominal obesity, hypertension and hyperglycemia.

Chaudary (2005) conducted a study in Ahmedabad on postmenopausal women for evaluation of osteoporosis. Average age of menopause was 46.7 years and women were +4 years (those who passed menopause 4 years back). Results showed severe osteoporosis were found in women from age 60 and above, most of them with moderate osteoporosis and majority required surgical treatment with added risk of surgery and anesthesia.

According to Jog (2005) conducted a study to assess the Bone Mineral Density (BMD) of women in post-menopausal age. Early detection of osteopenia and osteoporosis and its appropriate management was dealt in the study. Measurement of BMD was done in postmenopausal women (min. 2 years). Appropriate advice regarding diet, exercises and medication was given depending upon T-score and Z-score. Follow up BMD was done every year for 3 years. It was found that osteopenia responds better than they proved that Osteoporosis shows slow improvement and regular exercise gives early results.

Young kin & Davis, (2004) conducted a study to compare the non-pharmacological measures for the menopausal symptoms. Such as avoidance of caffeine, smoking, wearing cotton clothes is the measures for hot flushes. Exercising regularly in the morning or early evening, doing quiet activity just before the bedtime, sleeping in a comfortable environment, avoidance of sleeping medications, limited food intake prior to sleep are the measures for sleep problems and night sweats. Consuming calcium contained food items to minimize the joint and back discomforts. Stress reduction techniques are helpful for the psychological problems. Seeking medical help are for the sexual and urinary problems. They concluded that these the non-pharmacological measures are useful.

Smith, (2002) reported that immediate changes of menopause are hot flushes in the chest, face, neck and back, insomnia, mild to moderate depression, bone, joint, muscle aches, swelling, heart beat fluctuations, headache, vagina dryness and increased swelling.

Chim H, Tan BH et al, (2002) conducted a population based survey with a representative sample of 495 Singaporean migrant women aged 40 to 60 to determine

the prevalence of 17 menopausal symptoms. The mean age of participants was 49 years and the classical menopausal symptoms found were hot flushes (17.6%), vaginal dryness (20.7%) and night sweats (8.9%). The most prevalent symptom reported was low backache with aching muscle joints (51.4%). The most well-known effect of these is the "hot flash" or "hot flush", a sudden temporary increase in body temperature. They found that the symptoms were reported due to hormonal changes underlying menopause, which are caused by aging, other health states, psychosocial factors and life style.

2. LITERATURE RELATED TO SOYA PROTEIN CONSUMPTION

J.Lissa, (2011) conducted a randomized cross-over clinical trial to determine the effects of soya bean consumption on markers of inflammation and endothelial function in postmenopausal women with the metabolic syndrome. This study included postmenopausal women with the metabolic syndrome. Participants were randomly assigned to consume a control diet (Dietary Approaches to Stop Hypertension [DASH]), soya protein diet, or soya nut diet, each for 8 weeks. Red meat in the DASH diet (one serving/day) was replaced by soy protein in the soya protein diet and by soya nut in the soya nut diet. The results for nitric oxide levels, the difference from the control diet was 9.8% ($P < 0.01$) on the soya nut and -1.7% ($P = 0.10$) on the soy protein diets. The difference from the control diet for serum E-selectin was -11.4% ($P < 0.01$) on the soya nut consumption and -4.7% ($P = 0.19$) on the soya protein diet. Soya nut consumption reduced interleukin-18 compared with the control diet (difference from the control diet: -9.2% , $P < 0.01$), but soya protein did not (difference from the control diet: -4.6% , $P = 0.14$). For C-reactive protein, the difference from the control diet was -8.9% ($P < 0.01$) on the soya nut diet and -1.6% ($P < 0.01$) on the soya protein diet. The results revealed that Short-term soya nut

consumption reduced some markers of inflammation and increased plasma nitric oxide levels in postmenopausal women with the metabolic syndrome.

Silvina Levis, (2010) conducted a prospective clinical 6 week trial study was conducted in Australia enrolled 25 postmenopausal women who received a diet supplemented with soy flour, red clover sprouts or linseed each for 2 week in turn. Vaginal maturation value is increased after the 2 week soy rich diet ($P < 0.05$) but not after red clover or linseed.

Sharon R. Akabas, (2010) conducted a prospective clinical trials study in a United States 19 postmenopausal women 45-65 years old were randomized to soya foods, substituting one-third of their caloric intake, or usual diet for 4 week. One main dish made from whole soy beans or texturized vegetables soy protein was supplied by the study to provide a daily intake of 165mg of conjugated isoflavones. Compliance with the soya diet was 73%. In 68% of the women consuming soya foods, the percentage of superficial cells, an indication of the control group, did not change; it increased in 19% and decreased in 13%. Among the women in the control group, 71% showed no change, 8% had an increase, and 21% had a decrease. These differences were not significant.

Marica L Griebeler (2010) conducted a clinical trial study in Canada, 99 women aged 45-60 years and menopausal for 1-8 year were enrolled in a 16 week study of quality of life and hot flash frequency and severity. They received 1 muffin daily containing soy, wheat, or flaxseed flour. Soya muffins contained 25 gram of soya flour, supplying 42 mg of isoflavones daily. Among the 87 women who completed the trial, there was no significant difference in the frequency and severity of hot flashes between treatment groups.

Shu XO, Zheng Y et al, (2009) conducted a case cohort study to assess the association of soy food intake after diagnosis of breast cancer with mortality and cancer recurrence among 5042 female breast cancer survivors in china. Women aged 20 to 75 years with diagnoses between March 2002 and April 2006 were recruited and followed up through June 2009. Information on cancer diagnosis and treatment, life style exposures after cancer Diagnosis and disease progression was collected at approximately 6 months after cancer diagnosis and was reassessed at 3 follow-up interviews conducted at 18, 36, and 60 months after diagnosis. Annual record linkage with the Shanghai Vital Statistics Registry database was carried out to obtain survival information for participants who were lost to follow-up. Medical charts were reviewed to verify disease and treatment and total mortality and breast cancer recurrence or breast cancer-related deaths. Cox regression analysis was carried out with adjustment for known clinical predictors and other lifestyle factors. Soy food intake was treated as a time-dependent variable. The study results revealed that during the median follow-up of 3.9 years (range, 0.5-6.2 years), 444 deaths and 534 recurrences or breast cancer-related deaths were documented in 5033 surgically treated breast cancer patients. Soya food intake, as measured by either soy protein or soya isoflavone intake was inversely associated with mortality and recurrence. The hazard ratio associated with the highest quartile of soy protein intake was 0.71 (95% confidence interval [CI], 0.54-0.92) for total mortality and 0.68 (95% CI, 0.54-0.87) for recurrence compared with the lowest quartile of intake. The multivariate-adjusted 4-year mortality rates were 10.3% and 7.4%, and the 4-year recurrence rates were 11.2% and 8.0%, respectively, for women in the lowest and highest quartiles of soy protein intake. The inverse association was evident among women with either estrogen receptor-positive or -negative breast cancer and was present in both users

and nonusers of tamoxifen. The study concluded that, soya food consumption was significantly associated with decreased risk of death and recurrence among women with breast cancer.

Sun J (2006) conducted a clinical trial study to determine the efficacy of a morning/evening menopause formula (morning capsule contains panax ginseng, black cohosh, soya and green tea extracts; evening capsule contains black cohosh, soya, kava, hops, and valerian extracts) for relieving menopausal symptoms such as hot flashes and sleep disturbance. Healthy postmenopausal women, between 45 and 65 years of age, were asked to take the menopause formula orally, one capsule of the morning formula every morning and one capsule of the evening formula every evening for 2 months. The Greene Climacteric Scale (GCS) and the Pittsburgh Sleep Quality Index (PSQI) were used to determine the efficacy. Morning/evening menopause formula significantly reduced the number of hot flashes. The reduction in the number of hot flashes was observed as early as at the end of the second week. At the end of the second week, the number of hot flashes was reduced by 47%. The morning/evening menopause formula also significantly reduced the GCS total and subscale scores. At the end of the eighth week, the vasomotor, anxiety, and depression scores of GCS were reduced by 50%, 56%, and 32%, respectively. Furthermore, the morning/evening menopause formula significantly reduced global PSQI score and scores in five components (sleep quality, sleep latency, sleep duration, sleep disturbance, and daytime dysfunction) by 18%-46%. This study suggests that the morning/evening menopausal formula is safe and effective for relieving menopausal symptoms including hot flashes and sleep disturbance.

Jang He. (2005) conducted a randomized, double-blind, controlled trial was conducted on China to examine the effect of soya protein supplementation on blood pressure in persons with pre hypertension or stage hypertension. 302 participants 35 to 64 years of age with an initial untreated systolic blood pressure of 130 to 159 mm Hg, diastolic blood pressure of 80 to 99 mm Hg, or both were randomly assigned to receive 40 gm of isolated soya protein supplements per day or complex carbohydrate control for 12 weeks. Blood pressure measurements were obtained by using random-zero sphygmomanometers at baseline at 6 and 12 weeks. The study result revealed at baseline, the mean systolic and diastolic blood pressures were 135.0 mm Hg (SD 10.9) and 84.7 mm Hg (SD 6.9), respectively. Compared with the control group, the net changes in systolic blood pressure and diastolic blood pressure were -4.31 mm Hg (95% CI, -2.11 to -6.51 mm Hg; $P < 0.001$) and -2.76 mm Hg (CI, -1.35 to -4.16 mm Hg; $P < 0.001$), respectively, after the 12-week intervention. The net changes in systolic and diastolic blood pressure reductions were -7.88 mm Hg (CI, -4.66 to -11.1 mm Hg) and -5.27 mm Hg (CI, -3.05 to -7.49 mmHg), respectively, in persons with hypertension and -2.34 mmHg (CI, 0.48 to -5.17 mm Hg) and -1.28 mm Hg (CI, 0.52 to -3.07 mm Hg), respectively, in those without hypertension. The study concluded that Soya bean protein supplementation resulted in a reduction in systolic and diastolic blood pressure and increased intake of soya protein may play an important role in preventing and treating hypertension.

Xianglan Zhang, Xiao ouShu et al, (2003) conducted a population-based prospective cohort study of 75,000 Chinese women aged 40–70 years a baseline survey was conducted from 1997 to 2000 in Japan to examine the relationship between soya food intake and incidence of coronary heart disease (CHD). Participants included in this study were 64,915 women without previously diagnosed CHD, stroke,

cancer and diabetes at baseline. Information on usual intake of soya foods was obtained at baseline through an in-person interview using a validated food-frequency questionnaire. Cohort members were followed biannually through in-person interviews. After a mean of 2.5 yrs (162,277 person years) of follow-up, 62 incident cases of CHD (43 nonfatal myocardial infarctions and 19 CHD deaths) were documented. There was a clear monotonic dose-response relationship between soya food intake and risk of total CHD (P for trend = 0.003) with an adjusted relative risk (RR) of 0.25 (95% CI, 0.10–0.63) observed for women in the highest vs. the lowest quartile of total soy protein intake. The inverse association was more pronounced for nonfatal myocardial infarction (RR = 0.14; 95% CI, 0.04–0.48 for the highest vs. the lowest quartile of intake; P for trend = 0.001). This study provides, for the first time direct evidence that soy food consumption may reduce the risk of CHD in women.

Arezo Haghghian Roudsari, (2003), conducted a clinical trial study before and after type was carried out on 15 postmenopausal women 45-64 years of age. Women were given 35 gram soya protein per day for 12 weeks. Information on weight, height, body mass index, two 24 hour food consumption recall and physical activity were collected at the start, 6 and 12 weeks of the study. Soya protein at 35 g level containing 93.3mg Isoflavones were given to women daily. Women were provided with a special cup for measuring soya. Cooking instructions were also given to the women. Soya protein consumption resulted in a significant reduction in the urinary deoxypyridinoline and increasing of total alkaline phosphatase (P<.05), although the alterations in osteocalcin, c-telopeptide and type I collagen telopeptide were not significant. Mean age was 52.9± 4.3 years, years postmenopause 5.47±3.4 years and mean height 157.4±7.2 centimeters.

Vijayajeyagopal. (2002) conducted a study in the by department of medicine, university of hull, U.K to assess the effect of dietary supplement with soya protein and isoflavones on insulin resistance, glycemic control, and cardiovascular risk markers in women aged 56-69 with type 2 diabetes. A total of 32 women with diet-controlled type 2 diabetes completed a randomized, double blind, cross-over trial of dietary supplementation with phytoestrogens (soy protein 30 g/day, isoflavones 132 mg/day) versus placebo (cellulose 30 g/day) for 12 weeks, separated by a 2-week washout period. The study results revealed that Compliance with the dietary supplementation was >90% for both treatment phases. When compared with the mean percentage change from baseline seen after 12 weeks of placebo, phytoestrogen supplementation demonstrated significantly lower mean values for fasting insulin (mean \pm SD $8.09 \pm 21.9\%$, $P = 0.006$), insulin resistance ($6.47 \pm 27.7\%$, $P = 0.003$), HbA1c ($0.64 \pm 3.19\%$, $P = 0.048$), total cholesterol ($4.07 \pm 8.13\%$, $P = 0.004$), LDL cholesterol ($7.09 \pm 12.7\%$, $P = 0.001$), cholesterol/HDL cholesterol ratio ($3.89 \pm 11.7\%$, $P = 0.015$), and free thyroxin ($2.50 \pm 8.47\%$, $P = 0.004$). The study concluded that dietary supplementation with soya phytoestrogens favorably alters insulin resistance, glycemic control, and serum lipoproteins in postmenopausal women with type 2 diabetes, thereby improving their cardiovascular risk profile.

Kawakami N (2001) conducted a clinical trials study in Israel recruited 145 women ages 43-65 years to receive a soya rich diet or usual diet in a 2:1 ratio for 12 week. The dietary intervention consisted of daily consumption of food known to contain high concentrations of soy isoflavones and included tofu, soya drink, and miso plus flaxseed, substituting one-fourth of their caloric intake. Participants were evaluated with the Menopause Symptom Questionnaire, which includes questions on vasomotor and genitourinary symptoms. Although 82% of the women reported eating

all or part of their assigned foods, the study does not report the actual amount consumed. Hot flashes and vaginal dryness scores were significantly reduced in both groups.

3. LITERATURE RELATED TO EFFECT OF SOYA PROTEIN CONSUMPTION ON MENOPAUSAL SYMPTOMS

Cheng G, Wilczek B et al (2011) conducted a double-blind prospective study to evaluate the soya Isoflavone treatment for acute menopausal symptoms among sixty healthy postmenopausal women who were randomly assigned by computer into two groups to receive 60 mg soya isoflavones or placebo daily for 3 months. Climacteric symptoms were recorded before and after treatment, the study results revealed that hot flushes and night sweats were reduced by 57% and 43%, respectively. They concluded that soya isoflavones could be used to relieve acute menopausal symptoms.

Kyoko Taku, Melissa K. Melby et al (2010) conducted a clinical trials study to searched for relevant articles reporting double-blinded randomized controlled trials. This systematic review and meta-analysis, which evaluated the effects of isoflavones on the frequency, severity, or composite score (frequency ×severity) of hot flashes compared with placebo was conducted according to Cochrane Handbook guidelines. From 277 potentially relevant publications, 19 trials (reported in 20 articles) were included in the systematic review (13 included hot flash frequency; 10, severity; and 3, composite scores), and 17 trials were selected for meta-analyses to clarify the effect of soyabeanisoflavones on hot flash frequency (13 trials) and severity (9 trials). Meta analysis revealed that ingestion of soyaisoflavones (median, 54 mg; aglycone equivalents) for 6 weeks to 12 months significantly reduced the frequency (combined

fixed-effect and random effects model) of hot flashes by 20.6% (95% CI, j28.38 to j12.86; P G 0.00001) compared with placebo (heterogeneity P =0.0003, I2 = 67%; random effects model). Meta-analysis also revealed that isoflavones significantly reduced hot flash severity by 26.2% (95% CI: j42.23 to j10.15, P = 0.001) compared with placebo (heterogeneity, P G 0.00001, I2 = 86%; random effects. Isoflavone supplements providing more than 18.8 mg of genistein (the median for all studies) were more than twice as potent at reducing hot flash frequency than lower genistein supplements. Soyaisoflavone supplements, derived by extraction or chemical synthesis, are significantly more effective than placebo in reducing the frequency and severity of hot flashes.

Chedurui P, San Miguel et al (2010) conducted a study to evaluate the effect of soya-derived isoflavones over hot flushes, menopausal symptoms and mood in climacteric women with increased body mass index. Fifty symptomatic climacteric women aged 40 to 59 with increased BMI (≥ 25) were recruited to receive oral 100 mg/day of soya derived isoflavones for 3 months. Hot flushes (frequency/intensity), menopausal symptoms (Menopause Rating Scale [MRS]) and mood (Hamilton Depressive Rating Scale [HDRS]) were evaluated at baseline and at 90 days. Study results After 3 months of soya isoflavone supplementation revealed that hot flushes significantly decreased in percentage, number and severity (100% to 31.1%; 3.9 ± 2.3 to 0.4 ± 0.8 and 2.6 ± 0.9 to 0.4 ± 0.8 , respectively, $p < 0.001$). MRS scores (total and for subscales) reflecting general menopausal symptoms also significantly decreased compared to baseline. Regarding mood, after three months total HDRS scores and the rate of women presenting depressed mood (scores ≥ 8) significantly decreased (16.3 ± 5.4 to 6.9 ± 5.2 and 93.3% to 28.9%, respectively, $p < 0.05$). the study concluded that

In high risk climacteric population, soya derived isoflavone treatment improves mood as well as vasomotor and general menopausal symptoms.

Duru shah, Sangeetha Agrawal, (2009) conducted a prospective randomized double blind study to evaluate the effect of herbo mineral phytoestrogen formulation containing soya isoflavones in Indian women with signs and symptoms of menopause among 60 peri and post menopausal women in a public hospital. Women with symptoms related to menopause were randomized to either group A or group B(placebo) menopausal symptoms were graded along a scale of Kupper man index at base line and changes were noted every 2 months and there after for a total of 6 months. The group that received herbo mineral phytoestrogen showed 40% of improvement in psychological symptoms compared to placebo group. Improvement was noted in vasomotor symptoms, symptoms relating to sexual activity and urinary symptoms in group A Study concluded that herbo mineral phytoestrogen containing soya isoflavones is effective in management of symptoms in menopausal women.

Song Y, Palik HY et al, (2008) conducted a longitudinal study among 34 women to investigate effect of soybean and isoflavone intake on bone mineral density (BMD) and its change among young Korean women over 2 years, The BMD was measured 3 times with 1-year intervals by dual x-ray absorptiometry at the lumbar spine and femur (neck, Ward's triangle [WT], and trochanter). Dietary intake was assessed up to 8 times by 24-hour recall with average 4-month interval. During, this study period that, BMD increased significantly for lumber spine and WT (2.5% and 5.2%). The average daily intake of soya beans and isoflavones was 39 gm and 8 mg, respectively. Soyabean intake and total isoflavone intake had positive correlation on femoral neck (FN) and WT. By longitudinal mixed-model regression analysis, BMD

increased 0.26% per 1 mg of isoflavone intake per year in the FN and 0.31% for WT (P = .05 and .008). They concluded that soybean and isoflavone intake have a positive effect on the change of BMD on the FN and WT among young Korean women.

