DISSERTATION

ON

"A STUDY TO ASSESS THE EFFECTIVENESS OF SOYA BEAN ON MENOPAUSAL SYMPTOMS AMONG MENOPAUSAL WOMEN IN THE INSTITUTE OF OBSTETRICS AND GYNAECOLOGY, CHENNAI-08."

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CERTIFICATE

This is to certify that this dissertation titled, **"A STUDY TO ASSESS THE EFFECTIVENESS OF SOYA BEAN ON MENOPAUSAL SYMPTOMS AMONG MENOPAUSAL WOMEN IN THE INSTITUTE OF OBSTETRICS AND GYNAECOLOGY, CHENNAI-08."** is a bonafide work done by **Ms. M.KALAIVANI , M.Sc (N)** II Year College of Nursing, Madras Medical College, Chennai-03, submitted to **The Tamil Nadu 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 Gynaecological Nursing, under our guidance and supervision during academic period from 2012-2014.

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"Blessed is the man who trusts in the Lord and has made the Lord his hope and confidence."

-Jeremiah :17.7

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-Pslam: 86. 1

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ABSTRACT

Background: To assess the effectiveness of soya bean on menopausal symptoms among menopausal women. Menopause is a natural process that occurs in women's lives as part of normal aging. Many women go through the menopausal transition with few or no symptoms, wholesome have significant or even disabling symptoms. 60 Menopausal women were selected in gynecology outpatient department. **Method:** Quasi experimental research design was utilized and data collected by convenience sampling method by using the structured interview method. The collected data were analyzed by descriptive and inferential statistics. **Results:** In pre-assessment the menopausal symptoms mean score in Experiment group was 17.57 and in control group was 17.80 score. So the difference was 0.23.The calculated 't' value was 1.29 at P=0.21 respectively .This difference was small and it is not statistically significant. In pre-assessment the menopausal symptoms for the women in experiment group was Mild-23.3%, Moderate-70%, Severe-6.7%. In control group, Mild-20.0%, Moderate-73.3% and in Severe-6.7%. This difference was small and it is not statistically significant difference. In post-assessment the menopausal symptoms score in Experiment group was 12.07 and in control group was 18.73 score. The calculated 't' value was 8.77 at P=0.001*** .So the difference was 6.66. This difference is large and it is statistically significant. In post-assessment the menopausal symptoms for the women in experiment group was Mild-70.0%, Moderate-30%,Severe-None. In control group, Mild-16.6%, Moderate-76.7%, Severe-6.7%.This difference was small and it is not statistically significant difference. In experiment group the reduction score in effectiveness of soya bean consumption was 18.3% and in Control group it was increased as 3.1% problems more. Statistically there is a difference between experimental and control group. **Conclusion:** Soya bean is very effective in reducing the menopausal symptoms among the menopausal women .The difference was associated in Experimental group and control group.

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CHAPTER I

INTRODUCTION

"The journey of a thousand miles begins with but a single step."

-Confucius

Every living thing in nature is susceptible to change. The flower that blooms today will wilt tomorrow, the leaf that looks green today will fall off. This is the case with humans too. Human beings experience various turning points in their life cycle which may be developmental or transitional.

The transitional changes of a girl start when she attains **Menarche**. Thus a girl transformed to a women. At last woman will reach the stage of menopause in which various physiological as well as psychological changes will takes place. But these are usually neglected by most of the women.

Each stage of a woman's life is organized around what Goddess Cultures called the **blood mysteries: menarche (the first monthly flow of blood)**, childbirth, which is accompanied by blood from birthing; and menopause, when a woman's **'wise blood'** remained inside her to give her wisdom. These are still powerful landmarks, which profoundly influence women's lives. The increasing average length of the postmenopausal life span emphasizes the importance of menopause in today's society.

Women are the vital set up and heart of the family. When women have been tired, family function would be altered. Women are facing lot of problems throughout their life. One of the most common problem, they are facing is menopause and hormonal changes during their middle adulthood. The menopausal problems of women always make them so tired. So they need treatment and health education regarding menopausal care and prevention of menopausal problems.

When a women's hormone balance begins to shift, she may have menstrual cycles with no ovulation called anovulatory cycle. She may begin to have menopausal symptoms. Menopause is that stage in women's life when both physiological and emotional changes in their bodies are precipitated by hormonal deficiencies as a result of age. During pre-menopause, oestrogen levels drop because the ovaries ability to produce enough oestrogen has weakened. Pre menopause usually occurs five years before menopause - a period in women's life when the ovaries no long produce oestrogen and therefore completely without further egg production.

Menopause is defined as the time of cessation of ovarian function resulting in permanent amenorrhea. It takes 12 months of amenorrhea to confirm that menopause has set in and therefore it is retrospective diagnosis. As ovarian function diminishes, a sequential loss in the function of oestrogen dependent tissue occurs. Ovulation and menstruation cease. There are changes in vaginal and vulvar tissue and other oestrogen dependent tissue such as the breasts, with aging, fever follicles respond to gonadotropin stimulation, reducing the level of oestrogen resulting in the symptoms associated with menopause.

According to **World Health Organization** and the **Stages of Reproductive Aging Workshop Working Group -** Menopause is defined as the permanent cessation of menstrual periods that occurs naturally or is induced by surgery, chemotherapy, or radiation. It is a natural process that occurs in women's life   as part of normal aging. Many women go through the menopausal transition with few or no symptoms, wholesome have significant or even disabling symptoms. Currently men and women in India in the 50 plus age group number is 60 million that is about 6% of the population. Projection for the year 2025 shows that aging population would increase to about 12% of the total and roughly half of this population will be women in the elderly age group.

The symptoms of menopause usually last for the whole menopause transition (until the mid50s), but some women may experience them for the rest of their lives. The

most common symptoms are hot flushes , joint pain, sweat, fatigue and vaginal dryness .Proper diagnosis of menopausal symptoms, especially hot flushes can be availed out with proper diagnosis of oestrogen supplements. Certain foods which are rich in oestrogen supplements help in reducing the menopausal hot flushes. The dietary supplements like soya beans, wild yam and vitamin E like green leafy vegetables, nuts and almonds, as well as plenty of mineral- and fibre-rich foods, like whole grains and fresh vegetables and water helps in reducing menopausal symptoms like, hot flushes.

pre menopause is a very important period in women's life; informed knowledge of what to expect will go a long way to prepare a woman for what is to come during menopause proper, especially because each woman's transition from pre menopause to menopause may differ drastically due to the difference in the amount of the male hormone androgens that may be produced, which accounts for the devastating secondary male characteristics often exhibited by menopausal women.