Basaria S, Wisniewelci, (2008) conducted a clinical trial study to examine the safety and efficacy of an oral soya isoflavone extract on 177 postmenopausal women (mean age 55 years) experiencing five or more hot flashes per day. In this double-blind, placebo-controlled study the women were randomized to receive either soy isoflavone extract or placebo. Analysis after 12 weeks showed a statistically significant reduction in average hot flash severity and frequency in the soya isoflavone group compared with the placebo group. In addition, decreases in the incidence and severity of hot flashes occurred as soon as 2 weeks in the soya group; whereas, the placebo group experienced no relief the first four weeks.

Kakkar V (2007) conducted a double blind, placebo controlled trial study to examine effects of 6 months supplementation of isoflavone rich soya protein on menopausal symptoms, lipid profiles and bone density in postmenopausal women. In this study 100 healthy postmenopausal women not taking Hormone replacement therapy, were randomly assigned to consume either 25gm soya protein containing 75 mg isoflavones (study group) or 25 gm casein protein(control group) daily. Monthly assessment for acceptability & side effects, 3 monthly for menopausal symptoms (Kupperman Menopausal Index; KMI) and serum lipid-profile, 6 monthly for Follicular stimulating hormone, Estradiol levels, vaginal cytology, endometrial thickness and bone density were done. T-test, analysis of variance (ANOVA) and chi square tests were employed. In Result higher number of cases reported improvement

in hot-flashes, joint-pains and vaginal-dryness on soya treatment ($p < .05$). Soya supplement was significantly superior to placebo in reducing KMI ($p < .05$). Soya group showed 7.7% decrease in total cholesterol and 14% decrease in LDL study concluded that 25gm soya supplement containing 75mg of isoflavones may be an effective alternative therapy for menopausal symptoms and may offer a benefit to cardiovascular-system by altering lipid-profile favorably. Supplementation of Soya protein isolate containing phyto estrogens significantly decreases total and low density cholesterol and improves menopausal symptoms as compared to placebo.

De-Fu Ma, Li-Qiang Qin, Pei-Yu Wang, (2007) conducted a randomized controlled trials related to the effects of soyaisoflavone intake on spine bone mineral density or spine bone mineral content and performed meta-analysis with Review Manager 4.2 software. Ten studies with a total of 608 women were selected for meta-analysis. The spine bone mineral density in women who consumed isoflavones increased significantly by 20.6 mg/cm² (95% confidence interval: 4.5–36.6 mg/cm²) in comparison to that in women who did not consume isoflavones. Isoflavone intake vs placebo intake increased spine bone mineral content by 0.93 g (95% confidence interval: -0.37 to 2.24 g) with borderline significance. Increases in the spine bone mineral density with isoflavone intake of more than 90 mg/day and with treatment lasting 6 months were 28.5 mg/cm² (95% confidence interval: 8.4–48.6 mg/cm²) and 27 mg/cm² (95% confidence interval: 8.3–45.8 mg/cm²), respectively. Isoflavone intervention significantly attenuates bone loss of the spine in menopausal women. These favorable effects become more significant when more than 90 mg/day of isoflavones are consumed. And soy isoflavone consumption for 6 months can be enough to exert beneficial effects on bone in menopausal women.

Nahas EA, (2007) conducted a randomized, double-blind, placebo-controlled trial study among 104 post menopausal women to assess the effect of dietary soya supplementation on hot flashes in postmenopausal women. 51 patients took 40 gm of isolated soya protein daily and 53 patients took 60 gm placebo (casein) daily. The study lasted for 12 weeks and using analysis of covariance baseline in mean number of moderate to severe hot flashes including night sweats during treatment was analyzed. The study results revealed that in women taking soya had a 26% reduction in mean number of hot flashes by week 3 and 33% reduction by week 4 and 45% reduction by week 12 versus 30% reduction obtained with placebo group. Study concluded that soya protein diet reduces hot flashes in menopausal women.

Anja Jacobs (2007) conducted a randomized and placebo controlled studies to assessed the efficacy of isoflavone supplements to reduce vasomotor symptoms in menopausal women by reviewing all published randomized controlled trials. Systematic literature searches were carried out in 70 databases. Randomized and placebo controlled studies were included if they investigated the treatment of isoflavone supplements derived from soya or red clover on vasomotor symptoms in peri- or postmenopausal women for at least 12 weeks. Data were analyzed concerning outcome and methodological quality of the study. Twenty-three trials met the inclusion criteria, there of 17 investigated soyaisoflavones and 6 red clover isoflavones. Without exception, selected trials examining the effect of red clover isoflavones were already assessed in several meta-analyses and were therefore excluded from this evaluation. As the soyaisoflavone studies were very heterogeneous concerning interventions and outcome measures, meta-analysis could not be performed and trials were systematically assessed in a structured approach. Included soyaisoflavone studies had numerous quality deficiencies and did not consistently

show a reduction of flushes after treatment with soyaisoflavones. Therefore, there is no conclusive evidence, but only some indication of a benefit of soy isoflavones on hot flush frequency or severity.

Albertazzi et al(2006) conducted a randomized, double-blind, placebo-controlled trial to assess the effect of daily dietary supplementation of soya protein isolate powder on hot flashes in postmenopausal women. Age in the treatment group (n=51) was 48-61 years, while in the control group (n=53) it ranged from 45-62 years. The diets of the 104 women were supplemented with either 60 g soya powder (40 g isolated soya protein) or 60 g placebo (casein) daily for 12 weeks. By the end of the 12th week, women taking the soya protein isolate had a 45-percent reduction in daily hot flashes compared to a 30-percent reduction obtained with the placebo.

Faure ED, Chantre.P (2006) conducted a randomized, double-blind, 12-week study in Australia with 58 postmenopausal women compared soy flour, which contains daidzin, to wheat flour, which contains lignans. Both groups experienced a significant reduction in the frequency of hot flashes – 40 percent in the soy flour group and 25 percent in the wheat flour group. The reduction from soy flour occurred six weeks earlier than that produced by wheat flour. Vaginal cell maturation, plasma lipids, and urinary calcium remained unchanged.

Tomoko MD, somekawa et al, (2006) conducted a clinical trial study in 478 postmenopausal Japanese women. Estimated the daily intakes of isoflavones in the diets of 478 postmenopausal Japanese women who reported soy consumption. We recorded serum values of fasting total cholesterol, triglyceride, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and apolipoproteins. Bone mineral density was measured at the lumbar spine (L2–L4) by dual energy x-ray

absorptiometry. Women were assigned to two groups according to years since menopause (early and late postmenopausal groups), and each group was subcategorized into four groups according to dietary isoflavone intake. Relationships between isoflavone intake, menopausal symptoms, lipid profiles, and bone mineral density were examined in each group. The mean estimated intake of isoflavones among 478 women was 54.3 mg/day. With stepwise regression analysis we found that weight and years since menopause were significant independent predictors of bone mineral density. Bone mineral densities adjusted to years since menopause and weight were significantly different in the highest intake compared with lowest intake category ($P < .001$) within the early and late postmenopausal groups. In the early postmenopausal group, significant differences were found in palpitation and backaches between the high and low intake categories but were not significant in the late postmenopausal group.

Elkind Hirsh K (2005) conducted a randomized, double-blind, crossover study to evaluate statistically significant decrease in hot flashes occurred in 51 menopausal women consuming 20g soya protein (containing 34 mg isoflavones) in single or split dosages compared to placebo (20g complex carbohydrates). After six weeks, a significant improvement was observed for the perceived severity of vasomotor symptoms (i.e., hot flashes) in both soya groups compared with placebo, although in the “twice daily” group the effect was greater. This suggests having consistent circulating levels of phytoestrogens may be more efficacious than a single higher dose. In addition, significant improvements in lipid and lipoprotein levels, as well as blood pressure, were noted in the treatment groups.

Van Patten CL, Olivotto IA, Chambers GK, et al. (2005) conducted a randomized, double-blind, placebo-controlled clinical trial with 123 postmenopausal breast cancer survivors with hot flashes. Breast cancer patients may experience worsening of vasomotor symptoms due to chemotherapy, tamoxifen, and/or discontinuation of HRT. This study showed no significant difference in vasomotor symptoms between the soya (90 mg isoflavones daily) and placebo groups after 12 weeks; however, both groups had a significant reduction in hot flashes (30-percent reduction with soya, 40-percent reduction with placebo.) These results may not be extrapolated to a normal menopausal population due to the presence of chemotherapeutic medication.

Murkieset al, (2005) conducted a clinical trial studies were carried out on fifty eight postmenopausal women (age 54, range 30-70 years) with at least 14 hot flushes per week, that their daily diet supplemented with soy flour (n = 28) compared with wheat flour (n = 30) over 12 weeks. Hot flushes significantly reduced in the groups with soy and wheat flour (40% and 25% reduction, respectively < 0.001 for both) with a significant rapid response in the soya flour group in 6 weeks (P < 0.001) that continued. Menopausal symptom score decreased significantly in both groups (P < 0.05).

Hazel A. Philp (2003) conducted a randomized, double-blind, placebo-controlled study among 75 postmenopausal women (55 completed the study) experiencing at least seven hot flashes daily received either soya isoflavone extract (total of 70 mg genistin, the aglycone form of genistein, and daidzin, the aglycone form of daidzein, per day) or placebo. After 16 weeks, women taking the soya extract had a 61-percent reduction in daily hot flashes, versus a 21-percent reduction in the

placebo group. “Responders” (defined as patients whose hot flashes were reduced by at least 50 percent at the end of the treatment period) included 66 percent in the soya extract group and 34 percent in the placebo group.

Upmalis et al(2003) examined the safety and efficacy of an oral soy isoflavone extract on 177 postmenopausal women (mean age 55 years) experiencing five or more hot flashes per day. In this double-blind, placebo-controlled study the women were randomized to receive either soy isoflavone extract (total of 50 mg genistin and daidzin per day) or placebo. Analysis after 12 weeks showed a statistically significant reduction in average hot flash severity and frequency in the soy isoflavone group compared with the placebo group. In addition, decreases in the incidence and severity of hot flashes occurred as soon as two weeks in the soya group; whereas, the placebo group experienced no relief the first four weeks. Endometrial thickness, measured by ultrasound, did not change in either group.

Kang HJ, Ansbacher R, (2002) conducted a study to evaluate the effects of a 6 months soya rich diet on the vaginal epithelium of 187 menopausal women 39-60 years old in Italian. Participants were randomized to soya, oestrogen therapy or placebo. With the goal of providing 20-30mg/day of soya isoflavones, an intake comparable to the average consumption in Asian women, participants in the diet group were asked to add 1 soya food serving daily (soyamilk, miso, soup, tofu, etc) and a phytoestrogen food twice per week. The size of serving are not reported. Food diaries kept by the participants indicated a daily isoflavone consumption of 47mg, mostly from soya milk. Compliance in the study participants who remained in the study, assessed from pooled morning urine collected over 14 days, showed significantly higher urinary daidzein concentrations in the soya rich diet group. The

biggest increase in maturation value and karyopycnotic index was in the estrogen therapy group. These indices had a smaller but significant increase in the diet group and no change in the control.

CONCEPTUAL FRAMEWORK:

Conceptual framework deals with abstractions (concepts) that are assembled by virtue of their relevance to a common theme. Conceptualization is a process of forming ideas which is utilized and forms conceptual frame for development of research design. It helps the researcher by giving direction to go about entire research process.

Conceptual frame work facilitates communication and provides for a systematic approach to nursing research, education, administration & practice. Conceptual framework is a brief explanation of theory those portions of a theory which are to be tested in a study. It helps to organize the study and provide a context for the interpretation of the study results.

KENNY'S OPEN SYSTEM MODEL:

The study is based on J.W. KENNY'S OPEN SYSTEM MODEL (1991). All the living systems are open, in that there is continuous exchange of matter, energy and information.

Open system has changing degree of interaction with the environment from which the System receives input and gives back out put in the form of matter, energy and information. For survival, all systems of nursing receive varying type and amount of matter, energy and information.

The main concept of open system model is: Input, Through Put, Output and Feedback. In open system theory input refers to matter, energy and information that are processed. After processing the input the system returns to output (matter, energy and information to the environment in an altered state). Feedback refers to environment response to the systems output used by the system in adjustment correction and accommodation to the interaction with the environment.

The study is under taken to determine the effect of soya protein consumption on the menopausal symptoms.

Pre test conducted to assess the symptoms of menopause like hot flushes, sleeplessness, night sweats etc.

Input – Providing soya protein for reducing the menopausal symptoms.

Through put – Through put is the process of soya protein consumption on menopausal symptoms among women.

Post test – Again assessing the symptoms of menopause. Output – Refers to effect of soya protein consumption on menopausal symptom by post test.

This module of Kenny's Open System is best suited to this study

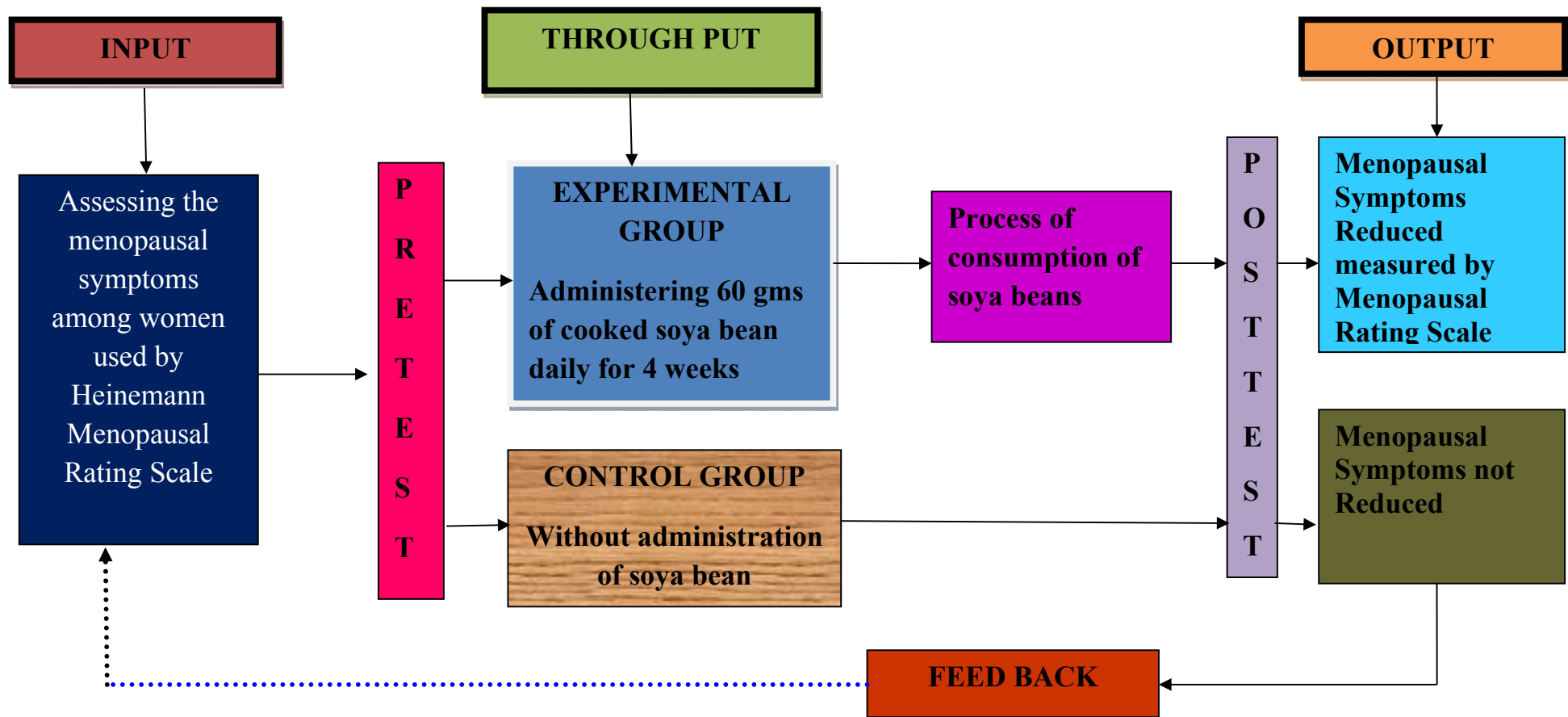


Fig: 1 Conceptual Framework based on J.W. Kenny's Open System Model (1991)

Methodology

CHAPTER - III

RESEARCH METHODOLOGY

METHODOLOGY

Research methodology is an overall plan to conduct research study, which involves the description of research approach, research design and variables under study, setting of the study, population, sample and sample size, sampling technique, Sampling criteria, development and description of the tool, content validity, reliability, Pilot study, data collection process and plan for analysis.

This chapter describes the methodology followed to assess the effectiveness of soya protein consumption on menopausal symptoms. It includes research approach, research design, and variables, setting of the study, population, inclusion criteria, sampling, development and description of tool, validity and reliability of tool, method of data collection and plan for data analysis.

3.1 RESEARCH APPROACH

Research approach involves the description of plan to investigate the phenomenon under the study in a structured (Quantitative), unstructured (Qualitative) or a combination of two methods (Quantitative – Qualitative integrated approach).

Quantitative research approach was used in this study to evaluate the effectiveness of soya protein consumption on menopausal women.

3.2 RESEARCH DESIGN

Research Design is a blue print that the researchers select to carry out their research study. The research design used in this study was Quasi-experimental–Non equivalent control group design. The study was conducted to evaluate the effectiveness of soya protein consumption on menopausal symptoms among women in Samayanallur at Madurai.

| GROUP | PRETEST | INTERVENTION | POST TEST |
|-----------------------|----------------|---------------------|------------------|
| CONTROL GROUP | O ₁ | X | O ₂ |
| EXPERIMENTAL GROUP | O ₁ | | O ₂ |

O₁= Pre test Assessment of the Menopausal symptoms in Control and Experimental group.

X = Consumption of Soya protein.

O₂= Post test Assessment of the Menopausal symptoms in Control and Experimental group.

3.3 RESEARCH VARIABLES

Attributes or characteristics that can have more than one value are known as variables.

VARIABLES IN THE STUDY:

Independent variable - Soya protein

Dependent variable - Menopausal symptoms

Demographic variable - Age, age of menarche, marital status, dietary pattern, religion, Educational status, occupation, income, type of family, habits and parity.

3.4 SETTING OF THE STUDY

The setting of the study was selected on the basis of feasibility for conducting the study and availability of samples. The study was conducted in Samayanallur at Madurai.

3.5 POPULATION

The entire set of individuals (or women) having common characteristics

-POLIT

Target Population

Population for the study comprises of menopausal women.

Accessible Population

Population for the study comprises of menopausal women living at Samayanallur, Madurai.

3.6 SAMPLE:

A sample is the representative unit of a target population.

Sample refers to the process of selecting a portion of the population which refers the entire population. The women were selected using purposive sampling technique.

3.7 SAMPLE SIZE

The sample size of the study was 60.

Control group = 30

Experimental group = 30

Total = 60

3.8 CRITERIA FOR SELECTION OF SAMPLES

Inclusion criteria

The study includes Women

- who are having menopausal symptoms
- between the ages 45-56years
- who are willing to participate
- who can understand and speak Tamil.

Exclusion criteria

The study excluded women

- who are not present at the time of data collection
- who are on any hormonal treatment

3.9 SAMPLING TECHNIQUE

The samples were selected by Nonprobability –Purposive sampling technique.

3.10 METHOD OF SAMPLE SELECTION:

The samples were selected those who met the inclusion criteria.

3.11 RESEARCH TOOL

The tool was developed after a wide literature review and by the guidance of the experts. The tool consists of two sections.

Section A: Demographic variables

Section B: Menopausal Rating Scale (Heinemann 2003)

3.12. Description of the tool

The tool consisted of two sections.

Section – A

Demographic variables: It consists of Age, Age of Menarche, Marital Status, Dietary Pattern, Religion, Educational status, Occupation, Family Monthly Income, Type of Family, Habits and Parity.

Section – B

Menopausal Rating Scale (Heinemann 2003)

- It consists of 11 items to assess the menopausal problems of women.
- It is a standardized, self-administered rating scale.

Scoring method:

| S.No | Menopausal Symptoms | Score |
|------|---------------------|-------|
| 1 | None | 0 |
| 2 | Mild | 1-11 |
| 3 | Moderate | 12-22 |
| 4 | Severe | 23-33 |
| 5 | Very severe | 34-44 |

3.13 TESTING OF THE TOOL:

VALIDITY:

The content validity of the tool was obtained by giving the tool to 3 of the nursing experts in the field of Obstetrics and Gynecological Nursing, HOD (Head of the Department) and Professor of Obstetrics and Gynecological Department,

Professor of Obstetrics and Gynecology and Statistian. Experts' suggestion were incorporated in the tool.

RELIABILITY:

The Menopause Rating Scale (MRS) is a well accepted instrument to measure the severity of menopausal symptoms. As yet however, investigations had not specifically been directed towards short-term test-retest reliability of the scale. The correlation coefficient (Pearson) of the sum-score of the two measurements was $r=0.82$. Hence the tool was considered highly reliable to precede the main study.

3.14 ETHICAL CONSIDERATION

The research proposal was approved by the experts of the Dissertation Committee in College of Nursing, Madurai Medical College, Madurai, and the same was approved by Institutional Review Board, Independent Ethical Committee of Government Rajaji Hospital, and Madurai-20 for conducting the pilot study and main study. The formal permission was obtained from DDHS(Deputy Director of Health Service), Madurai. The committee suggested the researcher to continue study with slight modification.

3.15 PILOT STUDY

Research proposal was approved by the Institutional Ethical Committee Prior to the pilot study. A formal permission was obtained for the Head of the Department in Obstetrics and Gynecology and Pilot study was conducted from 01.8.2014 to 07.8.2014 in Samayanallur, at Madurai. Formal permission was obtained from Block Medical Officer in Primary Health Centre, Samayanallur. Menopausal women were selected who fulfill the inclusion criteria of the study. Among 10 menopausal women, 5 samples in experimental and 5 samples in control group were selected for the study.

Informed written consent was obtained from sample who was taking part in this study. The samples were selected by purposive sampling technique. 10 women aged between 45-56 years, who satisfied the inclusion criteria were recruited and assigned 5 in experimental group and 5 in control group. Pretest data was collected by researcher using Heinemann menopausal rating scale for both the groups. Experimental group consumed 60 gm cooked soya bean daily for one week. Control group not consumed soya bean. Post test was conducted by researcher for both groups using the same menopausal rating scale on 1st day of second week. The study reveals that the study was feasible and practicable to conduct the main study.

3.15 DATA COLLECTION PROCEDURE:

The main study was conducted from 12.8.2014- 15.9.2014 at selected rural in Samayanallur. Formal permission was obtained from Deputy Director of Health Service, Vishwanathapuram and Medical Officer from Primary Health Center, Samayanallur. The purpose of the study was explained to the samples and confidentiality was maintained throughout the study. Informed written consent was obtained from sample who was taking part in this study. The samples were selected by purposive sampling techniques. 30 women in experimental group and 30 women in control group. Pretest data collected by the researcher using Heinemann Menopausal rating scale for both groups. Experimental group consumed 60 gm cooked soya bean daily for 4 weeks. Control group without administration soya bean. Post test conducted by researcher for the both groups using the same Menopausal Rating Scale on first day of the 5th week.

3.16 PLANS FOR DATA ANALYSIS:

Analysis and interpretation of data is the most important phase of research process, which involves the computation of certain measures along with searching for patterns of relationship that exist among data groups. Data were analyzed and interpreted in accordance with objectives. Data analysis is the process of organizing and synthesizing the data so as to answer the research questions and test hypothesis

- SURESH. K.SHARMA

Data were analyzed using descriptive and inferential statistics. Tests used in this study were frequency and percentage distribution, mean, standard deviation, chi-square test, and Paired 't' test.

DESCRIPTIVE STATISTICS:

Descriptive statistics is used to organize and summarize the data to draw meaningful interpretations.

- Frequency, Percentage distribution was used to analyze the demographic variables of women in control and experimental group.
- Mean and standard deviation were used to analyze the level of menopausal symptoms among women in control and experimental group.

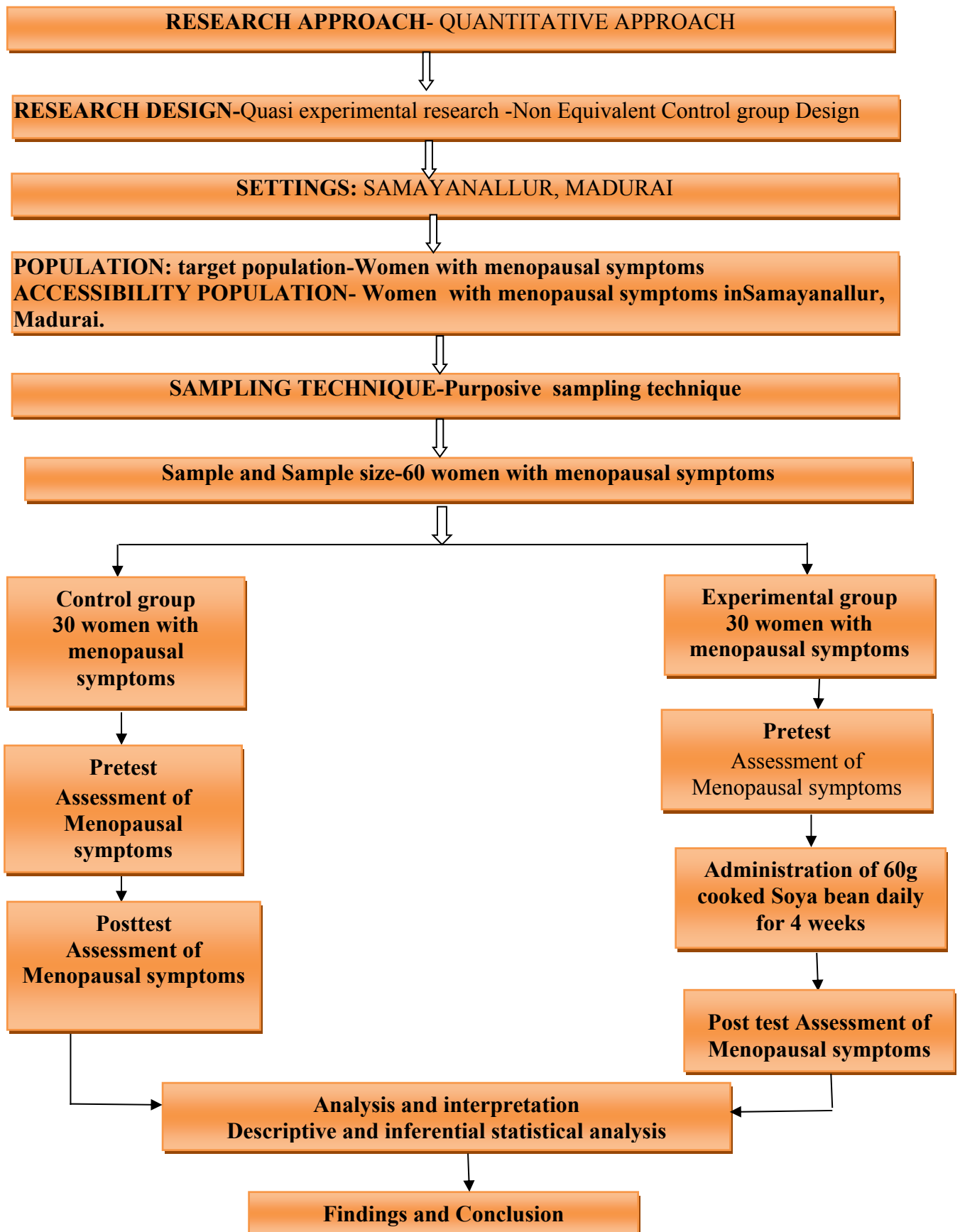
INFERENTIAL STATISTICS:

- Paired 't' test was used to analyze the effectiveness of soya protein consumption on women in control and experimental group.
- Chi- square test was used to find association between level of menopausal symptoms and demographic variables in control and experimental group.

3.17 PROTECTION OF HUMAN RIGHTS:

The proposed study was conducted after getting approval from the dissertation committee of College of Nursing, Madurai medical College Madurai. In order to protect the human rights ethical committee approval was obtained on the month of February. In addition permission was obtained from Deputy Director of Health Services and Block Medical Officer in Primary Health Centre in Samayanallur. Both verbal and written consent was obtained from sample. The advantages of the study were explained to the samples. Samples were explained that confidentiality was maintained throughout the study.

Fig.2. SCHEMATIC REPRESENTATION OF THE STUDY



*Data Analysis And
Interpretation*

CHAPTER – IV

DATA ANALYSIS AND INTERPRETATION

This chapter deals with the analysis and interpretation of data collected from 60 women with menopausal symptoms in Samayanallur at Madurai.

Analysis and interpretation of data is the important step in research process. It involves the computation of the certain measures along with searching for patterns of relationship that exists among the data groups.

Analysis is the process of organizing and synthesizing the data so as to answer the research questions and test the hypothesis.

- **SURESH. K. SHARMA**

The purpose of the analysis is to reduce the data to a manageable and interrupted form, so that research problem can be studied and tested. The data collected were analyzed according to the plan for data analysis and interpreted under the following objectives.

The data were collected from 60 women with menopausal symptoms with the help of demographic variables Performa. Rating scale on menopausal symptoms before and after soya protein consumption to determine the effectiveness of soya protein. The data was analyzed based on objectives and hypothesis of the study. Data analysis was completed after transferring the collected data into a master coding sheet. The data as tabulated analyzed and interpreted using descriptive and inferential statistics.

ORGANIZATION OF DATA:

SECTION A: Distribution of demographic variables

SECTION B: Description of level of Menopausal Symptoms for control and experimental group

SECTION C: Description the effectiveness of soya protein consumption control and experimental group

SECTION D: Comparison of level of Menopausal Symptoms between control and experimental group

SECTION E: Association between levels of Menopausal Symptoms among control and experimental group

SECTION A

DISTRIBUTION OF DEMOGRAPHIC VARIABLES

This analysis has been done to find out the frequency and percentage distribution of demographic variables such as Age in years, Age of menarche, Marital status, Diet habit, Religion, Educational status, Occupation, Family monthly income, Type of family, Habits and Parity in control and experimental group.

SECTION B

DESCRIPTION OF LEVEL OF MENOPAUSAL SYMPTOMS FOR CONTROL AND EXPERIMENTAL GROUP

Levelsof menopausal symptoms among the menopausal women has been assessed by Heinemann (2003) Menopausal Rating scale in five Stages (None, Mild, Moderate, Severe, Very severe) for control and experimental group.

SECTION C

EVALUATE THE EFFECTIVENESS OF SOYA PROTEIN CONSUMPTION CONTROL AND EXPERIMENTAL GROUP

Evaluate the effectiveness of the soya protein consumption among the women in control and experimental group.

SECTION D

COMPARISON OF LEVEL OF MENOPAUSAL SYMPTOMS BETWEEN CONTROL AND EXPERIMENTAL GROUP

Comparison of level of menopausal symptoms in experimental group and control group has been analyzed using mean score and its significance by statistical test.

SECTION E

ASSOCIATION BETWEEN LEVEL OF MENOPAUSAL SYMPTOMS AMONG CONTROL AND EXPERIMENTAL GROUP WITH SELECTED DEMOGRAPHIC VARIABLES

Demographic variables of experimental and control group has been analyzed in association with level of menopausal symptoms using chi-square test.

SECTION A

DISTRIBUTION OF DEMOGRAPHIC VARIABLES

TABLE 1 : FREQUENCY AND PERCENTAGE DISTRIBUTION OF DEMOGRAPHIC VARIABLES OF MENOPAUSAL WOMEN IN CONTROL AND EXPERIMENTAL GROUP

n=60

| Demographic data | Control group | | Experimental group | |
|---------------------------|---------------|------|--------------------|------|
| | n | % | n | % |
| 1.Age in years: | | | | |
| a)45-48 yrs | 17 | 56.7 | 10 | 33.3 |
| b)49-52 yrs | 9 | 30 | 4 | 13.3 |
| c)53-55 yrs | 4 | 13.3 | 16 | 53.3 |
| 2.Age of menarche: | | | | |
| a)Below 11 years | 7 | 23.3 | 15 | 50 |
| b)11-15 years | 22 | 73.3 | 14 | 46.7 |
| c)Above 15 years | 1 | 3.3 | 1 | 3.3 |
| 3.Marital status: | | | | |
| a)Married | 23 | 76.7 | 19 | 63.3 |
| b)Unmarried | 0 | 0 | 0 | 0 |
| c)Widower | 7 | 23.3 | 11 | 36.7 |
| 4.Diet habit: | | | | |
| a)Vegetarian | 8 | 26.7 | 8 | 26.7 |
| b)Mixed | 22 | 73.3 | 22 | 73.3 |
| 5.Religion: | | | | |
| a)Hindu | 24 | 80 | 26 | 86.7 |
| b)Christian | 6 | 20 | 4 | 13.3 |
| c)Muslim | 0 | 0 | 0 | 0 |
| d)Others | 0 | 0 | 0 | 0 |

| | | | | |
|----------------------------------|----|------|----|------|
| 6.Educational status: | | | | |
| a)Non formal education | 24 | 80 | 25 | 83.3 |
| b)School level | 6 | 20 | 5 | 16.7 |
| c)College level | 0 | 0 | 0 | 0 |
| 7.Occupation: | | | | |
| a)House wife | 24 | 80 | 25 | 83.3 |
| b)Private | 6 | 20 | 5 | 16.7 |
| c)Government | 0 | 0 | 0 | 0 |
| 8.Family monthly income: | | | | |
| a)<Rs.5000 | 30 | 100 | 26 | 86.7 |
| b)Rs.5001-10000 | 0 | 0 | 4 | 13.3 |
| c)Above Rs.10000 | 0 | 0 | 0 | 0 |
| 9.Type of family: | | | | |
| a)Nuclear family | 23 | 76.7 | 19 | 63.3 |
| b)Joint family | 7 | 23.3 | 9 | 30 |
| c)Extended family | 0 | 0 | 2 | 6.7 |
| 10.Habits: | | | | |
| a)Tobacco/betel chewing | 14 | 46.7 | 20 | 66.7 |
| b)Increased intake of coffee/tea | 16 | 53.3 | 10 | 33.3 |
| 11.Parity : | | | | |
| a)Nullipara | 2 | 6.7 | 2 | 6.7 |
| b)Multipara | 23 | 76.7 | 26 | 86.7 |
| c)Grand multipara | 5 | 16.7 | 2 | 6.7 |

The above the table represents that age group of women among control group 17 (56.7%) were in the age group of 45-48 years, 9 (30%) were in the age group of 49-52 years, and 4 (13.3%) were in the age group of 53-55 years. In Experimental group 10 (33.3%) were in the age group of 45-48 years, 4 (13.3%) were in the age group of 49-52 years, and 16 (53.3%) were in the age group of 53-55 years.

With the view of age of menarche, in the control group 7 (23.3%) of women attained menarche at the age of below 11 years, 22 (73.7%) attained menarche at the age of 11-15years, and 1 (3.3%) of women attained menarche at the age of above 15 years. In Experimental group 15 (50%) of women attained menarche at the age of below 11 years, 14 (46.7%) attained menarche at the age of 11-15years, and 1 (3.3%) of women attained menarche at the age of above 15 years.

In the view of marital status control group 23 (76.7%) women were married, 7(23.3%) women were widower. In experimental group 19 (63.3%) were married, 1(36.7%) women were widower.

In the aspect of dietary pattern, in control group majority of the women in 22 (73.3%) belongs to mixed diet and 8 (26.7%) belongs to vegetarian. In experimental group majority of the women in 22 (73.3%) belongs to mixed diet and 8 (26.7%) belongs to vegetarian.

With regard to religion, in control group 24 (80%) belongs to Hindu religion, 6(20%) belongs to Christian. In experimental group 24 (80%) belongs to Hindu religion, 6(20%) belongs to Christian.

In the view of educational status majority of the women in control group 24 (80%) were illiterate, and 6 (20%) had school level education. In experimental group women in 25 (83.3%) were illiterate and 5 (16.7%) had school level education.

In the view of occupational status majority of the women in control group 24(80%) were house wife and 6 (20%) women were working as a private company. In experimental group 25 (83.3%) were house wife and 5 (16.7%) women were working as a private company.

With regard of family monthly income majority of the women in control group 30 (100%) get less than Rs.5000/-. In experimental group majority of the women 26 (86.7%) get less than Rs.5000/-. And 4 (13.3%) women were get Rs 5001-10000/-.

In the view of type of family, in control group 23 (76.7%) belongs to nuclear family, 7 (23.3%) belongs to joint family. In experimental group 19 (63.3%) belongs to nuclear family, 9 (30%) belongs to joint family, 2 (6.7%) belongs to extended family.

With the view of habits majority of the women in control group 16 (53.3%) were increased intake of coffee/tea, 14 (46.7%) were tobacco/betel chewing. In experimental group 20 (66.7%) were tobacco/betel chewing, 10 (33.3%) were increased intake of coffee/tea.

With the view of the parity majority of the women in control group 23 (76.7) were multipara, 5(16.7) were grandmultipara and 2 (6.7) were Nullipara. Majority of the women in experimental group 26 (86.7) were multipara, 2 (6.7) were grandmultipara and 2 (6.7) were Nullipara.