Pre menopause symptoms vary from person to person: some women will experience hot flashes, mood swings, dry vaginal canal, loss of sex drive, irritability, gums bleeding, tinnitus or even heart attack or stroke, while others will experience just a few of those as pre menopause symptom.

Pre menopause is the physiological termination of normal menstrual cycles. Pre menopause is generally caused more early than the normal age which is associated with the cessation of the menstrual cycles. Pre menopause occurs when the ovaries virtually stops producing the oestrogen which generally leads the fertility aspect of the women to shut down.

Signs and effects of the menopause transition can begin as early as age 35, although most women become aware of the transition in their mid to late 40s, 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 40.32 to 48.48 years. Symptoms of menopause that are difficult to deal during this period include hot flushes, mood changes, irritability, depression, night sweats, insomnia, weight gain, changes in breast size, or the development of facial, chest, or abdominal hair.

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 Post-menopausal 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. The conventional treatment for menopausal symptoms is Hormone replacement therapy. Hormone replacement therapy may be good at relieving some of those torturous menopausal symptoms by replacing the lost hormones in the female body. But analysis from the Women's Health Initiative indicates that combination hormone therapy increases cancer and heart disease risk.

Soy products are considered to have phytoestrogen properties. Soy products are particularly rich in isoflavones, primarily genistein and daidzein. Soy acts as oestrogens, anti –oestrogens', antioxidants and immune enhancers. They are structurally similar to oestrogen hormones women produce, but they are different enough not to be fully fledged steroidal hormones. They also act as anti – oestrogens and that is why they reduce the risk of cancer. Oestrogen signal cells to proliferate, that is why it is carcinogenic. Genistein has only 1/ 1000 the hormonal activity of oestrogen, attaches to the breast cells

oestrogen receptors and thereby blocks the most potent female hormones from attaching , so in oestrogen deficiency states, isoflavones can attach to open oestrogen receptor sites on cells and produce a weak oestrogen effect. Isoflavones can reduce cancer risk by inhibiting the activity of tyrosine kinase, an enzyme that promotes cancer cell growth, and therefore they are cancer enzyme inhibitor. They are antioxidants by preventing free radical damage to DNA, the complex molecule that contains genes. They reduce the risk of cancer by activating immune cells, thereby an immune enhancer.

1.1 NEED FOR THE STUDY

"Awareness is infinite treasure ….Trace it, Try it, Trust it".

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

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.

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 .

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 47.5years.

Laxmi Narayanabairy, shaliny adega,(2009) conducted a study that in the **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.

Although menopause is 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 need of natural approaches to relieve menopausal discomfort and soya is considered as **"super food "**for relieving menopausal symptoms.

Coplin S. (2000) states that Soybean is commonly called wonder bean since it is an excellent source of nutrients such as proteins, fats, carbohydrates, vitamins and minerals. . It contains 43 grams of protein per 100 grams which is the highest among the pulses. It also contains 19.5 grams of fat, 21 grams of carbohydrate and provides 432 kcal per 100 gm. Soybean also contains a family of chemical compounds called phytoestrogens. Phytoestrogens have chemical structures similar to the oestrogens

produced in the body and it is believed that eating foods rich in phytoestrogens can help alleviate low oestrogen production in the body. Isoflavones are the active ingredients in soybeans which have oestrogen-like properties .Isoflavones reduces 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 .Soybean is used extensively as human food, animal feed and for industrial purposes. All the products of soybean are of dietary importance such as soybean cheese, soybean milk, soybean oil, soybean meal.

Firedikronenberg, Adriane Fugh et.al (2002) conducted a study to review randomized, controlled trials of complimentary therapies for menopausal symptoms in order to better inform practice and guide future research. 29 randomized, controlled clinical trials of complimentary therapies for hot flushes and other menopausal symptoms were identified, and of these 12 dealt with soy or soy extracts, 10 with herbs, and 7 with other complimentary therapies. **This study concluded that food containing** phytoestrogens show promise for the treatment of menopausal symptoms. The best source is soya in various forms such as soya beans, fortified soya milk, tofu and soya flour which contain high levels of isoflavones and calcium. More than 12% of our population will be 60 or more by 2010. By the year 2020, 45.9 million women will be experiencing menopause. Despite an aggressive marketing, women are always reluctant to take oestrogen replacement therapy. Even in developed countries, only 35% of women started taking oestrogen replacement therapy and only 15 % continued it.

Phytoestrogens on the other hand are natural products that offer the beneficial effects of oestrogens minus their adverse effects. Epidemiological studies (observational) revealed that rates of cardiovascular diseases and colon, prostate and breast cancers were low in societies consuming high quantities of soy in their diet.

Japanese women have a much lower incidence of hot flushes, as their diet is rich in soya. Phytoestrogens have been found to reduce vasomotor symptoms in most of the epidemiological studies. One study found a 45% decrease in menopausal flushes on women using 40-60 mg of soy products per day. Phytoestrogens also have other benefits, like improved vascular compliance by 26% is noted, they cause a favourable alteration in insulin resistance, improves glycaemic control and serum lipoproteins are altered favourably. They also have lowered the incidence of osteoarthritis and prevent cardiac diseases in predisposed women.

This natural therapy is more cost effective too. In India, about 19% women have hot flushes. Plants have been used as medicine since time immemorial, therefore phytoestrogens (occurring naturally in certain food products) should not be set aside as quackery, but should be studied more vigorously to further elaborate the efficacy on human body.

With the latest findings from **Women's Health Initiative** confirming what made headline news in 2002- that hormone therapy is now more presumed harm than potential benefit , particularly for women with or at a risk for cardiovascular disease or cancer, women are turning to alternative therapies to treat the signs and symptoms of menopause.

Ginrich. P.M, Fogel. C.I, in the USA (2000) conducted a study that more than two thirds of the women in the study used herbal therapy, out of which 77.5% got information from books,62.5 % from family and friends ,one third from physicians and only 7.5 % from registered nurses. Patients long for guidance, support and collaboration with their health care providers in finding efficacious treatments for their symptoms. **All India Institute of Medical Science (2002)** conducted a study at, New Delhi in 2002 among 180 women over the age of 45 on effect of soya as an alternative to hormone replacement therapy. Half of them were administered 30 grams of soya in their daily meals, while the other half was studied without changing their diet. At the end of 6 months, hot flushes were reduced by 8% in the experimental group. The result at the one

year showed a decline of 18% and at the mean time hot flushes in the second group has increased by 20%.