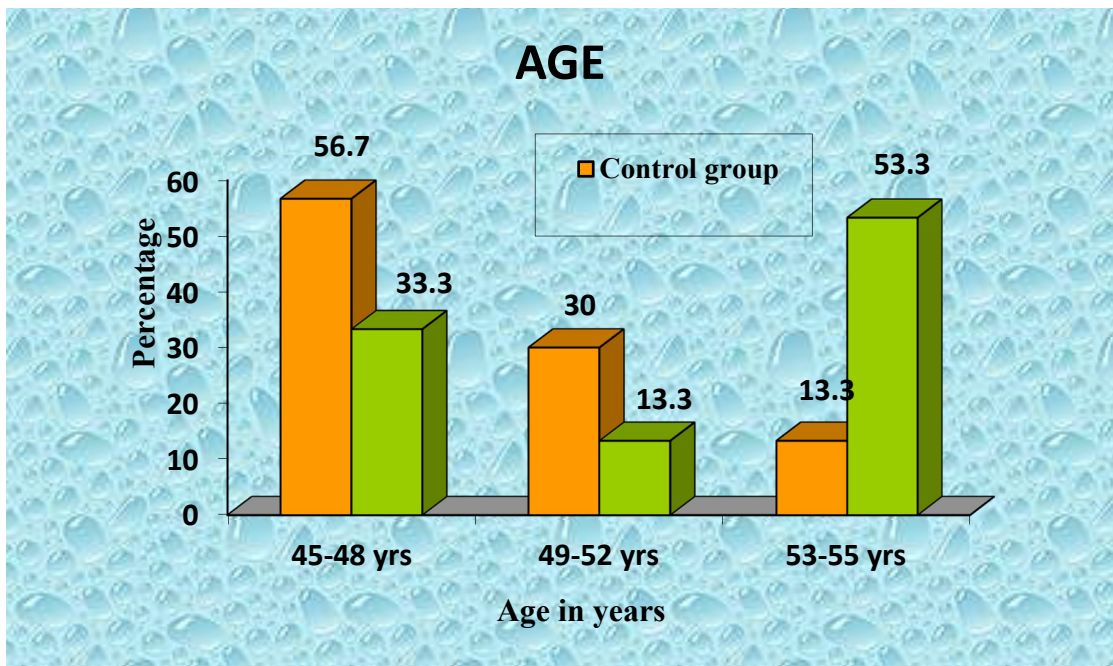


Fig.2 Multiple bar diagram depicts distribution of women according to their age.

Majority of the women among control group 17 (56.7%) were in the age group of 45-48 years. In experimental group majority of the women 16 (53.3%) were in the age group of 53-55 years.

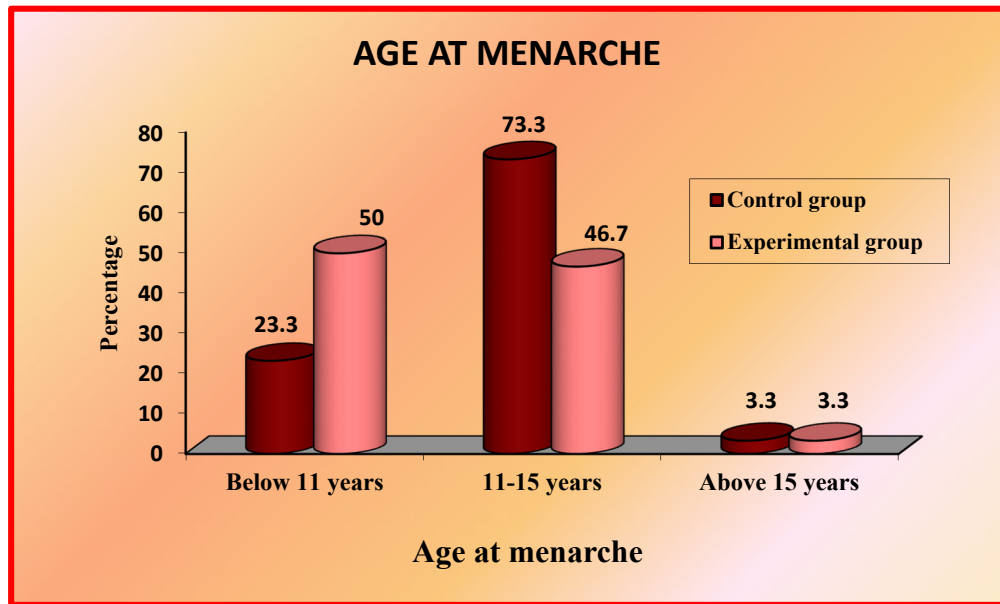


Fig.3. Multiple cylinder diagram depicts distribution of women according to their age at menarche.

Majority of the women in control group 22 (73.3%) attained menarche at the age of 11-15 years. Majority of the women in experimental group 15 (50%) attained menarche at the age of below 11 years.

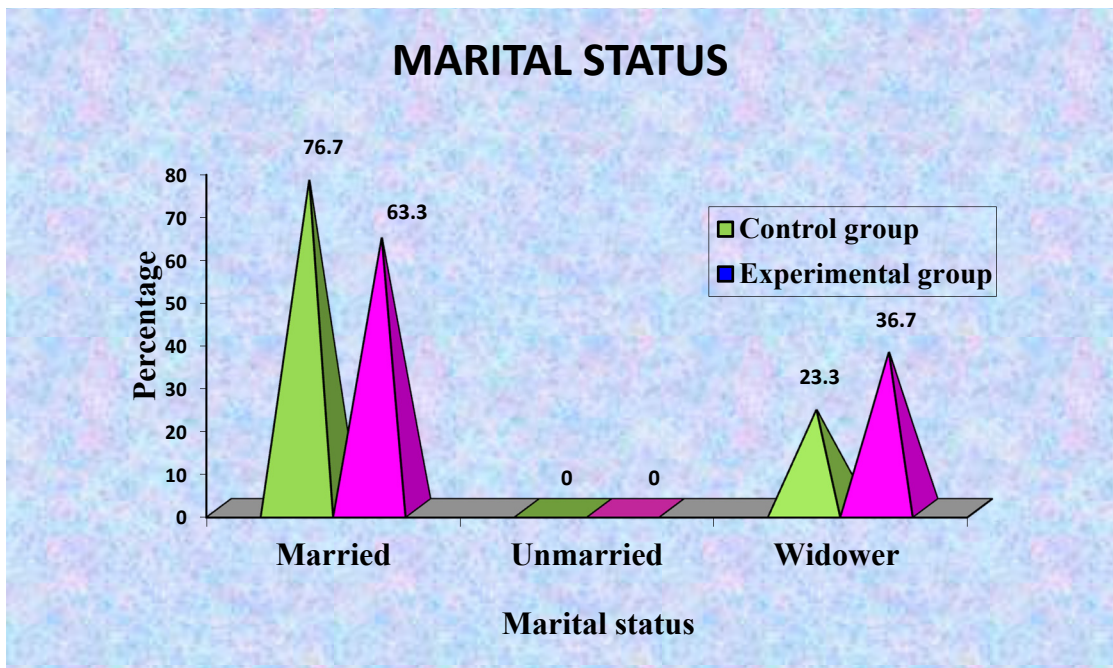


Fig.4 Multiple pyramid diagrams depicts distribution of women according to their Marital Status.

Majority of the women among control group 23 (76.7%) women were married. Majority of the women in experimental group 19 (63.3%) were married.

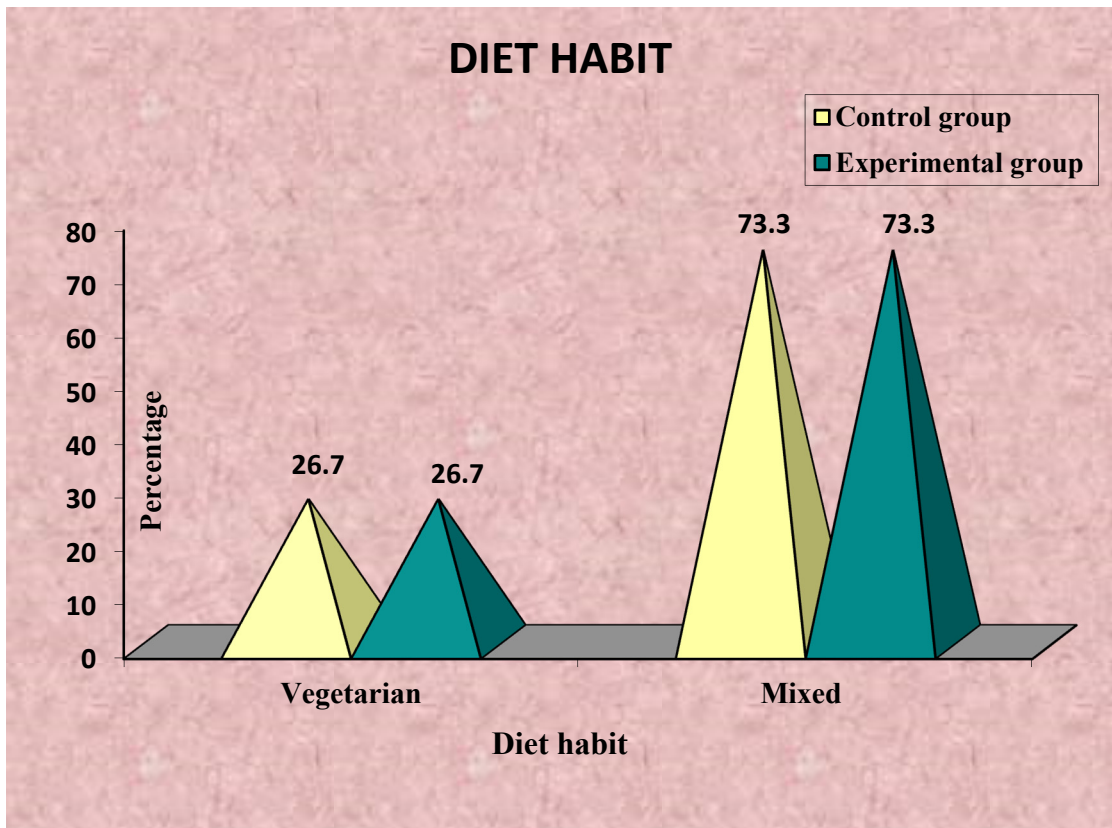


Fig.5. Multiple pyramid diagram depicts distribution of women according to their diet habit.

It reveals that the aspect of dietary pattern, majority of the women in control group 22 (73.3%) belongs to mixed diet. Majority of the women in experimental group 22(73.3%) belongs to mixed diet.

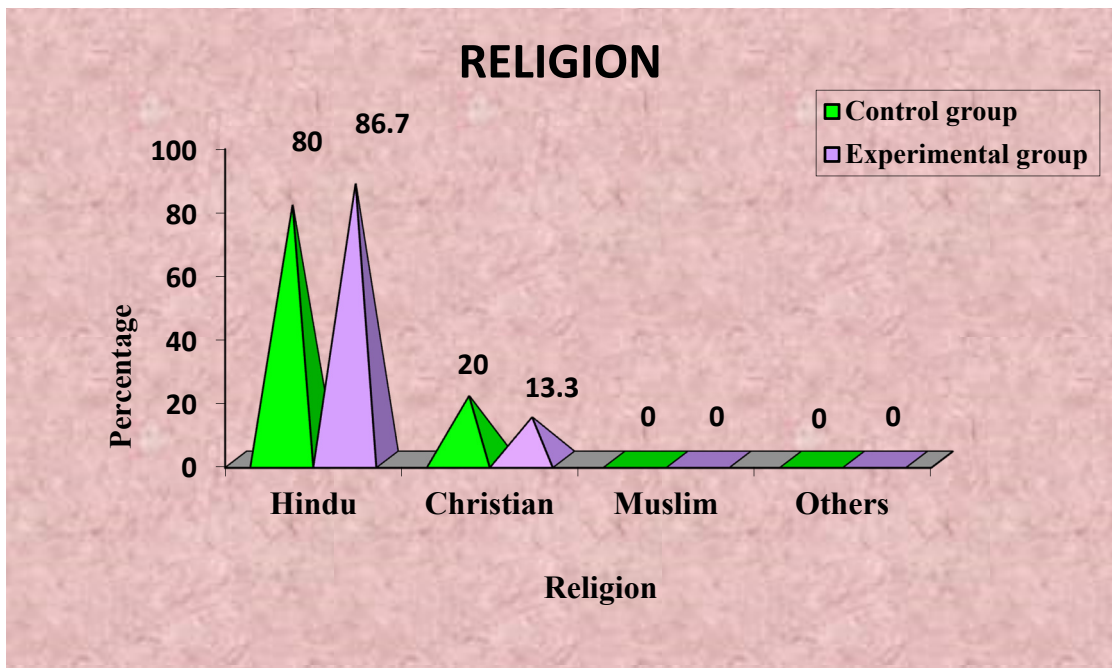


Fig.6. Multiple pyramid diagrams depicts distribution of women according to their religion.

The aspect of Religion, a majority of the women in control group 24 (80%) belongs to Hindu religion. Majority of the women in experimental group 25(86.7%) belongs to Hindu religion.

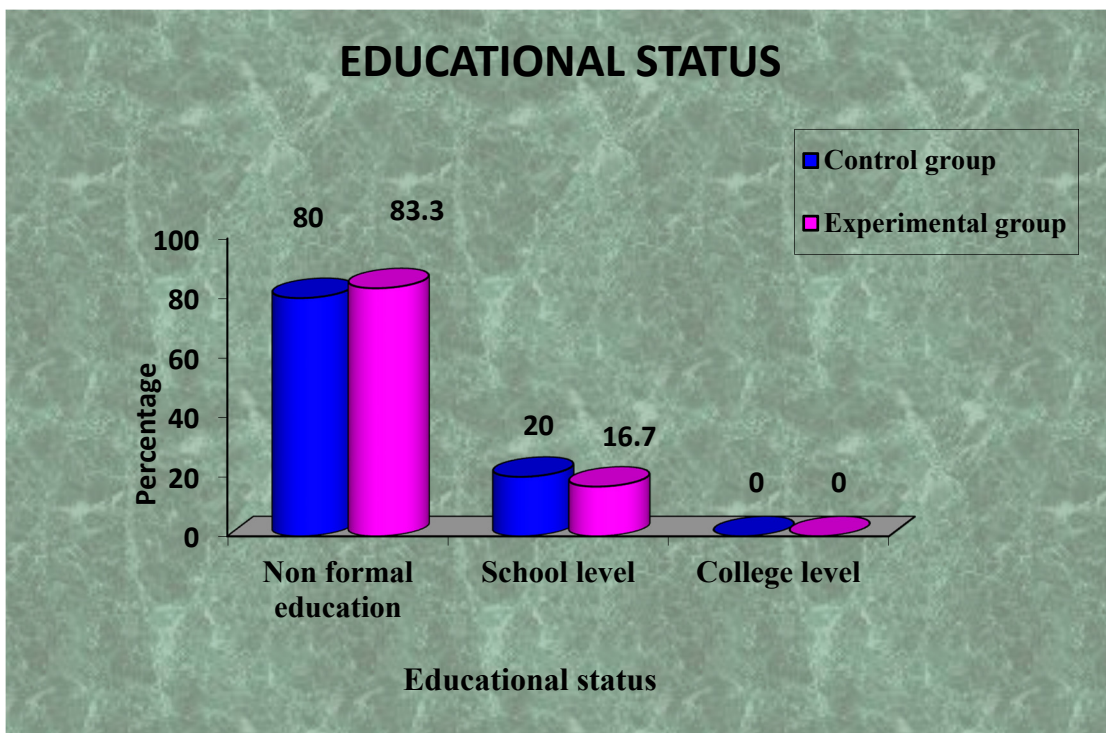


Fig.7: Multiple cylinder diagrams depicts distribution of women according to their educational status.

Regarding educational status majority of the women in control group 24 (80%) were illiterate. Majority of the women in experimental group 25 (83.3%) were school level education.

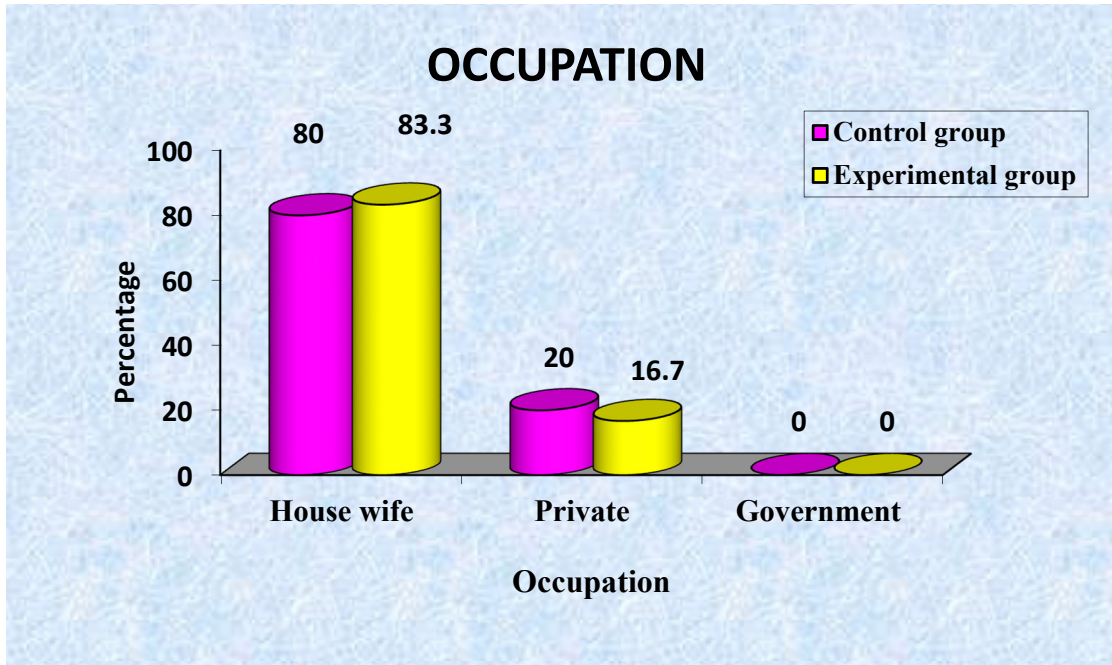


Fig.8. Multiple cylinder diagram depicts distribution of women according to their occupation.

Regarding occupation majority of the women in control group 24 (80%) were house wife. Majority of the women in experimental group 25 (83.3%) were house wife.

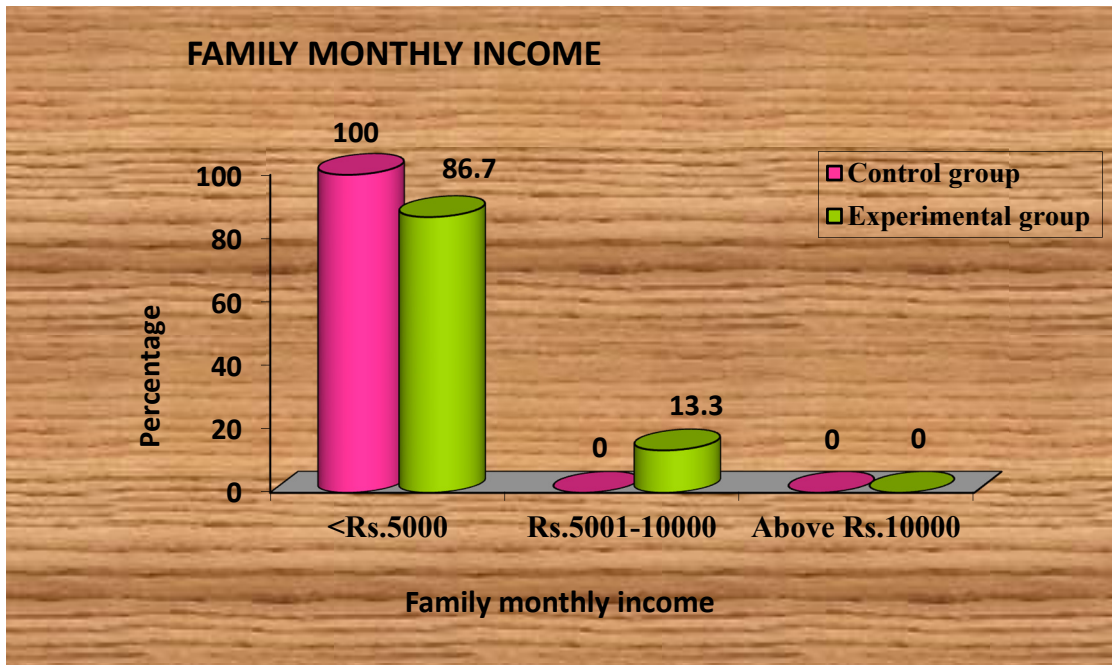


Fig.9: Multiple cylinder diagrams depicts distribution of women according to their family monthly income.

It reveals that majority of the women in control group 30 (100%) were get less than Rs.5000/-. Majority of the women in experimental group 26 (86.7%) were get less than Rs.5000 per month.

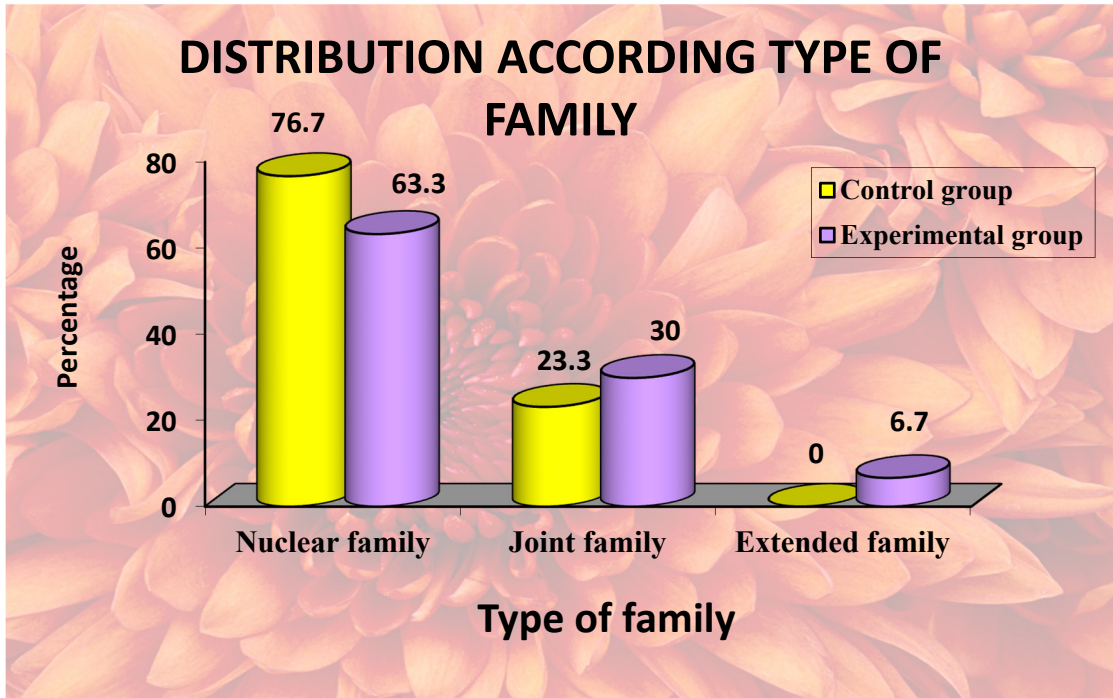


Fig.10: Multiple cylinder diagrams depicts distribution of women according to their type of family.

Regarding type of family majority of the women in control group 23 (76.7%) belongs to nuclear family. Majority of the women in experimental group 19 (63.3%) were belongs to Nuclear family.

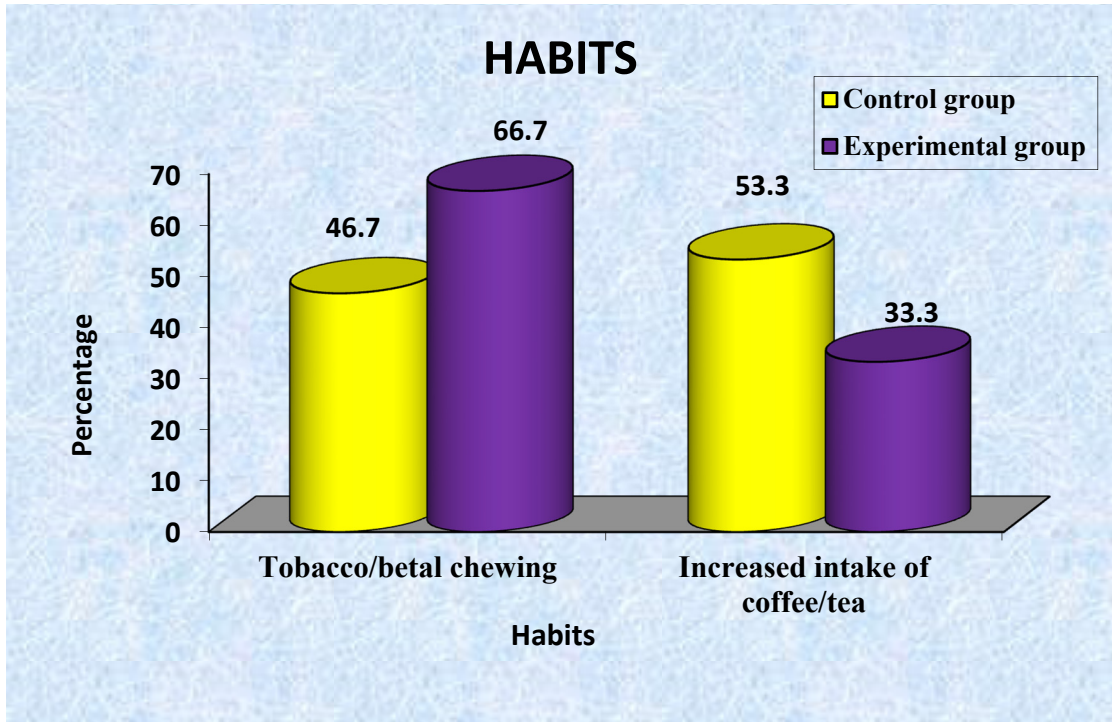


Fig.11: Multiple cylinder diagrams depicts distribution of women according to their habits.

Regarding habits most of the women among control group (46.7%) and experimental group (66.7%) were having betel chewing habits. Some of the women in control group (53.3%) and experimental group (33.3%) were having increased intake of coffee/tea habits.

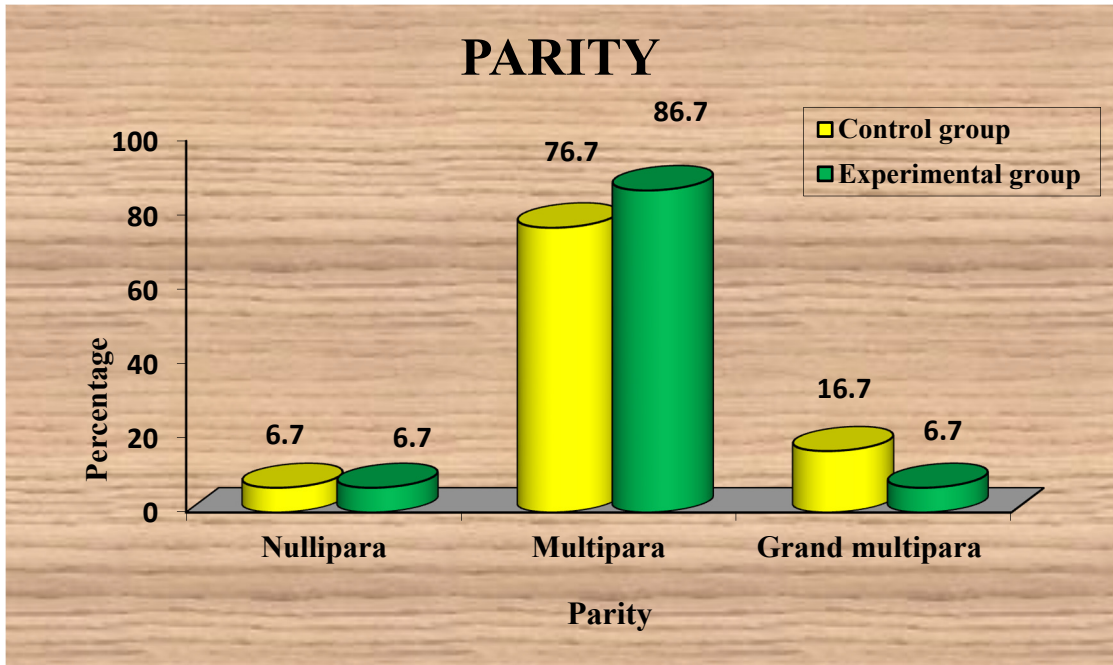


Fig.12. Multiple cylinder diagram depicts distribution of women according to their parity

Majority of the women among control group 23 (76.7%) and experimental group 26 (86.7%) were Multipara women.

SECTION II
DISTRIBUTION OF LEVEL OF MENOPAUSAL SYMPTOMS FOR
CONTROL AND EXPERIMENTAL GROUP

TABLE 2 : Frequency and percentage distribution the level of menopausal Symptoms among women in control and experimental group

n=60

| Level of menopausal symptoms | Control group | | Experimental group | |
|------------------------------|---------------|-----|--------------------|------|
| | Pre test | | Pre test | |
| | f | % | f | % |
| None | - | - | - | - |
| Mild | 3 | 10 | 2 | 6.7 |
| Moderate | 27 | 90 | 28 | 93.3 |
| Severe | - | - | - | - |
| Very severe | - | - | - | - |
| Total | 30 | 100 | 30 | 100 |

This table reveals the majority of the women among control group pretest score is 27 (90%) women were moderate menopausal symptoms and 3(10%) of women were mild menopausal symptoms. Majority of the women among in experimental group pretest score is 28(93.3%) women were moderate level of Menopausal symptoms and 2 (6.7%) women were mild level of Menopausal symptoms.

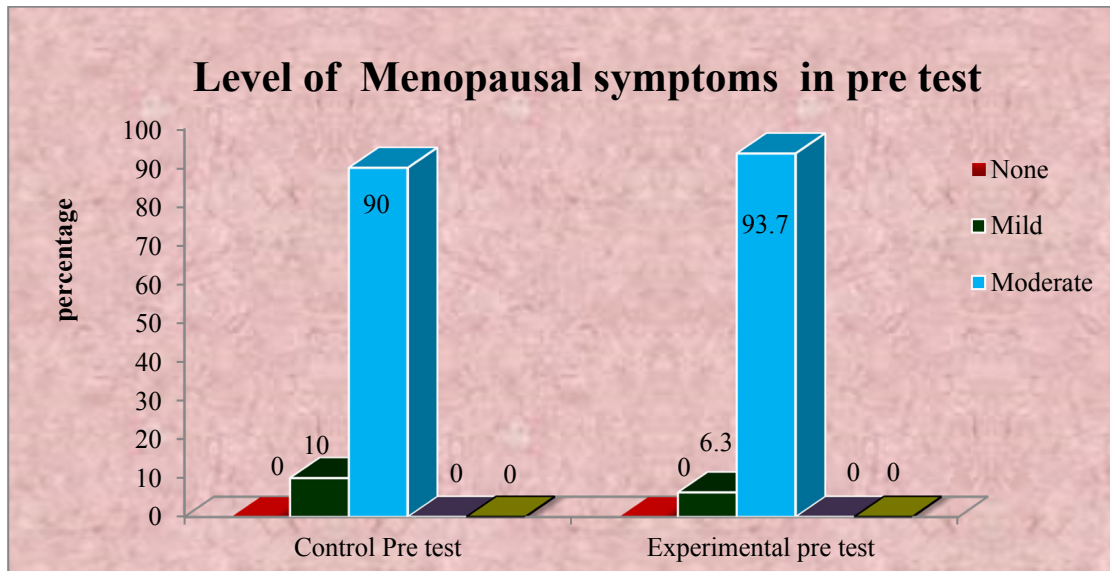


Fig: 13 Multiple bar diagram depicts distribution of pretest level of Menopausal symptoms among women before intervention

Majority of the women among control group 27 (90%) women were moderate level of menopausal symptoms. Majority of the women among experimental group 28 (93.7%) were moderate level of menopausal symptoms and 2 (6.3%) women were mild level of menopausal symptoms.

SECTION III
EVALUATE THE EFFECTIVENESS OF SOYA PROTEIN CONSUMPTION
CONTROL AND EXPERIMENTAL GROUP

TABLE 3: Frequency and percentage distribution to evaluate the effectiveness of soya protein consumption on the menopausal Symptoms among women control and experimental group

n=60

| Level of menopausal symptoms | Control group | | Experimental Group | |
|------------------------------|---------------|------|--------------------|------|
| | Post test | | Post test | |
| | f | % | f | % |
| None | - | - | 2 | 6.7 |
| Mild | 4 | 13.3 | 19 | 63.3 |
| Moderate | 26 | 86.7 | 9 | 30 |
| Severe | - | - | - | - |
| Very severe | - | - | - | - |
| Total | 30 | 100 | 30 | 100 |

This table reveals the majority of the women among control group post test score is 26(86.7%) of women were moderate level of menopausal symptoms, 4(13.3%) women were mild level of menopausal symptoms. Majority of the women among in experimental group post test score is 19(63.3%) women were mild level of menopausal symptoms and 9 (30%) women were moderate level of menopausal symptoms and 2 (6.7%) women were none of the menopausal symptoms.

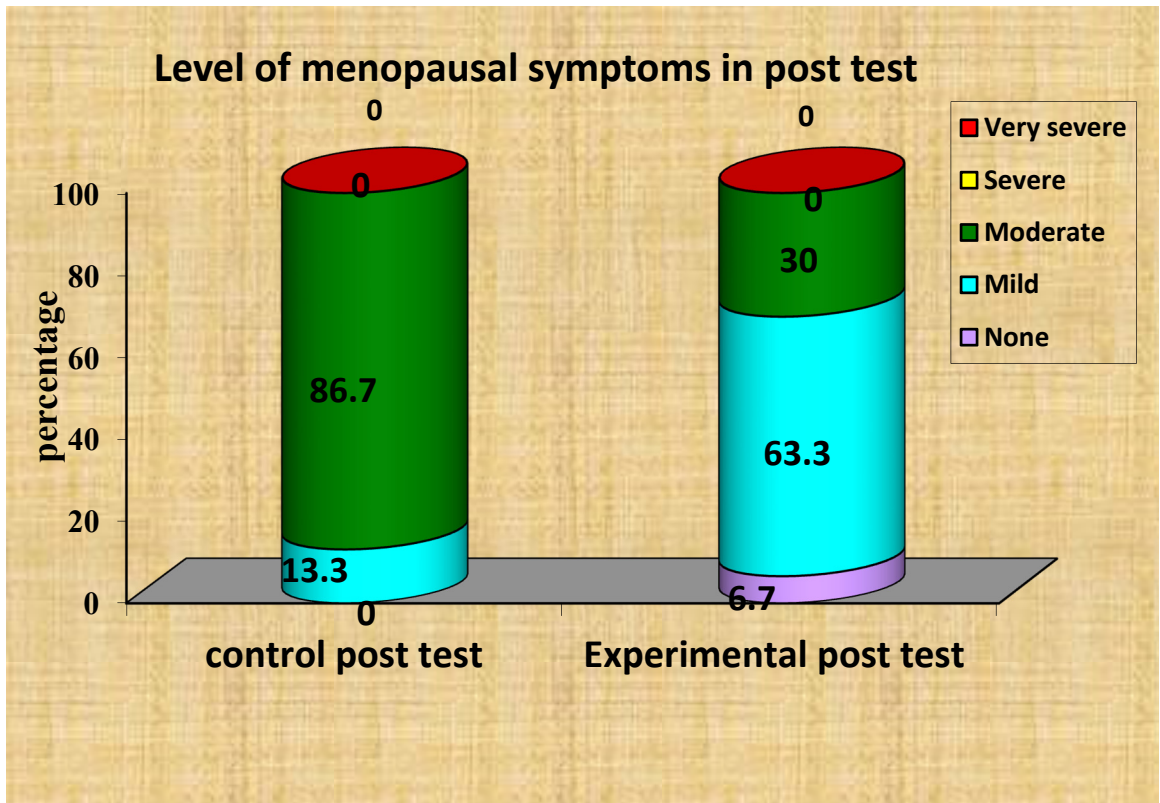


Fig: 14 Multiple bar diagram depicts distribution of post test level of Menopausal symptoms among after intervention

After the intervention majority of the women among control group 26 (86.7%) women were moderate level of menopausal symptoms and 4 (13.3%) women were mild level of menopausal symptoms. Majority of the women among experimental group 19 (63.3%) were mild level of menopausal symptoms and 9 (30%) women were Moderate level of menopausal symptoms and 2 (6.7%) women were none of the menopausal symptoms.

SECTION D
COMPARISON OF LEVEL OF MENOPAUSAL SYMPTOMS WOMEN
BETWEEN CONTROL AND EXPERIMENTAL GROUP

TABLE NO 4 : Distribution of mean, SD and mean percentage of control pre and post test to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women in Samayanallur at Madurai.

n=60

| Level of menopausal symptoms | Max score | Control-pre test | | | Control-post test | | | Difference in mean % |
|------------------------------|-----------|------------------|------|--------|-------------------|------|--------|----------------------|
| | | Mean | SD | Mean % | Mean | SD | Mean % | |
| | 44 | 17.3 | 3.42 | 39.3 | 17.07 | 3.39 | 38.7 | 0.6 |

The above table portrays that in control group pre test mean score was 17.3, Standard Deviation 3.42, Mean % 39.3%. Where as in post test score Mean and Standard Deviation (M=17.07, SD=3.39, Mean % =38.7%). The mean difference was 0.6.