American College of Obstetrics and Gynaecology–(2002) conducted a study as when 10,000 women were on Hormone replacement therapy for one year, eight more of the women will develop breast cancer, seven more of the women develop coronary events, eight more will have pulmonary embolism, but six fewer will have colorectal cancer and five fewer will have hip fractures.

Bowman Gray in (**2009)** conducted a study at School of Medicine in North Carolina   a randomized double blind study to assess the efficacy and safety of a standardized compound based on extract of soy phytoestrogen in management of hot flushes among 100 older women and found that peri-menopausal women taking a soya supplement reported a 50% reduction in the severity of their hot flashes. However, the placebo group also reported a reduction in severity of 35%.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 bean on menopausal symptoms.

Basaria.s ,Dupree K et.al (2009) conducted a double blinded randomized study in tertiary care centres united states to assess the effect of soy protein containing isoflavones on quality of life in post-menopausal women. A sample of 93 healthy, ambulatory women were randomly assigned to receive 20 grams 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 soy protein and no changes were seen in placebo, the study concluded that use of soya

isoflavones as an alternative to oestrogen therapy may be potentially safe and seeming safe in women who are looking for relief from menopausal symptoms.

Lakshmi K.S, (2010) Conducted a study in selected villages of Coimbatore district, Tamil Nadu to assess the effectiveness of soya bean consumption on menopausal symptoms among women between 45-56 years. A sample of 60 menopausal women from 2 villages were selected by convenient sampling technique and divided 30 into experimental and 30 into control group.60gm of cooked soya bean was administered to experimental group 2 times daily and no intervention was been given to control group. Self-administered questionnaire was used to measure the menopausal symptoms before and after soya bean consumption. The study results revealed that post-assessment mean 11.5 was lesser than pre-assessment mean 14.5 in experimental group. The obtained 't' value 7.761 was highly significant at 0.05 level. The study concluded that soya bean consumption was effective on 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 bean on menopausal symptoms.

1.2 STATEMENT OF THE PROBLEM

"A Study to assess the effectiveness of soya bean on menopausal symptoms among menopausal women in the Institute of Obstetrics and Gynaecology , Chennai-08 ".

1. 3 OBJECTIVES

1. To assess the menopausal symptoms among menopausal women before the consumption   of soya bean in experimental group and control group.
2. To assess the menopausal symptoms among menopausal women after the consumption   of soya bean in experimental group and control group.

3. To compare the effectiveness of soya bean consumption in   reducing   the menopausal symptoms between   the experimental group and control group.
4. To find out the association between the experimental group and control group with selected demographic variables.

1.4 OPERATIONAL DEFINITIONS

a) EFFECTIVENESS

It refers to the change in intensity of menopausal symptoms among menopausal women before and after the consumption of soya bean measured by the Wiklund menopausal symptom scale.

b) SOYABEAN

It refers to 50gms of soya bean is taken and it is soaked in 100ml of water for four hours and boiled in 100ml of water. The boiled soya is given to the menopausal women.

c) MENOPAUSAL SYMPTOMS

It refers to Wiklund menopausal symptom scale, rating the severity of 10 menopausal symptoms; hot flashes, sleep disturbances, Night sweat, fatigue, vaginal dryness, headache, irritability, joint pain, breast tenderness, palpitations .

d) MENOPAUSAL WOMEN

It refers to women with natural menopause (after 12 months of amenorrhea) or surgical menopause (after six weeks have elapsed) presenting with any two symptoms per day in the Wiklund menopausal symptom scale.

1. 5. ASSUMPTIONS

➢ Women between 45 – 56 years will suffer from menopausal symptoms.

➢ Women those who are taking soya bean will experience less menopausal symptoms.

➢ Reduction of menopausal symptoms may improve the quality of life of menopausal women

1.6. HYPOTHESIS

➢ There is a significant difference in the menopausal symptoms among menopausal women between experimental group and control group.

➢ There is a significant association between the menopausal symptoms among the menopausal woman with their selected demographic variables.

CHAPTER –II
REVIEW OF LITERATURE

"A great literature is chiefly the product of inquiring minds in revolt against the immovable certainties of the human."

-H.L. Mencken

According to **Polit and Hungler (1999)** the task of reviewing research literature involves the identification, selection, critical analysis, and written description of existing information on the topic .The review of literature was done from the published articles, textbooks, reports, and Medline search. Literature review is organized and presented under the following headings.

The investigator carried out an extensive review of literature on the research topic in order to gain insight into the problem and to collect maximum relevant information for building up the study in a scientific manner so as to achieve the desired results.

2.1 REVIEW OF RELATED LITERATURE

The retrieved literature was done for the present study and presented in the following headings.

SECTION A **:** Literature related to Menopause Symptoms

SECTION B **:** Literature related to soya bean consumption

*SECTION C***:** Literature related to Effect of soya bean consumption on menopausal symptoms.

SECTION A : *Literature related to Menopause Symptoms*

Nagata C, Takatsuka N, et al (2001), conducted a cross-sectional postal survey of a menopausal sample was composed of four thousand and seventy-three women; they were sent a questionnaire designed on the basis of the Women's Health Questionnaire (WHQ). One thousand three hundred and forty-five women provided usable questionnaires. Factor analysis resulted in eight clusters: somatic symptoms, depressive symptoms, depressed mood with anxiety symptoms, cognitive difficulties, anxiety, sexual functioning, vasomotor symptoms and sleep problems. Mood and sexual function were impaired through the menopausal transition, with depressive and sexual symptoms being higher in the post-menopausal group compared to the pre-menopausal one.

Rossouw JE, (2002), conducted a study that in 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 Problems al symptoms such as irritability, anxiety, depression, decreased libido, and difficulty sleeping. The frequency, severity, and duration of vasomotor symptoms vary according to the population. Hot flashes are the most common menopausal symptom in North America and Europe; up to ~70% of women are affected. Symptoms can begin during the menopausal transition up to 2 years before the cessation of menses. The average duration of hot flashes is 6 months to 5 years, although 20% of women continue with symptoms into their 70s and 80s. Night sweats can interfere with sleep and lead to chronic sleep deprivation, chronic fatigue, and mood changes. Oestrogens are effective in decreasing the frequency and severity of these symptoms and are commonly used as a positive control in clinical trials.