TABLE NO 5: Distribution of mean, SD and mean percentage of experimental pre and post test to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women in Samayanallur at Madurai

n=60

| Level of menopausal symptoms | Max Score | Experimental –pretest scores | | | Experimental –posttest scores | | | Difference in mean % |
|------------------------------|-----------|------------------------------|------|--------|-------------------------------|------|--------|----------------------|
| | | Mean | SD | Mean % | Mean | SD | Mean % | |
| | 44 | 19.53 | 3.67 | 44 | 10.6 | 3.70 | 24 | 20 |

The above table manifests that in Experimental group pretest value Mean and Standard Deviation (M=19.53, SD=3.67, Mean %=44%). Where as experimental post test mean score was (M=10.6, SD=3.70, Mean %=24%). The mean difference was 20.

TABLE NO 6: Distribution of mean, SD and mean percentage of experimental post and control post scores to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women in Samayanallur at Madurai

n=60

| Level of menopausal symptoms | Max score | Control-post scores | | | Experimental post scores | | | Difference in mean % |
|------------------------------|-----------|---------------------|------|--------|--------------------------|------|--------|----------------------|
| | | Mean | SD | Mean % | Mean | SD | Mean % | |
| | 44 | 17.07 | 3.39 | 38.7 | 10.6 | 3.70 | 24 | 14.7 |

The above table shows that level of menopausal symptoms in control group post test Mean score was 17.07, standard deviation 3.49, mean percentage 38.7. Where as in experimental group post test mean 10.6, standard deviation 3.70, mean percentage 24. Difference between the control group and experimental group mean was 14.7%.

TABLE NO 7: Paired t-test for control pre and control post test to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women in Samayanallur at Madurai

n=60

| Level of menopausal symptoms | Control-Pre scores | | Control-post scores | | 't'-value | P-value |
|------------------------------|--------------------|------|---------------------|------|-----------|-------------|
| | Mean | SD | Mean | SD | | |
| | 17.3 | 3.42 | 17.07 | 3.39 | 1.91 | 0.06 |

The above table portrays that in control group pre test mean 17.3, SD=3.42. In post test score mean 17.07, standard deviation 3.39. The 't' value is 1.91 and the P-value is 0.06. The difference was not found to be statistically significant at 0.001 levels.

TABLE NO 8: Paired t-test for experimental pre and experimental post test to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women Samayanallur at Madurai

n=60

| Level of menopausal symptoms | Experimental –pre scores | | Experimental -post scores | | ‘t’-value | P-value |
|------------------------------|--------------------------|------|---------------------------|------|-----------|-----------------|
| | Mean | SD | Mean | SD | | |
| | 19.53 | 3.67 | 10.6 | 3.70 | 21.52 | 0.000*** |

(* P<0.001 highly significant)**

The table shows in Experimental group Mean and Standard Deviation of pre test score (M=19.53, SD=3.67) was higher than the post test value is (M=10.6, SD=3.70). ‘t’ value is 21.52. P-value is 0.000. The difference was found to be statistically significant at 0.001 levels and can be attributed to effectiveness of soya protein consumption. Hypothesis is accepted. Hence it concludes the experimental group perceived less level of menopausal symptoms. Thus the soya protein consumption helps in reducing the menopausal symptoms.

TABLE 9 :Unpaired t-test for control post and experimental post test to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women Samayanallur at Madurai

n=60

| Level of menopausal symptoms | Control -post scores | | Experimental -post scores | | 't'-value | P-value |
|------------------------------|----------------------|------|---------------------------|------|-----------|-----------------|
| | Mean | SD | Mean | SD | | |
| | 17.07 | 3.39 | 10.6 | 3.70 | 7.05 | 0.000*** |

(* P<0.001 highly significant)**

The above table identifying that experimental group mean 10.6, and standard deviation 3.70. In control group post test mean score was 17.07, and standard deviation 3.39. 't' value is 7.05. P-value is 0.000. The experimental group mean value is lower than the control group. The difference was found to be statistically significant at 0.001 levels and can be attributed to effectiveness of soya protein consumption.

SECTION E

ASSOCIATION BETWEEN LEVELS OF MENOPAUSAL SYMPTOMS AMONG CONTROL AND EXPERIMENTAL GROUP WITH DEMOGRAPHIC VARIABLES

TABLE 10: Association between control post test regarding to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women in Samayanallur at Madurai with selected demographic data.

n=60

| Demographic variables | Mild | | Moderate | | X ² -value (df) | p-value |
|------------------------------|------|------|----------|------|-------------------------------|---------|
| | f | % | f | % | | |
| 1.Age in years: | | | | | | |
| a.45-48 yrs | 3 | 10 | 14 | 46.7 | 2.13 (df=2) | 0.345 |
| b.49-52 yrs | 0 | 0 | 9 | 30 | | |
| c.53-55 yrs | 1 | 3.3 | 3 | 10 | | |
| 2.Age of menarche: | | | | | | |
| a.Below 11 years | 2 | 6.7 | 5 | 16.7 | 1.903 (df=2) | 0.386 |
| b.11-15 years | 2 | 6.7 | 20 | 66.7 | | |
| c.Above 15 years | 0 | 0 | 1 | 3.3 | | |
| 3.Marital status: | | | | | | |
| a.Married | 3 | 10 | 20 | 66.7 | 0.007 (df=1) | 0.933 |
| b.Unmarried | 0 | 0 | 0 | 0 | | |
| c.Widower | 1 | 3.3 | 6 | 20 | | |
| 4.Diet habit: | | | | | | |
| a.Vegetarian | 0 | 0 | 8 | 26.7 | 1.68 (df=1) | 0.195 |
| b.Mixed | 4 | 13.3 | 18 | 60 | | |
| 5.Religion: | | | | | | |
| a.Hindu | 3 | 10 | 21 | 70 | 0.07 (df=1) | 0.788 |
| b.Christian | 1 | 3.3 | 5 | 16.7 | | |
| c.Muslim | 0 | 0 | 0 | 0 | | |
| d.Others | 0 | 0 | 0 | 0 | | |
| 6.Educational status: | | | | | | |
| a.Non formal education | 2 | 6.7 | 22 | 73.3 | 2.59 (df=1) | 0.107 |
| b.School level | 2 | 6.7 | 4 | 13.3 | | |
| c.College level | 0 | 0 | 0 | 0 | | |
| 7.Occupation: | | | | | | |
| a.House wife | 3 | 10 | 21 | 70 | 0.07 (df=1) | 0.788 |
| b.Private | 1 | 3.3 | 5 | 16.7 | | |
| c.Government | 0 | 0 | 0 | 0 | | |

| Demographic variables | Mild | | Moderate | | X ² -value | p-value |
|----------------------------------|------|------|----------|------|-----------------------|---------|
| | f | % | f | % | | |
| 8.Family monthly income: | | | | | | |
| a.<Rs.5000 | 4 | 13.3 | 26 | 86.7 | | |
| b.Rs.5001-10000 | 0 | 0 | 0 | 0 | 0 | 1 |
| c.Above Rs.10000 | 0 | 0 | 0 | 0 | | |
| 9.Type of family: | | | | | | |
| a.Nuclear family | 4 | 13.3 | 19 | 63.3 | 1.41 | 0.236 |
| b.Joint family | 0 | 0 | 7 | 23.3 | (df=1) | |
| c.Extended family | 0 | 0 | 0 | 0 | | |
| 10.Habits: | | | | | | |
| a.Tobacco/betal chewing | 2 | 6.7 | 12 | 40 | 0.02 | 0.886 |
| b.Increased intake of coffee/tea | 2 | 6.7 | 14 | 46.7 | (df=1) | |
| 11.Parity : | | | | | | |
| a.Nullipara | 0 | 0 | 2 | 6.7 | 0.502 | 0.778 |
| b.Multipara | 3 | 10 | 20 | 66.7 | (df=4) | |
| c.Grand multipara | 1 | 3.3 | 4 | 13.3 | | |

The above table represents that there was no significant between the selected Demographic Variables and post test score level of Menopausal symptoms in control group.

TABLE NO 11: Association between experimental post test regarding to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women in Samayanallurat Madurai with selected demographic data.

n=60

| Demographic variables | None | | Mild | | Moderate | | X ² -value (df=) | p-value |
|---------------------------------|------|-----|------|------|----------|------|--------------------------------|---------|
| | f | % | f | % | f | % | | |
| 1.Age in years: | | | | | | | | |
| a)45-48 yrs | 0 | 0 | 6 | 20 | 4 | 13.3 | 4.33 (df=4) | 0.363 |
| b)49-52 yrs | 1 | 3.3 | 3 | 10 | 0 | 0 | | |
| c)53-55 yrs | 1 | 3.3 | 10 | 33.3 | 5 | 16.7 | | |
| 2.Age of menarche: | | | | | | | | |
| a)Below 11 years | 1 | 3.3 | 8 | 26.7 | 6 | 20 | 1.808 (df=4) | 0.771 |
| b)11-15 years | 1 | 3.3 | 10 | 33.3 | 3 | 10 | | |
| c)Above 15 years | 0 | 0 | 1 | 3.3 | 0 | 0 | | |
| 3.Marital status: | | | | | | | | |
| a)Married | 1 | 3.3 | 11 | 36.7 | 7 | 23.3 | 1.204 (df=2) | 0.548 |
| b)Unmarried | 0 | 0 | 0 | 0 | 0 | 0 | | |
| c)Widower | 1 | 3.3 | 8 | 26.7 | 2 | 6.7 | | |
| 4.Diet habit: | | | | | | | | |
| a)Vegetarian | 0 | 0 | 3 | 10 | 5 | 16.7 | 5.72 (df=2) | 0.047* |
| b)Mixed | 2 | 6.7 | 16 | 53.3 | 4 | 13.3 | | |
| 5.Religion: | | | | | | | | |
| a)Hindu | 2 | 6.7 | 17 | 56.7 | 7 | 23.3 | 1.204 (df=2) | 0.548 |
| b)Christian | 0 | 0 | 2 | 6.7 | 2 | 6.7 | | |
| c)Muslim | 0 | 0 | 0 | 0 | 0 | 0 | | |
| d)Others | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 6.Educational status: | | | | | | | | |
| a)Non formal education | 2 | 6.7 | 16 | 53.3 | 7 | 23.3 | 0.61 (df=1) | 0.737 |
| b)School level | 0 | 0 | 3 | 10 | 2 | 6.7 | | |
| c)College level | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 7.Occupation: | | | | | | | | |
| a)House wife | 2 | 6.7 | 16 | 53.3 | 7 | 23.3 | 0.61 (df=2) | 0.737 |
| b)Private | 0 | 0 | 3 | 10 | 2 | 6.7 | | |
| c)Government | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 8.Family monthly income: | | | | | | | | |
| a)<Rs.5000 | 2 | 6.7 | 16 | 53.3 | 7 | 23.3 | 0.61 (df=1) | 0.737 |
| b)Rs.5001-10000 | 0 | 0 | 3 | 10 | 2 | 6.7 | | |
| c)Above Rs.10000 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 9.Type of family: | | | | | | | | |
| a)Nuclear family | 2 | 6.7 | 12 | 40 | 5 | 16.7 | 2.98 (df=2) | 0.561 |
| b)Joint family | 0 | 0 | 5 | 16.7 | 4 | 13.3 | | |

| Demographic variables | None | | Mild | | Moderate | | X ² -value | p-value |
|----------------------------------|------|-----|------|------|----------|------|-----------------------|---------|
| | f | % | f | % | f | % | | |
| c)Extended family | 0 | 0 | 2 | 6.7 | 0 | 0 | | |
| 10.Habits: | | | | | | | | |
| a)Tobacco/betal chewing | 1 | 3.3 | 13 | 43.3 | 6 | 20 | 0.28 (df=1) | 0.871 |
| b)Increased intake of coffee/tea | 1 | 3.3 | 6 | 20 | 3 | 10 | | |
| 11.Parity : | | | | | | | | |
| a)Nullipara | 0 | 0 | 2 | 6.7 | 0 | 0 | 1.67 (df=4) | 0.796 |
| b)Multipara | 2 | 6.7 | 16 | 53.3 | 8 | 26.7 | | |
| c)Grand multipara | 0 | 0 | 1 | 3.3 | 1 | 3.3 | | |

(*-P<0.05, significant and **-P<0.01 & ***-P<0.001, highly significant)

The above table represents that there was significant association between the dietary pattern and post test level of Menopausal symptoms in Experimental group.

Discussion

CHAPTER - V

DISCUSSION

This chapter deals with the detailed discussion of the results of the data interpreted through statistical analysis. The focus of the study was to assess the effectiveness of soya protein consumption on the menopausal symptoms among women in Samayanallur at Madurai. The investigator adopted quasi experimental design. 60 menopausal women were selected from the age group of 45-56 years and having mild to moderate level of Menopausal Symptoms. The level of Menopausal Symptoms experienced by the menopausal women was assessed by Heinemann Menopausal Rating Scale. The results are discussed according to the objectives and supporting studies.

FINDINGS BASED ON DEMOGRAPHIC VARIABLES

Most of the women with Menopausal Symptoms in Control group were in the age group of 45-48years (56.7%), had age of menarche between 11-15years (73.3%), majority of them were married (76.7%), with mixed dietary pattern (73.3%), belonging to Hindu Religion (80%), were illiterate (80%), women were house wife (100%), with family income less than Rs.5000/- (100%), living in nuclear family (76.7%), had the habit of increased intake of coffee/Tea (53.3%).

Most of the women with Menopausal Symptoms in Experimental group were in the age group of 53-55years (53.3%), had age of menarche below the 11years (50%), majority of them were married (63.3%), with mixed dietary pattern (73.3%), belonging to Hindu Religion (86.7%), were illiterate (83.3%), women were house

wife (83.3%), with family income less than Rs.5000/- (86.7%), living in nuclear family (63.3%), had the habit of increased intake of coffee/Tea (66.7%).

With respect of age group of women among control group 17 (56.7%) were in the age group of 45-48 years, 9 (30%) were in the age group of 49-52 years, and 4 (13.3%) were in the age group of 53-55 years. In Experimental group 10 (33.3%) were in the age group of 45-48 years, 4 (13.3%) were in the age group of 49-52 years, and 16 (53.3%) were in the age group of 53-55 years.

With the view of age of menarche, in the control group 7 (23.3%) of women attained menarche at the age of below 11 years, 22 (73.7%) attained menarche at the age of 11-15years, and 1 (3.3%) of women attained menarche at the age of above 15 years. In Experimental group 15 (50%) of women attained menarche at the age of below 11 years, 14 (46.7%) attained menarche at the age of 11-15years, and 1 (3.3%) of women attained menarche at the age of above 15 years.

In the view of marital status control group 23 (76.7%) women were married, 7(23.3%) women were widower. In experimental group 19 (63.3%) were married, 11(36.7%) women were widower.

In the aspect of dietary pattern, in control group majority of the women in 22 (73.3%) belongs to mixed diet and 8 (26.7%) belongs to vegetarian. In experimental group majority of the women in 22 (73.3%) belongs to mixed diet and 8 (26.7%) belongs to vegetarian.

With regard to religion, in control group 24 (80%) belongs to Hindu religion, 6(20%) belongs to Christian. In experimental group 24 (80%) belongs to Hindu religion, 6(20%) belongs to Christian.

In the view of educational status majority of the women in control group 24 (80%) were illiterate, and 6 (20%) were school level education. In experimental group majority of the women in 25 (83.3%) were illiterate and 5 (16.7%) were school level education.

In the view of occupational status majority of the women in control group 24(80%) were house wife and 6 (20%) women were working as a private company. In experimental group 25 (83.3%) were house wife and 5 (16.7%) women were working as a private company.

With regard of family monthly income majority of the women in control group 30 (100%) get less than Rs.5000/-. In experimental group majority of the women 26 (86.7%) get less than Rs.5000/-. And 4 (13.3%) women were get Rs 5001-10000/-.

In the view of type of family, in control group 23 (76.7%) belongs to nuclear family, 7 (23.3%) belongs to joint family. In experimental group 19 (63.3%) belongs to nuclear family, 9 (30%) belongs to joint family, 2 (6.7%) belongs to extended family.

With the view of habits majority of the women in control group 16 (53.3%) were increased intake of coffee/tea, 14 (46.7%) were tobacco/betel chewing. In experimental group 20 (66.7%) were tobacco/betel chewing, 10 (33.3%) were increased intake of coffee/tea.

With the view of the parity majority of the women in control group 23 (76.7) were multipara, 5(16.7) were grandmultipara and 2 (6.7) were Nullipara. Majority of the women in experimental group 26 (86.7) were multipara, 2 (6.7) were grandmultipara and 2 (6.7) were Nullipara.

FINDINGS BASED ON OBJECTIVES:

The first objective was to assess the level menopausal symptoms among women both Control and experimental group

The level of menopausal symptoms among menopausal women in control group was assessed by Menopausal Rating Scale with use of this technique the majority of the women 27 (90%) women were moderate level of Menopausal symptoms and 3 (10%) women were mild level of menopausal symptoms. Majority of the women among in experimental group score is 28 (93.3%) women were moderate level of Menopausal symptoms and 2 (6.7%) women were mild level of Menopausal symptoms.

This study can be compared to the study conducted by **Chim H, Tan BH et al, (2005)** among 495 Singaporean migrant women aged 40 to 60 to determine the prevalence of 17 menopausal symptoms. The mean age of participants was 49 years and the classical menopausal symptoms found were hot flushes (17.6%), vaginal dryness (20.7%) and night sweats (8.9%). The most prevalent symptom reported was low backache with aching muscle joints (51.4%). The most well-known effect of these is the "hot flash" or "hot flush", a sudden temporary increase in body temperature. These symptoms were reported due to hormonal changes underlying menopause, which are caused by aging, other health states, psychosocial factors and life style.

The second objective was to evaluate the effectiveness of soya bean consumption on menopausal symptoms among women:

After the intervention assessed the level of menopausal symptoms by using same menopausal rating scale. The majority of the women among control group post test score is 26 (86.7%) of women were moderate level of Menopausal symptoms 4 (13.3%) women were mild level Menopausal symptoms. Majority of the women among in experimental group 19 (63.3%) women were mild level of Menopausal symptoms and 9 (30%) women were moderate level of Menopausal symptoms and 2 (6.7%) women were none of the Menopausal Symptoms. Mean and Standard Deviation of post test Menopausal symptoms score in Control group (M=17.7, SD=3.39) and Experimental group (M=10.60, SD=3.70). 't' value is 7.09. P-value is 0.000. The difference was found to be statistically significant at 0.001 levels and can be attributed to effectiveness of soya bean consumption. The obtained mean post test of level of Menopausal symptoms score is 10.6 which were lower than the mean pre test level of Menopausal symptoms score is 19.53 in experimental group. The obtained 't' value is 21.53 statistically significant by used the paired 't' test. The reduction indicated that effectiveness of soya protein was given on Menopausal symptoms in experimental group.

The present study is consistent with the study conducted by **Muthamilselvi (2010)** to evaluate the effectiveness of pretest and posttest level of knowledge on soya bean consumption in reducing Menopausal symptoms among women. A Menopausal rating scale was used in this study. Knowledge Pre test (M=13%, SD=1.94) and Post test (M=27.36%, SD=1.11) 't'-value is 46.22, P-value is 0.000. It was evident that overall knowledge in post test score was higher than the pretest score. Hence there was significant gain in level of knowledge. So that the intervention is effective.

Another study also consistent with the present study which was conducted by **Silvina Levis (2010)**. A prospective clinical 6 week trial study was conducted in Australia enrolled 25 postmenopausal women who received a diet supplemented with soya flour, red clover sprouts or linseed each for 2 week in turn. Vaginal maturation value is increased after the 2 week soya rich diet ($P < 0.05$) but not after red clover or linseed.

Hence the Hypothesis1 (H₁): There is a significant difference between the pretest and posttest level of Menopausal Symptoms among the menopausal women in Samayanallur at Madurai was accepted.

The third objective was to associate the level of menopausal symptoms with selected demographic variables among women in control and experimental group:

Statistical association between the post test score and selected demographic variables were calculated in both group experimental and control group using Chi square test. In control group the results showed that there was no association found between the post test level of menopausal symptoms and selected demographic variables like age, age of menarche, marital status, dietary pattern, religion, educational status, occupation, income, type of family, habits and parity. In experimental group the calculated χ^2 value 5.57 at calculated P value is 0.01 which showed that there was significant association between post test score of level of menopausal symptoms and the dietary pattern of women.

The present study is consistent with the study conducted by **Shilpa D.V (2013)** a clinical study was conducted in Kolar. The investigator used convenient sampling technique to select the samples from the total population. Mean and

Standard deviation of post test menopausal symptom score were low in experimental group (M=12.950, SD=2.5849) compared to control group (M=17.550, SD= 3.5314). The difference was found to be statistically significant at 0.05 levels and can be attributed to effectiveness of soya bean consumption. There was significant association between the dietary pattern and post test menopausal symptoms in experimental group.

Thus, Hypothesis 2 (H₂): There is a significant association between level of menopausal symptoms with selected demographic variables (dietary pattern) was accepted.

*Summary,
Conclusion &
Recommendations*

CHAPTER – VI

SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS

This chapter deals about summary of the study findings, conclusion, implications of the study in different areas of nursing like nursing education, nursing administration, nursing practice and nursing research and Recommendations.

“A study to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women in Samayanallur at Madurai.”

6.1 SUMMARY OF THE STUDY:

Menopause is a natural phenomenon, but then it causes many symptoms which deteriorates the health of the women and makes her in trouble for the increased chance of many complications. In the menopausal years, many women undergo noticeable and clinically observable physical changes resulting from hormonal fluctuations.

Signs and effects of the menopause transition can begin as early as age 40, although most women become aware of the transition in their mid to late 45s, often many years after the actual beginning of the perimenopausal window. The typical age range of menopause is between ages of 40 and 54 and the average for last period is 51 years in western countries. In some developing countries, the median age for natural menopause is at 44 years. In India as per the 2007 reports, the mean age at menopause ranges from 40 to 50 years.

Menopause doesn't creep up on women and hit them all of a sudden. There are Three distinct stages to menopause; Premenopause, Perimenopause and Post menopause. Premenopausal is the word used to describe the years leading up to last period, when the levels of reproductive hormones are already becoming lower.

Perimenopause is defined as the period immediately prior to menopause and the first year after menopause and Post menopause is the period after the final menstrual period. Climacteric is the phase of aging process during which a woman passes from the reproductive to the non-reproductive stage. This phase 4 covers 5-10 years on each side of menopause, premenopause and post menopause. **(Alan H.DeCherney)**.

Many pharmacological and nonpharmacological measures are being used by perimenopausal women for centuries to overcome these devastating symptoms. Soya protein one such agent used by perimenopausal women is (glycine max) a leguminous plant containing 40% protein, minerals (like calcium, iron, phosphorus, and zinc), vitamins (like B complex, vitamin E) and phytoestrogen and lecithin. FDA (Food and Drug Administration) has recommended adding 45 to 100 mg of soya diet in a day is beneficial to alleviate menopausal symptoms.

Soya beans are very rich in nutritive components. Besides the very high protein content. It contains a lot of fiber and is rich in calcium, magnesium. 100g soya bean contains 36.5gm of protein and 200 mg of is flavones. 60gm soya bean contains 21.9 gm. Daily recommended protein for women and is 46gm per day. According to an article published in a 2007 edition of the “**Journal of the International Society of sports Nutrition**” physically active women require protein 1.4 to 2.0 gram per kilogram of body weight. According to the Institute of medicine 0.8gram of protein per kilogram of body weight.

So the investigator conducted a study to assess the effectiveness of soya protein consumption on the menopausal Symptoms among women in Samayanallur at Madurai.

Objectives of the study were

1. To assess the level menopausal symptoms among women in experimental and control group.
2. To evaluate the effectiveness of soya protein consumption on menopausal symptoms among women.
3. To find the association between menopausal symptoms with selected demographic variables in experimental and control group.

The following hypothesis were tested at 0.05% level

- H₁:** There is a significant difference between the menopausal symptoms before and after soya protein consumption among women in control and experimental group.
- H₂:** There is a significant association between menopausal symptoms with their selected demographic variable among control and experimental group.

The setting of the study was conducted in Samayanallurat Madurai. The research approach used in the study was quantitative approach and the design was Quasi experimental Non randomized control group design. Non probability purposive sampling technique was used in this study. The sample size of the study was 60 among that 30 were in experimental group, 30 were in control group. Heinemann Menopausal Rating scale was used to assess the level of menopausal symptoms. A wide review of related literature, professional experience and expert's guidance provided strong foundation for the study. The content validity and reliability for the tool was obtained prior to the study. A pilot study was conducted prior to the main study and it showed that the study was feasible and practicable. The study is based on J.W.KENNY'S OPEN SYSTEM MODEL 1991. All the living systems are open, in that there is continuous exchange of matter, energy and information. Open system has changing degree of interaction with the environment from which the System receives

input and gives back out put in the form of matter, energy and information. For survival, all systems of nursing receive varying type and amount of matter, energy and information. The data collection was done for a period of four weeks from 12.8.2014-15.9.2014. Purposive sampling technique was used to selected the experimental group and control group. Assessed the level of menopausal symptoms for both control and experimental group. Cooked soya bean 60 gram was given to the experimental group daily for four weeks. Control group without administration soya bean. Post test was conducted on first day of fifth week using Heinemann Rating scale. The data were analyzed using descriptive and inferential statistics.

MAJOR FINDINGS OF THE STUDY:

Majority of the women among control group 17 (56.7%) were in the age group of 45-48 years. In experimental group majority of the women 16 (53.3%) were in the age group of 53-55years.

Majority of the women in control group 22 (73.3%) attained menarche at the age of 11-15 years. Whereas in experimental group majority of the women 15 (50%) attained menarche at the age of below 11 years.

Majority of the women among control group 23 (76.7%) women were married. In experimental group majority of the women 19 (63.3%) were married.

The aspect of dietary pattern, in control group a majority of the women 22 (73.3%) belongs to mixed diet. In experimental group majority of the women 22(73.3%) belongs to mixed diet.

Regarding religion in control group majority of the women 24 (80%) belongs to Hindu religion. In experimental group majority of the women 25 (86.7%) belongs to Hindu Religion.

Regarding educational status in control group majority of the women 24 (80%) was illiterate. In experimental group majority of the women 25 (83.3%) were school level education.

Regarding occupation in control group majority of the women 24 (80%) was house wife. In experimental group majority of the women 25 (83.3%) were house wife.

In control group majority of the women 30 (100%) were get less than Rs.5000/-. In experimental group majority of the women 26 (86.7%) were get less than Rs.5000 per month.

Regarding type of family in control group majority of the women 23 (76.7%) belongs to nuclear family. In experimental group majority of the women 19 (63.3%) were belongs to Nuclear family.

Regarding habits most of the women among control group (46.7%) and experimental group (66.7%) were betel chewing habits. Some of the women in control group (53.3%) and experimental group (33.3%) were increased intake of coffee/tea habits.

The majority of the women among control group pretest score was 27 (90%) women were moderate level of menopausal symptoms and 3(10%) of women were mild menopausal symptoms. Majority of the women among in experimental group pretest score is 28(93.3%) women were moderate symptoms and 2 (6.7%) women were mild symptoms.

The majority of the women among control group post test score was 26(86.7%) of women were moderate level of menopausal symptoms, 4(13.3%)

women were mild level of menopausal symptoms. Majority of the women among in experimental group post test score was 19(63.3%) women were mild level of menopausal symptoms and 9 (30%) women were moderate level of menopausal symptoms and 2(6.7%) women were none of the level of menopausal symptoms.

In control group pre test mean score was 17.3, Standard Deviation 3.42, Mean % 39.3%. Where as in post test score Mean and Standard Deviation (M=17.07, SD=3.39, Mean % =38.7%). The mean difference was 0.6.

In Experimental group pretest value Mean and Standard Deviation (M=19.53, SD=3.67, Mean %=44%). Where as experimental post test mean score was (M=10.6, SD=3.70, Mean %=24%). The mean difference was 20.

The level of menopausal symptoms in control group post test Mean score was 17.07, standard deviation 3.49, mean percentage 38.7. Where as in experimental group post test mean 10.6, standard deviation 3.70, mean percentage 24. Difference between the control group and experimental group mean was 14.7%.

In control group pre test mean 17.3, SD=3.42. In post test score mean 17.07, standard deviation 3.39. The 't' value is 1.91 and the P-value is 0.06. The difference was not found to be statistically significant at 0.001 levels.

In Experimental group Mean and Standard Deviation of pre test score (M=19.53, SD=3.67) was higher than the post test value is (M=10.6, SD=3.70). 't' value is 21.52. P-value was 0.000. The difference was found to be statistically significant at 0.001 levels and can be attributed to effectiveness of soya protein consumption. Hypotheses was accepted. Hence it concludes the experimental group perceived less level of menopausal symptoms. Thus the soya protein consumption helps in reducing the menopausal symptoms.

In experimental group mean 10.6, and standard deviation 3.70. In control group post test mean score was 17.07, and standard deviation 3.39. 't' value is 7.05. P-value is 0.000. The experimental group mean value is lower than the control group. The difference was found to be statistically significant at 0.001 levels and can be attributed to effectiveness of soya protein consumption.

Mean and Standard Deviation of pre test Menopausal symptoms score Experimental group (M=19.53, SD=3.67) and post test value is (M=10.6, SD=3.70). 't' value is 21.52. P-value is 0.000. The difference was found to be statistically significant at 0.001 levels and can be attributed to effectiveness of soya protein consumption. Hypothesis is accepted. Hence it concludes the experimental group perceived less level of menopausal symptoms. Thus the soya protein consumption helps in reducing the menopausal symptoms.

There is no significant between the selected Demographic Variables and post test score of Menopausal symptoms in control group.

There is significant association between the dietary pattern and post test Menopausal symptoms in Experimental group.

In experimental group there is significant association between the dietary pattern and post test Menopausal symptoms in Experimental group. Hence the Hypothesis is accepted.

Hence it concludes the experimental group perceived less level of menopausal symptoms. Thus the soya bean consumption helps in reducing the menopausal symptoms.

6.2 CONCLUSION:

According to the results of this study the menopausal women who consuming of soya bean 60grams in 4 weeks had significantly reduction in level of menopausal symptoms. So the soya protein consumption in menopausal symptoms was one among the alternative form of medicine, very effective on reducing menopausal symptoms among the women. Soya bean is a natural food. It contains phytoestrogen and Isoflaven need for menopausal women. It is one of the best alternative method and treatment of menopausal symptoms. So the researcher concludes that soya protein consumption is an effective intervention to reduce menopausal symptoms.

6.3 IMPLICATIONS OF THE STUDY:

The study has implications in nursing practice, nursing education, nursing research and nursing administration.

NURSING PRACTICE:

- The nurses should enlighten their knowledge on reducing menopausal symptoms by using non-pharmacological measures like alternative and complementary medicine.
- Nurse can use evidenced based practice in improving and standard of care.
- Nursing care is an art and science in providing quality care.
- Health teaching is an integral part of nursing care. The nurse personnel need to educate women about menopausal symptoms and dietary modifications in managing symptoms with emerging health trends.
- Health teaching can be imparted through mass media radio, television, etc.
- As nurse counselor she can conduct individual and group counseling to educate women with menopausal symptoms regarding complementary and alternative therapies.

- Nurses must also know about soya protein supplements and its benefits and health promoting practices.
- This helps clinical nurse to use and recommended soya protein to manage menopausal symptoms

NURSING EDUCATION

- With the emerging health care trends, nursing education must focus on non pharmacological therapies to enhance nursing care.
- The nursing students should be taught about the importance of alternative measures to relieve menopausal symptoms such as Soya bean.
- The nurse educator need to prepare the students to obtain skills in educating the mother about the importance of Soya protein on menopausal symptoms and motivate the students in group discussions regarding menopause and importance of Soya protein.
- Nurse educators should incorporate various alternative methods for reliving menopausal symptoms in their curriculum.

NURSING ADMINISTRATION

- With technological advances and the ever growing challenges of Health Care Needs, the administrators have a responsibility to provide nurses with substantive continuing education opportunities.
- This will enable the nurses to update their knowledge, acquire special skills and demonstrate high quality care.
- Nurse administrator should take initiative in organizing seminar, discussion and conference on Soya Protein and Menopausal symptoms.

- The nurse administrator should provide opportunities to the staff to attend training program on complementary and alternative therapy for reducing menopausal symptoms.
- The nurse administrator can encourage staff nurses and student nurses and multiple health workers to involve in research activities of menopausal related problems.

NURSING RESEARCH

- There is need for extensive and intensive research in this area. More research Studies in India are needed to identify menopausal problems and importance of Alternative therapies.
- It opens a big avenue for research on natural remedies, consumption of Soya Protein to decrease severity of menopausal symptom focus on quality, cost effective soas to generate more scientific data base on which new strategies for reducing theSymptoms can be developed.

6.4 RECOMMENDATIONS:

The study had drawn the following recommendation:

- A similar study can be done with other type of soya products.
- A similar study can be replicated with a larger sample
- A similar study can be conducted in urban settings.
- A Similar study can be done with the comparison of other alternative method.

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Appendices

APPENDIX-I

From

Mrs.A.Chitra Devi
I year M.Sc (N) student,
College of Nursing,
Madurai Medical College,
Madurai - 20.

To

The Block Medical officer,
Primary Health Centre,
Samayanallur,
Madurai.

Through: The proper Channel

Respected madam,

Sub : Permission for conducting dissertation study at Samayanallur, Madurai - I year M.Sc (N) Obstetrics and Gynaecological Nursing student- College of Nursing, Madurai Medical College, Madurai-20 requested -regarding.

As per the curriculum recommended by The Tamilnadu Dr.MGR Medical University i have selected the study topic **“A study to evaluate the effectiveness of soya protein conception on the menopausal symptom among women between ~~45-55~~ years in selected Rural community at Samayanallur, Madurai”** for the partial fulfillment of the PG course. I assure that I will not interfere with the routine activity of the area.

Kindly consider my request and permit me to conduct the study.

Thanking you,

Place:

Date:

Yours faithfully,

A. Chitra Devi

(A.CHITRA DEVI)

*Forwarded
S.P.
3/1/14*

Samy
BLOCK MEDICAL OFFICER
Govt. Primary Health Centre,
Samayanallur
Madurai Dist

Permitted

A
3/1/14

Deputy Director of Health Services
Madurai-14.

From

Mrs.A.Chitra Devi
I year M.Sc (N) student,
College of Nursing,
Madurai Medical College,
Madurai - 20.

To

The Deputy Director of Health Services,
Health and Preventive Medicine,
Viswanathapuram,
Madurai.

Through: The proper Channel

Respected madam,

Sub : Permission for conducting dissertation study at Samayanallur,
Madurai - I year M.Sc (N) Obstetrics and Gynaecological
Nursing student- College of Nursing, Madurai Medical
College, Madurai-20 requested -regarding.

As per the curriculum recommended by The Tamilnadu Dr.MGR Medical University
i have selected the study topic "**A study to evaluate the effectiveness of soya protein
conception on the menopausal symptom among women between 45-55 years in selected
Rural community at Samayanallur, Madurai**" for the partial fulfillment of the PG course.
I assure that I will not interfere with the routine activity of the area.

Kindly consider my request and permit me to conduct the study.

Thanking you,

Place: *madurai*

Date: *3/1/14*

Yours faithfully,

A. Chitra Devi
(A.CHITRA DEVI)

Forwarded
S.P
3/1/14
Principal
COLLEGE OF NURSING
Madurai Medical College
Madurai-20.

PERMISSION LETTER

From

Mrs. A. Chitra devi,
II year M.Sc Nursing Student,
College of Nursing,
Madurai Medical College,
Madurai – 20.

To

The Block Medical Officer,
Primary Health Centre,
Samayanallur,
Madurai – 20.

Through - The Proper Channel

Respected Sir / Madam,

Sub: II year M.Sc Nursing Student – College of Nursing, Madurai Medical College, Madurai – conducting dissertation study – Samayanallur, Madurai – permission – requested regarding.

As per the curriculum recommended by the Tamil Nadu Dr. M.G.R. Medical University, I have selected the topic “A Study to assess the effectiveness of soya protein consumption on the menopausal symptoms among women in a selected rural population at Samayanallur, Madurai.” for the partial fulfilment of the PG course.

I kindly request you to consider my letter and allow me to conduct the Pilot Study.

-01.08.2014 to 07.08.14

Thanking you,

Date: 31.7.2014

Place: madurai

Yours faithfully,

A. Chitra Devi

(A. CHITRA DEVI)

Forwarded
S.P.
31/7/14
Principal
BLOCK MEDICAL OFFICER COLLEGE OF NURSING
GOVT PRIMARY HEALTH CENTRE Madurai Medical College
SAMAIYANALLUR -625 402
MADURAI - DISTRICT
Madurai-20.

APPENDIX – II

Ref. No. 68/E4/2/2014,

Govt. Rajaji Hospital,
Madurai.20. Dated: 24.02.2014

Institutional Review Board / Independent Ethics Committee.

Capt. Dr.B. Santhakumar, M.D., (F.M.,) deanmdu@gmail.com

Dean, Madurai Medical College &

Govt Rajaji Hospital, Madurai 625020. **Convenor**

Sub: Establishment-Govt. Rajaji Hospital, Madurai-20-
Ethics committee-Meeting Minutes- for February 2014
Approved list - Regarding.

The Ethics Committee meeting of the Govt. Rajaji Hospital, Madurai was held on 07.02.2014, Friday at 10.00 am to 12.00.noon at the Anaesthesia Seminar Hall, Govt. Rajaji Hospital, Madurai. The following members of the committee have attended the meeting.