Beresford SA , Anderson GL, et al (2002), conducted a population-based study involving a rural Taiwanese population. A total of 1273 women with no history of surgical menopause and hormonal therapy history participated. The mean anxiety, depression, and total HADS scores were 4.3±3.3, 3.3±2.8 and 7.6±5.3, respectively, and did not differ according to menopausal status. A total of 10.5% participants reported hot flashes within the previous 2 weeks. After controlling for educational status and insomnia, anxiety (6.0±3.8 versus 4.1±3.1) and depression scores (4.0±3.3 versus 3.2±2.7) were significantly higher (p<0.001) compared with those without hot flashes. These differences were attributed to peri- and postmenopausal subjects. Hot flashes in peri- and postmenopausal women were associated with anxious and depressive symptoms in East Asian population with low prevalence of vasomotor symptoms.

Keenan. R, (2003), conducted a cross sectional phone survey to assess severity of menopausal symptoms and use of both conventional and complementary therapies. In this study 2,602 women aged 45 years or older were selected, the participants were asked a series of questions about their menopausal states, menopausal symptoms, healthcare provider selection and therapies used for menopausal symptoms, the highest prevalence estimates were reported for hot flashes (62.9%), night sweats (48.3%) and trouble sleeping (41.1%). The researcher concluded that. 46% of women used complementary / alternative therapies either alone or in combination with conventional therapies, whereas a one third of the women did not use any therapy in relation to menopause.

Shah Rashmi (2004), conducted a population based cross sectional study on prevalence of menopausal symptoms in Mumbai among 500 women age of 40-56 years the study finding reports that over 64% menopausal women complaints of 37.4 % muscular and joint pain ,35.6% fatigue, the other symptoms reported were 19.4% hot flushes,18.6% sweating , 20.6% insomnia ,13.8% head ache and 7.6 % of urogenital problems .The study concluded that higher proportion of menopausal women suffers from vasomotor symptoms when compared to psychological and urogenital problems.

Reed SD , Grothaus L, et al (2005), 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%). 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 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 menopauses.

Manson JE, et al (2007), conducted a study in Women's Health Initiative (WHI) conducted a population based survey on 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. These symptoms were reported due to hormonal changes underlying menopause, which are caused by aging, other health states, psychosocial factors and life style.

Wei F, Miglioretti DL, (**2008),** conducted a study on observational design was used to recruit 179 postmenopausal women attending a menopause clinic for the first time. All of the women were postmenopausal, with a mean age of 50-74 years (SD=4.75). Stressful events were categorized into family problems, menopause symptoms, work problems, daily hassles and other health problems. The most

commonly reported coping styles were in order, catharsis 68%, direct action 66%, and seeking social support 63%. Logistic regression was used to determine what predicts coping style. Socio-demographic variables, menopausal symptoms and general stress levels were not predictive of coping styles in this study.

Gharaibeh (2009) , conducted a descriptive study to assess the severity of menopausal symptoms of Jordanian women. Cross-sectional design was used. Data were collected from 350 Jordanian women using a self-administered questionnaire consisting of socio demographic, medical and obstetrical history form and the Greene climacteric scale. The result 0f the study on the severity of menopausal symptoms showed that 15.7%, 66.9% and 17.4% were experiencing severe, moderate and mild menopausal symptoms, respectively.

Buist DS, Hartsfield CL et.al (2009) conducted a cross-sectional descriptive study using a community-based convenience sample of 119 women aged 37–70 years. There was a common pattern of menstrual change which was of heavier, less frequent, irregular menstruation. Forty one per cent of post-menopausal and 40% of women still in the menopause transition stated that, in terms of overall perception, the changes to menstruation experienced during the menopause transition were not problematic or disruptive. When specific change characteristics were examined, significant differences were found in duration of menses (p=0.014) and cycle irregularity (p=0.005) but no significant differences were found on the amount of flow (p=0.125) or frequency of cycles (p=0.142). Increased amount of menstrual flow at each period and increased frequency of cycles are not problematic changes.

Zhang Q, Sheng Q, et.al (**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 dyslipidaemia. The study concluded that there is an alarmingly high prevalence of Cardio vascular risk factors especially diabetes, hypertension, dyslipidaemia and obesity in postmenopausal women from rural areas.

Rahman et.al (2010) conducted a descriptive study to assess the menopausal symptoms using modified menopause rating scale (MRS) among middle age women in Sara wale. The result of study was, the mean age of menopause was 51.3 years (range 47-56 years). The most prevalent symptoms reported were joint and muscular discomfort (80.1%), physical and mental exhaustion (67.1%) and sleeping problems (52.2%). Followed by symptoms of hot flushes and sweating (41.6%), irritability (37.9%), dryness of vagina (37.6%), anxiety (36.58%), and depressive mood (32.6%). Other complaints noted were sexual problem (30.9%), bladder problem (13.8%) and heart discomfort (18.3%). It was concluded that the prevalence of menopausal symptoms using modified MRS in this study correspond to other studies on Asian women.

Bair YA ,Gold EB, (2011), conducted a study in which a sample of 5510 Finnish women who were 42–46 or 52–56-years-old was selected to this 'Quality of Life among Middle-aged women' Study and received a menopause-specific questionnaire. Only 5% of the older and 36% of the younger women was totally asymptomatic. Altogether, 2% of the younger and 11% of the older women had severe climacteric symptoms. In the younger age group, a high symptom intensity was associated with living in town, having a low level of professional education, and being unemployed/laid off, whereas in the older age group, the experience of severe symptoms was associated with those having a couple relationship. Altogether 95% of women in the productive working age (52–56-years-old) surprisingly suffer from

mild, moderate, or severe climacteric symptoms. Further even up to 64% of the younger women (42–46-years-old) suffered from similar symptoms.

Vermer HM, Hammoud MM , (**2012),** conducted a cross-sectional, observational and descriptive study conduct a total of 300 women between 40 and 59 years of age were evaluated using Greene scale for climacteric symptoms, Cooper questionnaire for psychosomatic symptoms of stress, Smilk stein family Apgar for family dysfunction,. Vasomotor symptoms in the pre-menopause are associated with increased risk of anxiety (OR: 3.7, IC: 1.4–9.7; $P<0.008$), depression (OR: 8.1, IC: 2.5–26.4; $P<0.0005$), somatic symptoms (OR: 14.9, IC: 3.4–65.3; $P<0.0003$), sexual dysfunction (OR: 7.2, IC: 2.5–20.6; $P<0.0002$) and stress (OR: 7.5, IC: 3.5–15.9; $P<0.0001$). Psychological symptoms are frequent in the pre-menopause and are associated to vasomotor symptoms.

SECTION B : **Literature related to soya bean consumption**

Kyung. K.Soares. M. J. Haidar (2002) conducted a randomized double blinded study in Brazil was conducted among 80 women between 45- 55 years, to assess the effectiveness of soy isoflavone. The subjects were subject to the therapy and re – examined after 4 months. The statistical analysis showed a decrease in menopausal symptoms after 4 months ($p < .01$) between baseline and isoflavone group and ($p< .01$) between placebo and isoflavone and group. This study also showed that there was a decrease in low density lipoproteins levels, which suggest a positive effect on the cardiovascular system.

Umbach DM ,Lansdell L et al (2004) , conducted a study in U.S, 19 postmenopausal women 45–65 y old were randomized to soy foods, substituting one-third of their caloric intake, or usual diet for 4 week . One main dish made from whole soybeans or texturized vegetable soy protein was supplied by the study to provide a daily intake of 165 mg of conjugated isoflavones. Compliance with the soy diet was 73%. In 68% of the women consuming soy foods, the percentage of superficial cells, an indication of oestrogenicity, 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.

Mukries AL ,Lombard C, et al (**2005),** conducted a study in Australia, 58 postmenopausal women ages 30–70 years were randomized to receive soy flour over 12 week .The flour was mixed in a drink . Participants recorded their vasomotor symptoms and had assessments of their vaginal cytology at baseline and at 6 and 12 week. Vasomotor symptoms decreased in both groups by 12 week, with no significant difference between groups. The vaginal MI did not change over time in either group.

Shaoul R, Rosier A   (2006) conducted a study in Israel recruited 145 women ages 43–65 y to receive a soy-rich diet or usual diet in a 2:1 ratio for 12 week. The dietary intervention consisted of daily consumption of foods known to contain high concentrations of soy isoflavones and included tofu, soy drink, and miso plus flaxseed, substituting one-fourth of their caloric intake. Participants were evaluated with the Menopause Symptom Questionnaire, 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.

Murkies et al (2008), conducted a randomized double blind study done in Brighton medical clinic Australia to assess the effect of soy and wheat flour among 58 menopausal women with at least 14 hot flushes per week, showed that their hot flushes significantly reduced by 40 % and 25 % in soy and wheat flour group respectively (p < 0.001).

Basaria S,Wisnieweki A, (2009), conducted a double blind randomized study was conducted in tertiary care centres united states to assess the effect of soy 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 soy protein and no changes were seen in placebo, the study concluded that use of soya isoflavones as an alternative to oestrogen therapy may be potentially safe and seeming safe in women who are looking for relief from menopausal symptoms.

Ehrlich K ,Gultinan J (2009) conducted a the herbal alternatives for Menopause Study in India and recruited 351 menopausal women between the ages of 45 and 55 y who had ≥2 vasomotor symptoms/d; 52% were in the menopausal transition and 48% were postmenopausal . Participants were randomized to 1 of 5 interventions: multi botanical plus soy dietary counseling vs. multi botanical vs. black cohosh vs. estrogen therapy vs. placebo. The women in the soy food intervention group reported an average of 0.6 servings/d of soy at baseline and increased dietary soy by 1.1 servings/d between baseline and 3 months . A serving was defined as 240 mL of soy milk or 1/4 cup (60 mL) of soy nuts. At 12 months, the multi botanical plus soy intervention group had higher (worse) symptoms relative to placebo ($P = 0.016$).

The study did not detect differences < 1.5 vasomotor symptoms/d between treatment groups.

Lewis JE , Nickell LA et al (2010) ,conducted a study in Canada, 99 women aged 45–60 years and menopausal for 1–8 years 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. Soy muffins contained 25 g of soy 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.

Welty FK , Lee KS (2012), conducted a study in the US, 82 women with irregular menses or in amenorrhea for at least 12 months were randomized in a cross-over design between 2 diet sequences: therapeutic lifestyle changes diet with soy or without soy . Participants received 1/2 cup of soy nuts (roasted soybeans) containing 25 g of soy protein and 101 mg a glycine isoflavones daily to be eaten throughout the day. The main outcome of this study was changes in blood pressure. Of the 60 women who finished the study, 39 had hot flashes. Participants recorded the number of hot flashes in calendars and were asked to complete the Menopause-Specific Quality of Life Questionnaire at the end of each 8-week period. Soy nut ingestion was associated with a 45% decrease in hot flashes in women with >4.5 hot flashes/d at baseline ($P < 0.001$) and a 41% decrease in those with ≤4.5 hot flashes/d. The reduction in hot flashes was apparent at 2 week in both groups, although there was some attenuation in the benefit of soy nuts over time in the low-hot flash group. When hot flashes were assessed by the menopausal symptom quality of life questionnaire, the group consuming soy nuts reported a 19% decrease in vasomotor score ($P = 0.004$).

SECTION C : Literature related to Effect of soya bean consumption on menopausal symptoms.

Petri Nahas E, De Luca L, et al (2004) conducted a study at Botucatu Medical School, Brazil in 2004 to evaluate the effects of isoflavones on vasomotor symptoms and blood lipids in postmenopausal women with contraindication for conventional hormone replacement therapy (HRT).The samples included 50 postmenopausal women randomly divided into two groups: 25 women on soy germ isoflavones (60 mg per day, capsules) and 25 women on placebo. The result showed that isoflavone was significantly superior to placebo in reducing hot flushes (44% versus 10%, respectively) ($P < 0.05$). After 6 months, the isoflavone group showed increased oestradiol levels with unchanged FSH, LH, and vaginal cytology, and a reduction of 11.8% in LDL and an increase of 27.3% in HDL ($P < 0.05$). In the placebo group, just a reduction in MV was observed after 6 months ($P < 0.05$)The study concluded that Soya germ isoflavone exerted favorable effects on vasomotor symptoms and lipid profile.