-
- | | | |
|--|---|---------------------|
| 1. Dr.V. Nagarajan, M.D., D.M (Neuro) Ph: 0452-2629629 Cell.No 9843052029 nag9999@gmail.com | Professor of Neurology (Retired) D.No.72, Vakkil New Street, Simmakkal, Madurai -1 | Chairman |
| 2. Dr.Mohan Prasad , M.S M.Ch Cell.No.9843050822 (Oncology) drbkcmp@gmail.com | Professor & H.O.D of Surgical Oncology(Retired) D.No.32, West Avani Moola Street, Madurai -1 | Member Secretary |
| 3. Dr. Parameswari M.D (Pharmacology) Cell.No.9994026056 drparameswari@yahoo.com | Director of Pharmacology Madurai Medical College | Member |
| 4. Dr.S. Vadivel Murugan, MD., (Gen.Medicine) Cell.No 9566543048 svadivelmurugan_2007@rediffmail.com | Professor & H.O.D of Medicine Madurai Medical College | Member |
| 5. Dr.S. Meenakshi Sundaram, MS (Gen.Surgery) Cell.No 9842138031 drsundarms@gmail.com | Professor & H.O.D of Surgery Madurai Medical College | Member |
| 6. Mrs. Mercy Immaculate Rubalatha, M.A., Med., Cell. No. 9367792650 lathadevadoss86@gmail.com | 50/5, Corporation Officer's quarters, Gandhi Museum Road, Thamukam, Madurai-20 | Member |
| 7. Thiru..Pala. .Ramasamy , BA.,B.L., Cell.No 9842165127 palaramasamy2011@gmail.com | Advocate, D.No.72.Palam Station Road, Sellur, Madurai -2 | Member |
| 8. Thiru. P.K.M. Chelliah ,B.A Cell.No 9894349599 pkmandco@gmail.com | Businessman, 21 Jawahar Street, Gandhi Nagar, Madurai-20 | Member |

The following Projects was approved by the committee.

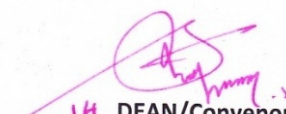
| Name of P.G. | Course | Name of the Project | Remarks |
|---------------|---|---|----------|
| A.Chitra Devi | M.Sc., (Nursing) College of Nursing, Madurai Medical College, Madurai. | A study to assess the effectiveness of soya protein consumption on the menopausal symptom among women between 45-55 years in selected rural community at samayanallur, Madurai. | Approved |

Please note that the investigator should adhere the following: She/He should get a detailed informed consent from the patients/participants and maintain it Confidentially.

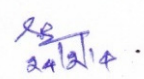
1. She/He should carry out the work without detrimental to regular activities as well as without extra expenditure to the institution or to Government.
 2. She/He should inform the institution Ethical Committee, in case of any change of study procedure, site and investigation or guide.
 3. She/He should not deviate the area of the work for which applied for Ethical clearance.
- She/He should inform the IEC immediately, in case of any adverse events or Serious adverse reactions.
4. She/He should abide to the rules and regulations of the institution.
 5. She/He should complete the work within the specific period and if any Extension of time is required He/She should apply for permission again and do the work.
 6. She/He should submit the summary of the work to the Ethical Committee on Completion of the work.
 7. She/He should not claim any funds from the institution while doing the work or on completion.
 8. She/He should understand that the members of IEC have the right to monitor the work with prior intimation.


Member Secretary

Chairman
Ethical Committee


26.2.14 DEAN/Convenor
Govt. Rajaji Hospital,
Madurai- 20.

To
The above Applicant
-thro. Head of the Department concerned



APPENDIX – III
CONTENT VALIDITY

CERTIFICATE OF VALIDATION

This is to certify that the tool

SECTION A – Demographic Data

SECTION B – Heinmann Menopause Rating Scale


Prepared for data collection by, Mrs.A.Chitra Devi, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai. Who has undertaken the study field on thesis entitled “Effectiveness of soya protein consumption on the menopausal symptoms among women between 45-55 years in a selected rural population at Samayanallur, Madurai.” has been validated by me.

SIGNATURE OF THE EXPERT

NAME:

DESIGNATION:

DATE:


26/7/14
PROF. & HOD
DEPT. OF O & G
Madurai Medical College
Madurai

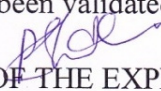
CERTIFICATE OF VALIDATION

This is to certify that the tool

SECTION A – Demographic Data

SECTION B – Heinmann Menopause Rating Scale

Prepared for data collection by, Mrs.A.Chitra Devi, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai. Who has undertaken the study field on thesis entitled “Effectiveness of soya protein consumption on the menopausal symptoms among women between 45-55 years in a selected rural population at Samayanallur, Madurai.” has been validated by me.


SIGNATURE OF THE EXPERT

NAME:

P. SHANMUGA

DESIGNATION:

Professor in
09 Dept

DATE:

25/7/14

CERTIFICATE OF VALIDATION

This is to certify that the tool

SECTION - A Demographic Data

SECTION – B Heinemann Menopausal Rating Scale

Prepared for data collection by, Mrs.A.Chitra Devi, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai Who has undertaken the study field on thesis entitled “A study to assess the effectiveness of soya protein consumption on the menopausal symptoms among women between 45-56 years in Samayanallur, Madurai” has been validated by me.

SIGNATURE OF THE EXPERT



NAME: R. AARTHY SOODI

DESIGNATION: ASS. PROFESSOR.

DATE:

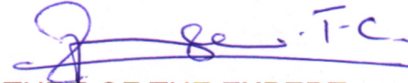
CERTIFICATE OF VALIDATION

This is to certify that the tool

SECTION - A Demographic Data

SECTION - B Heinemann Menopausal Rating Scale

Prepared for data collection by, Mrs.A.Chitra Devi, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai Who has undertaken the study field on thesis entitled “A study to assess the effectiveness of soya protein consumption on the menopausal symptoms among women between 45-56 years in Samayanallur, Madurai” has been validated by me.



SIGNATURE OF THE EXPERT

NAME: T. C. SUGUNA

DESIGNATION: PROFESSOR

DATE: 28/8/14

CERTIFICATE OF VALIDATION

This is to certify that the tool


SECTION A – Demographic Data

SECTION B – Heinmann Menopause Rating Scale

Prepared for data collection by, Mrs.A.Chitra Devi, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai. Who has undertaken the study field on thesis entitled “Effectiveness of soya protein consumption on the menopausal symptoms among women between 45-55 years in a selected rural population at Samayanallur, Madurai.” has been validated by me.

SIGNATURE OF THE EXPERT

NAME:


21/8/14
Dr. G. S. CHITRA

DESIGNATION:

Professor
Dept. of O&G
Govt. Rajaji Hospital
Madurai.

DATE:

APPENDIX-IV

INFORMED CONSENT FORM

ஓப்புதல் அறிக்கை

பெயர்:

நாள்:

எனக்கு இந்த செவிலிய ஆய்வினைப் பற்றிய முழு விவரம் விளக்கமாக எடுத்துரைக்கப்பட்டது. இந்த ஆய்வில் பங்குகொள்வதில் உள்ள நன்மைகள் மற்றும் தீமைகள் பற்றி முழுமையாக புரிந்துகொண்டேன். இந்த ஆய்வில் தானாக முன் வந்து பங்குபெறுகிறேன். மேலும் எனக்கு இந்த ஆய்விலிருந்து எந்த சமயத்திலும் விலகிக் கொள்ள முழு அனுமதி வழங்கப்பட்டுள்ளது. என்னுடைய பெயர் மற்றும் அடையாளங்கள் ரகசியமாக வைத்துக்கொள்ளப்படும் என்றும் எனக்கு உறுதியளிக்கப்பட்டுள்ளது.

கையொப்பம்

APPENDIX - V

DATA COLLECTION TOOL

SECTION – A: DEMOGRAPHIC VARIABLE

(Please put ✓ mark in correct one)

Sample No:

1.Age in years

a. 45-48 years

b. 49- 52 years

c.53-55 years

2. Age of Menarche

a. Below 11 years

b. 11-15 years

c. Above 15 years

3. Marital status

a. Married

b. Unmarried

c. Widower

4. Diet habit

a. Vegetarian

b.Mixed

5. Religion

a. Hindu

b. Christian

c. Muslim

d. Others

6. Educational status

- a. Non formal education
- b. School level
- c. College level

7. Occupation

- a. House wife
- b. Private
- c. Government

8. Family monthly income

- a. < Rs 5000
- b. Rs 5001 – 10000
- c. Above Rs 10000

9. Type of family

- a. Nuclear family
- b. Joint family
- c. Extended family

10. Habits

- a. Tobacco/betel chewing
- b. Increased intake of coffee/tea

HEINEMANN MENOPAUSAL RATING SCALE (MRS)

| Symptoms | None 0 | Mild 1 | Moderate 2 | Severe 3 | Very Severe 4 |
|---|-------------------|-------------------|-----------------------|---------------------|------------------------------|
| 1. Hot flushes, sweating. (episodes of sweating). | | | | | |
| 2. Heart discomfort (unusual Awareness of heart beat, heart skipping, heart racing, and tightness). | | | | | |
| 3. Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early). | | | | | |
| 4. Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings). | | | | | |
| 5. Irritability (feeling nervous, inner tension, feeling aggressive). | | | | | |
| 6. Anxiety (inner restlessness, feeling panicky). | | | | | |
| 7. Physical and mental exhaustion (general decrease in concentration, forgetfulness) | | | | | |
| 8. Sexual problem (change in sexual desire, in sexual activity and satisfaction) | | | | | |
| 9. Bladder problem (difficulty in urinating, increased need to urinate, bladder incontinence) | | | | | |
| 10. Dryness of vagina (sensation of dryness or burning in the vagina, difficulty with sexual intercourse) | | | | | |
| 11. Joint and muscular discomfort (pain in the joints, rheumatoid complaints) | | | | | |

INTERPRETATION:

| Menopausal symptoms | Score |
|----------------------------|--------------|
| None | 0 |
| Mild | 1-11 |
| Moderate | 12-22 |
| Severe | 23-33 |
| Very severe | 34-44 |

APPENDIX – VI

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þ) 53 Ó¾ø 56 ÁÁÐ Á Á

2. ÀÕÁÁ ¼ó¾ ÁÁÐ

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7. $\frac{1}{2}x + \frac{3}{4}y = A$

«) $\frac{1}{2}x + \frac{3}{4}y = A$ | $\frac{1}{2}x = A - \frac{3}{4}y$

→) $\frac{1}{2}x = A - \frac{3}{4}y$ | $x = 2A - \frac{3}{2}y$

b) « $\frac{1}{2}x = A - \frac{3}{4}y$

8. $\frac{1}{3}x + \frac{1}{4}y = 5$

«) $\frac{1}{3}x + \frac{1}{4}y = 5$ | $\frac{1}{3}x = 5 - \frac{1}{4}y$

→) $\frac{1}{3}x = 5 - \frac{1}{4}y$ | $x = 15 - \frac{3}{4}y$

b) $\frac{1}{3}x = 5 - \frac{1}{4}y$

9. $\frac{1}{2}x + \frac{1}{3}y = 10$

«) $\frac{1}{2}x + \frac{1}{3}y = 10$ | $\frac{1}{2}x = 10 - \frac{1}{3}y$

→) $\frac{1}{2}x = 10 - \frac{1}{3}y$ | $x = 20 - \frac{2}{3}y$

b) $\frac{1}{2}x = 10 - \frac{1}{3}y$

10. $\frac{1}{2}x + \frac{1}{3}y = 10$

«) $\frac{1}{2}x + \frac{1}{3}y = 10$ | $\frac{1}{2}x = 10 - \frac{1}{3}y$ | $x = 20 - \frac{2}{3}y$

→) $\frac{1}{2}x + \frac{1}{3}y = 10$ | $\frac{1}{3}y = 10 - \frac{1}{2}x$ | $y = 30 - \frac{3}{2}x$

b) $\frac{1}{2}x = 10 - \frac{1}{3}y$

11. பிரசவத்தின் எண்ணிக்கை

அ) குழந்தையின்மை

ஆ) இரண்டு குழந்தைகளுக்கு மேல்

இ) ஐந்து குழந்தைகளுக்கு மேல்

Á;¼Á¼;ö Á¼òÀí « Ç×S, iø

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|----------|--|------------|------------|------------|-----------------|-----------------------|
| 1. | ¼ø ¿ ÁòÁ ¿· Á ÁíüÈö, ÁÁ÷ò¼ø (« Èí ¿ ÁÁ÷ò¼ø) | | | | | |
| 2. | p¼Áí S, iÇiÜ, ü (p¼ÁÐÈòÀø ÁíüÈö, p¼Áò¼¼¼ò p¼Á pÜí, ö) | | | | | |
| 3. | à í, ò¼ø ¿üÁí ö ÁÁí °· È, ü (à í Ì Á¼ø °ÁÁö, à í Ì ö\$ÁíÐ °ÁÁòÁí ¼ø, °í ¿Áí, ±Øó¼ö¼ø) | | | | | |
| 4. | ÁÉ « Øò¼ö (ÁÉ í \$°í÷×, ¿Á· ÁòÁí ¼ø, ¿ñ ½£ Áí ¼ø, ÁöòÁÁý· Á, ÁÉ ¿· Á ÁíüÈö) | | | | | |
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| 7. | $\frac{1}{4}\varnothing \text{ ÁüÜö}$ $\text{ÁÉ}\hat{\tau}\text{S}^{\circ}\text{j}\div\times (\text{!}^{\circ}\text{Á}\varnothing\text{Á}\hat{\tau}$ $\hat{\text{I}} \ddot{\text{E}}\frac{3}{4}\varnothing, \text{¿}\hat{\text{C}} \ddot{\text{E}}\text{Á}\hat{\text{j}}\hat{\text{ü}}\hat{\text{E}}\varnothing$ $\hat{\text{I}} \ddot{\text{E}}\frac{3}{4}\varnothing, \text{Ö}\varnothing\frac{3}{4}\varnothing \text{Ü}\div \ddot{\text{A}}$ $\hat{\text{I}} \ddot{\text{E}}\frac{3}{4}\varnothing, \text{Á}\hat{\text{E}}\frac{3}{4}\varnothing)$ | | | | | |
| 8. | $\text{Á}\hat{\text{j}}\text{Á}\hat{\text{C}}\hat{\text{A}}\varnothing \text{Á}\hat{\text{C}}\hat{\text{A}}\hat{\text{T}}^{\circ}\hat{\text{E}}\hat{\text{ü}}$ $(\text{Á}\hat{\text{j}}\text{Á}\hat{\text{C}}\hat{\text{A}}\varnothing$ $\text{Á}\hat{\text{C}}\hat{\text{O}}\hat{\text{A}}\hat{\text{A}}\hat{\text{y}} \ddot{\text{A}}, \text{Á}\hat{\text{j}}\text{Á}\hat{\text{C}}\hat{\text{A}}\varnothing$ $\text{¿}\frac{1}{4}\hat{\text{A}}\hat{\text{E}}\hat{\text{i}} \ddot{\text{A}}\varnothing \text{Á}\hat{\text{j}}\hat{\text{ü}}\hat{\text{E}}\hat{\text{ö}},$ $\text{Á}\hat{\text{j}}\text{Á}\hat{\text{C}}\hat{\text{A}}\varnothing \frac{3}{4}\hat{\text{O}}\hat{\text{ö}}\frac{3}{4}\hat{\text{C}}$ $\hat{\text{I}} \ddot{\text{E}}\times)$ | | | | | |
| 9. | $^{\circ}\hat{\text{U}} \text{¿}\hat{\text{E}}\hat{\text{o}} \ddot{\text{A}}$ $\text{Á}\hat{\text{C}}\hat{\text{A}}\hat{\text{T}}^{\circ}\hat{\text{E}}\hat{\text{ü}} (^{\circ}\hat{\text{U}} \text{¿}\hat{\text{E}}$ $\text{¿}\hat{\text{E}}\hat{\text{ö}}\hat{\text{A}}\frac{3}{4}\varnothing ^{\circ}\hat{\text{A}}\hat{\text{A}}\hat{\text{ö}},$ $\ll \hat{\text{E}}\hat{\text{i}} \text{¿}\hat{\text{E}} ^{\circ}\hat{\text{U}} \text{¿}\hat{\text{E}}$ $\text{¿}\hat{\text{E}}\hat{\text{ö}}\frac{3}{4}\varnothing, ^{\circ}\hat{\text{U}} \text{¿}\hat{\text{E}}$ $\ll \frac{1}{4}\hat{\text{i}} \text{¿}\hat{\text{O}}\hat{\text{E}}\hat{\text{A}} \ddot{\text{A}})$ | | | | | |
| 10. | $\text{S}\hat{\text{A}}\hat{\text{j}}\hat{\text{E}}\hat{\text{C}}\hat{\text{A}}\hat{\text{E}}\hat{\text{ö}}^{\circ}\hat{\text{C}} (\hat{\text{A}}\hat{\text{E}}\hat{\text{ö}}^{\circ}\hat{\text{C}}$ $\text{¿}\frac{1}{2}\div\times, \pm\text{j}\hat{\text{C}}^{\circ}\varnothing,$ $\text{¿}\frac{1}{4}\hat{\text{O}}\hat{\text{E}}\hat{\text{A}}\varnothing ^{\circ}\hat{\text{A}}\hat{\text{A}}\hat{\text{ö}})$ | | | | | |
| 11. | $\hat{\text{a}} \hat{\text{o}}\hat{\text{I}} \text{ ÁüÜö } \frac{3}{4} \hat{\text{C}}^{\circ}$ $\text{Á}\hat{\text{C}}\hat{\text{A}}\hat{\text{T}}^{\circ}\hat{\text{E}}\hat{\text{ü}}$ $(\hat{\text{a}} \hat{\text{o}}\hat{\text{I}} \text{ ¿}\hat{\text{C}}\varnothing \text{Á}\hat{\text{A}}\hat{\text{C}}, \hat{\text{a}} \hat{\text{o}}\hat{\text{I}}$ $\text{Á}\hat{\text{C}}\hat{\text{A}}\hat{\text{T}}^{\circ}\hat{\text{E}}\hat{\text{ü}})$ | | | | | |

APPENDIX-VII

CERTIFICATE OF ENGLISH EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation “ A Study to assess the effectiveness of soya protein consumption on the menopausal symptoms among women in a selected rural population at Samayanallur, Madurai.” done by Mrs,A. Chitra Devi M.Sc Nursing II Year student, college of Nursing, Madurai Medical College Madurai-20 has been edited for English language appropriateness.

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APPENDIX-VIII

CERTIFICATE OF TAMIL EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation “ A Study to assess the effectiveness of soya protein consumption on the menopausal symptoms among women in a selected rural population at Samayanallur, Madurai.” done by by Mrs,A. Chitra Devi M.Sc Nursing II Year student, college of Nursing, Madurai Medical College Madurai-20 has been edited for Tamil language appropriateness.

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APPENDIX-IX



THE INVESTIGATOR DISTRIBUTE THE SOYA BEAN