Cheng G, Wilczek B, et al (2005), conducted a double-blind prospective study was conducted by Nutrition institute Sweden. The objective of the study was to evaluate the effects of isoflavone treatment in postmenopausal women. The sample was sixty healthy postmenopausal women were randomly assigned by computer into two groups to receive 60 mg isoflavones or placebo daily for 3 months. Before and after treatment, climacteric symptoms were recorded; In women receiving 60 mg isoflavones daily, hot flashes and night sweats were reduced by 57% and 43%, respectively. The study concluded that short-term prospective study implies that isoflavones could be used to relieve acute menopausal symptom.

Duru Shah, Sangeetha Agrawal ,et al (2006), conducted a prospective randomized double blind study to evaluate the effects of herbo mineral phyto oestrogen 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 kupperman index at base line and changes were noted every 2 months and thereafter for a total of 6 months. The group that received herbo mineral phyto oestrogen 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 phyto oestrogen containing soya isoflavones is effective in management of symptoms in menopausal women.

Shetty J,Gupta S ,et al (2006) ,conducted a randomized, placebo-controlled clinical trial study was conducted by San Marcos University, Lima. The sample selected was postmenopausal women affected with hot flashes attributed to the climacterium (without cancer background). The minimum heterogeneity was observed in the "isoflavone concentrate" group. In the "extract" and "dietary supplement" groups, heterogeneity reached an intermediate level, $I(2) = 42\%$ and 59.73%, respectively. The overall result showed a standardized mean difference of -0.39 (95%) in favour of soy as well as -0.45 (95%) -0.51 (95%) and -0.20 (95%) for the "concentrate," "extract," and "dietary supplement" subgroups, respectively. The study showed a significant tendency in favour of soy, it is still difficult to establish conclusive results given the high heterogeneity found in the studies.

Kakkar V et al (2007), conducted a quasi-experimental study to find out the variation in menopausal symptoms with age ,education and non-working status in north Indian sub population . The Menopausal Rating scale ,a self-administered standardized questionnaire was applied with additional patients related information

for analysis .Data analysis revealed that statistically significant interactions were found for age, education ,and working status with menopausal symptoms.

Cheng G, Wilczek B, et al (2007), conducted a double-blind prospective study was done on 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. The study concluded that soya isoflavones could be used to relieve acute menopausal symptoms.

Borchers (2008), conducted study to find effectiveness of soy isoflavones modulate immune function in healthy post- menopausal women. Post -menopausal women aged 50-65 year enrolled in this 16 weeks double blind, placebo controlled trial were randomly assigned to 1 of 3 experimental group: 1) control, 706ml cow milk/day plus a placebo supplement 2) Soy milk, 71.6 mg of isoflavones derived from 70.6ml soy milk/day plus a placebo supplement 3) Supplement, 70mg isoflavones in a supplement plus 706 ml cow milk/day. Plasma and 24 hours urine sample were obtained at baseline and at 16 weeks. The researcher concluded that soy milk and supplemental isoflavone modulate Bull populations and appear to be protective against DNA damage in postmenopausal women.

Song Y,Paik HY ,et .al (2008), conducted a longitudinal study was conducted 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, 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 Ward's Triangle . (2.5% and 5.2%). soybean 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). The study concluded that soybean and isoflavone intake have a positive effect on the change of BMD on the FN and WT among young Korean women.

Kamath A , Traiman P , et al (2009) , conducted a prospective study to evaluate the efficacy of soy isoflavone on menopausal symptoms as an alternative to Hormone Replacement therapy in Karnataka. The samples were 46 menopausal women, requesting treatment for climacteric symptoms and no history of uncontrolled hypertension. The 12 month programme consisted of supplementation of 75 mg soy isoflavone daily and the Menopausal Kupperman Index was used to assess change in menopausal symptoms. The study results revealed that menopausal symptoms were significantly lower (P<.001) than the pre- treatment period (P = 0.02).The study concluded that soy isoflavone treatment was safe and effective alternative therapy for menopausal symptoms.

Ragland K, Lee J et al (2010), conducted by medical centre USA. To assess the effect of soy nuts on hot flashes and menopausal symptoms. The sample Sixty healthy postmenopausal women were randomly selected to a therapeutic lifestyle changes (TLC) diet alone and a TLC diet of similar energy, fat, and protein content in which one-half cup soy nuts divided into three or four portions spaced throughout the day (containing 25 g soy protein and 101 mg glycine isoflavones) replaced 25 g of non-soy protein. Soy nut intake was also associated with significant improvement in scores on the menopausal symptom quality of life questionnaire: 19% decrease in vasomotor score (p = 0.004), 12.9% reduction in psychosocial score (p = 0.01), 9.7% decrease in physical score (p = 0.045), and a trend toward improvement in the sexual score, with a 17.7% reduction in symptoms (p = 0.129). The study concluded that substituting soy nuts for non-soya protein in a TLC diet and consumed

three or four times throughout the day is associated with a decrease in hot flashes and improvement in menopausal symptom.

J. Lissa (2010), conducted an experimental study to evaluate the effectiveness of soya bean on menopausal problems in Madurai. The study results reveals that in experimental group the mean post-assessment status of the selected menopausal problems 13.5 is lower than the mean pre-assessment status 18.3 , the mean difference is 4.53 and the obtained 't' value 12.58 is significant at 0.05 level .The study concluded that there is a typical reduction in the level of menopausal symptoms after administration of soya.

Chenduraui P ,San Miguel, et .al (2011), conducted a study to evaluate the effect of soy-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 ($\geq$ 25) were recruited to receive oral 100 mg/day of soy derived isoflavones for 3 months. Study results After 3 months of soy isoflavone supplementation revealed that hot flushes significantly decreased in percentage, number and severity (100% to 31.1%; 3.9 $\pm$ 2.3 to 0.4 $\pm$ 0.8 and 2.6 $\pm$ 0.9 to 0.4 $\pm$ 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 $\geq$ 8) significantly decreased (16.3 $\pm$ 5.4 to 6.9 $\pm$ 5.2 and 93.3% to 28.9%, respectively, p < 0.05).the study concluded that In high risk climacteric population, soy derived isoflavone treatment improves mood as well as vasomotor and general menopausal symptom.

Jenks BH, Iwashita S (2012), was conducted a double-blind study at USA .This study compared the efficacy of the natural S-equol supplement with isoflavones for relieving hot flashes and other menopausal symptoms. A subgroup analysis further indicated that for subjects with >8 hot flashes/day at baseline, 20 and 40 mg/day S-

equol were superior to isoflavones in reducing hot flash frequency (p=0.045 and p=0.001, respectively). In addition, 10 and 20 mg/day S-equol improved muscle and joint pain score compared with isoflavones (p=0.003 and p=0.005, respectively).Study concluded that S-equal, 10 mg/day, appears to be as effective as soy isoflavones at reducing hot flash frequency and more effective for relieving muscle and joint pain in postmenopausal women.

2.2 CONCEPTUAL FRAMEWORK

Conceptual Framework work are global ideas about a concept in relation to a specific disciple . Concept models are made up of concepts which describes the physical and mental images of a phenomenon and integrate them into a meaningful configuration .A conceptual framework refers to concept that structure or efforts of a framework of propositions for conducting research.

A group of concepts are broadly defined and systematically organized to provide a focus, a rationale, and a tool for the integration and interpretation of information. Usually expressed abstractly through word models, a conceptual framework is the conceptual basis for many theories, such as communication theory and general systems theory. Conceptual frameworks also provide a foundation and organization for the educational plan in schools of nursing.

(Mosby's medical dictionary, 8th edition. © 2009, Elsevier.)

General system theory

System theory may be considered as a specialization of systems thinking and a generalization of systems' science. First proposed by Ludwig Von Bertalanffy (1901-1972) as General System theory. General systems theory is a general science of 'wholeness'. Systems theory has been applied in developing nursing theories and conducting nursing research.

As a biologist Von Bertalanffy knew that such an assumption is simply impossible for most practical phenomena. Organisms are open systems: they cannot survive without

continuously exchanging matter and energy with their environment. The peculiarity of the open systems is that they interact with other systems outside of themselves. This interaction has two components: input, that what enters the system from the outside and output, that what leaves the system for the environment.

Input

Input is something put into a system or expended in its operation to achieve output or a result. The input includes age, education ,religion ,occupation, income, marital status, type of family, number of children ,medical problems treatment taken and age at which menopause attained of the menopausal women .After collecting the data using the structured interview the group was divided into two ,one is the experimental group and another one was the control group .pre- assessment of the menopausal problems were assessed by modified wiklund menopausal rating scale by questionnaire. The main aspect input leads to the throughput.

Throughput

Throughput is a process that converts the input into a final product or outcome. This study plans for intervention of providing 50 grams of soya bean for 20 days which is the through put.

Output

An output is the final product or service provided by a system. Adaptive responses were the reduction of menopausal symptoms. In this study there was a maximum reduction of menopausal symptoms in the experimental group.

The investigator embraced the General system model as the key for the current study which focuses to identify the effectiveness of soya bean to reduce the menopausal symptoms. The model represents the effectiveness of soya bean and the relationship between the demographic variables. This model explains the concept of the research work in these three components.
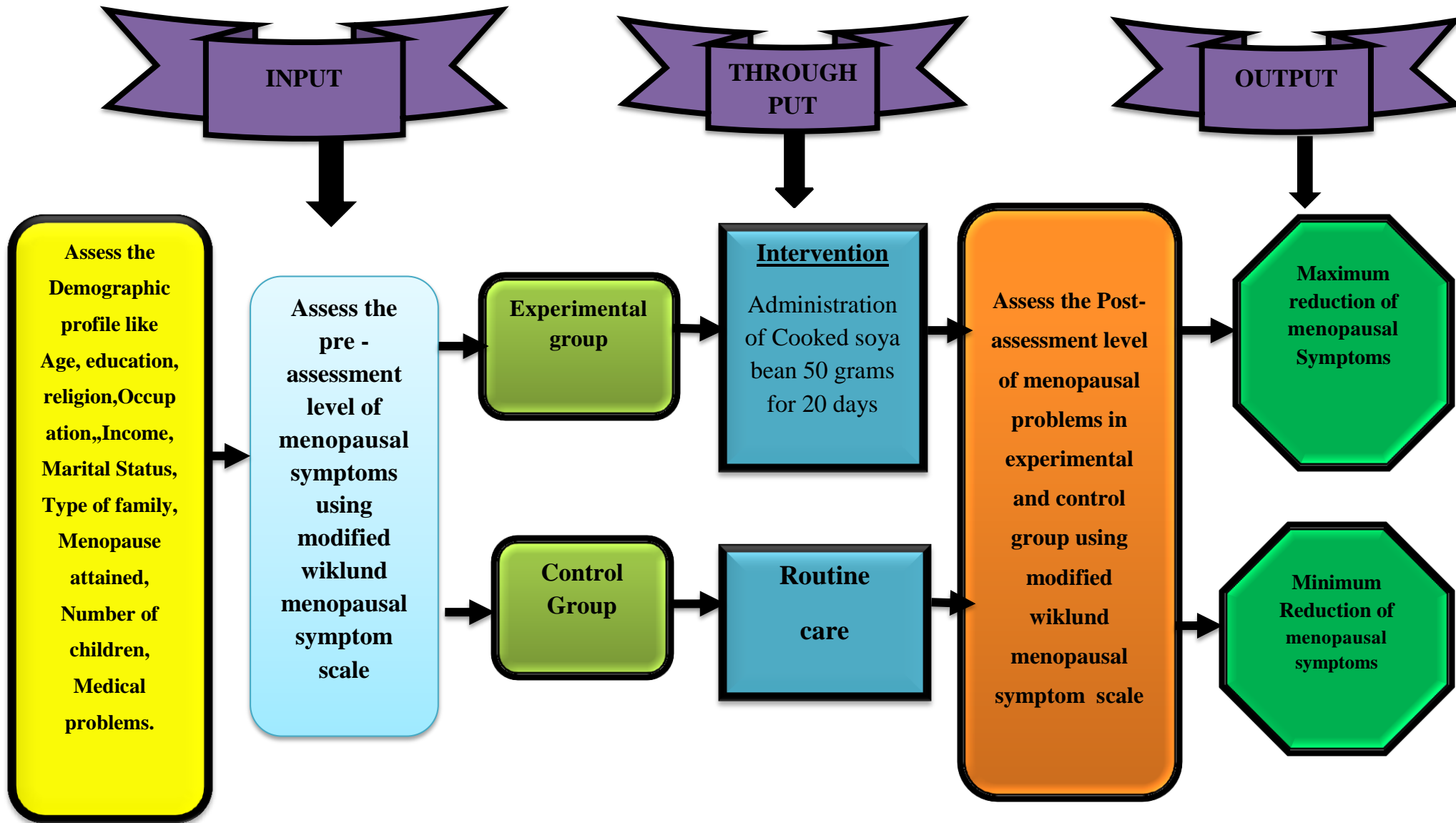
Fig No: 1 CONCEPTUAL FRAME WORK BASED ON LUDWIG VON BERTALANFFY'S MODIFIED GENERAL SYSTEM MODEL (1901-1972)

CHAPTER-III

METHODOLOGY

"Research methodology is the way to solve the problems systematically .It indicates the general pattern of organizing the procedures for gathering the valid and reliable data for the purpose of investigation."

-Denise and polit

This chapter deals with description of research approach, research design, setting ,population, sample ,and sampling technique ,details of instruments ,description of tools ,content validity ,testing of tool ,pilot study ,data collection procedure ,plan for data analysis.

3.1 RESEARCH APPROACH

According to Polit and Hungler,(1999) Quantitative research is an applied format research that involves finding out how well a programme ,practice, procedure or policy is working .It involves the collection and analysis of information relating to the functioning of a programme or procedure. With the aim of assessing the effectiveness.

The research approach adopted for the study was Quantitative approach. This study was aimed at assessing the menopausal symptom among menopausal women by the soya bean consumption.

3.2 RESEARCH   DESIGN

      According to Kothari.C.R.(2003)"A research design is defined as the overall plan for collecting and analysing data, including specification for enhancing the internal and external validity of the study."

      The research design is concerned with overall framework for conducting the study. The research design used for this study is Quasi experimental design.

3.3 VARIABLES

INDEPENDENT VARIABLE

      Oral   administration of   soya bean for the menopausal women.

DEPENDENT VARIABLE

      Reduction   of Menopausal symptoms among the menopausal women.

DEMOGRAPHIC VARIABLE

      Age, Education ,Religion ,Occupation ,Income, marital status, Type of family, Number of children, Medical problems, Treatment taken, Menopause attained.

3.4 SETTING OF THE STUDY

      The study was conducted in gynaecology out- patient department at gynaecology outpatient department at the Institute Of Obstetrics And Gynaecology, Chennai. This institute was unveiled on 26th July 1844 for public service. The total bed strength is about 754.It is situated in the heart of Chennai city. It offers advanced and needs of poor and serving at least 33120 inmates per year and average of 18000 per year. In a month nearly 30,000 women were attending the gynaecology outpatient department.

3.5 STUDY POPULATION

The population of the present study comprised of 60 Menopausal women in Gynaecology outpatient department at Institute Of Obstetrics and Gynaecology, Chennai.

3.6 SAMPLE

The Menopausal women who fulfil the inclusion criteria will be considered as sample.

3.7 SAMPLE SIZE

The sample size for the study was 60 menopause women, out of which 30 women belong to experimental group and 30 women belong to control group were selected for the study.

3.8 SAMPLING TECHNIQUE

Non Probability Convenient sampling technique was used to select the 60 menopausal women.

3.9 CRITERIA FOR SAMPLE SELECTION

a) INCLUSION CRITERIA

1. Menopausal women suffering from two or more symptoms mentioned in wiklund menopause symptom scale persisting for the last one month.
2. Menopausal women with natural or surgical menopause (after 6 weeks have elapsed).
3. Menopausal women who are willing to participate in the study
4. Menopausal women who able to communicate in Tamil.

EXCLUSION CRITERIA

1. Menopausal women who already consumed soya bean regularly.
2. Menopausal women who are on hormonal replacement therapy.
3. Menopausal women with thyroid disorders and renal disorders.
4. Menopausal women who are not able to communicate in Tamil .
5. Menopausal women who develop complication during the period of data collection.

3.10 DEVELOPMENT AND DESCRIPTION OF THE TOOL

DEVELOPMENT OF THE INSTRUMENT

A structured interview schedule was developed based on the objectives of the study. Various sources of literature and opinion from the subject experts are obtained to ascertain the effectiveness and to bring out the correct items in the questionnaire .All these helped in the ultimate development of the tool.

DESCRIPTION OF THE TOOL:

The instrument used in this study consists of two sections which are as follows.

Section A – Description of demographic variables such as age, educational status, religion ,occupation ,income, marital status ,type of family, number of children of menopausal women. It consists of 11 questions.

Section B -   It consists of Wiklund menopausal symptom scale .This scale consists of 10 Menopausal symptoms scale in which the symptoms were assessed using this scale and the scoring will be given as

> Frequently-3
> Occasionally-2
> Rarely-1 and
> Never -0

3.11 ETHICAL CONSIDERATION

Formal permission was obtained from the institutional ethical committee before conducting the study .No ethical issues aroused during the course of the study.

3.12   TESTING OF THE TOOL

1. CONTENT VALIDITY

The content of the tool was established on the basis of opinion from Medical expert and nursing expert in the field of Obstetrics and Gynaecology and the tool was finalized.

2. PILOT STUDY

It is the rehearsal of the main study .The researcher obtained formal permission from the Head of the department in obstetrics and gynaecological nursing and content validity from the experts and from the Director of Institute of Obstetrics and Gynaecological Nursing in Chennai .The study was conducted at the Institute of Obstetrics and Gynaecological Nursing in gynaecology outpatient department .By the convenient sampling technique, Six samples were selected. Pre assessment of menopausal symptoms was done by using modified wiklund menopausal rating scale. For the experimental group

50gms of cooked soya bean had been administered orally for two weeks only for the experimental group and for control group routine care was followed. Then the post-assessment was done by the same modified wiklund menopausal symptom scale for both the experimental and control group. The experimental group showed the significant reduction in menopausal symptoms. The study shows the feasibility to conduct the proposed study as planned.

3. RELIABILITY

After pilot study reliability of the tool was assessed by using inter- rater method and its correlation coefficient r –value was 0.82. This correlation coefficient was very high and it was a good tool for assessing the effectiveness of soya bean in reducing the menopausal symptoms among menopausal women in the gynaecology outpatient department at the Institute of Obstetrics and Gynaecology

3.13 DATA COLLECTION PROCEDURE

The study was conducted with the permission from the principal and research ethical committee of Madras Medical College and HOD of Obstetrics and Gynaecology Nursing .A formal permission was obtained from the Director of Institute of Obstetrics and Gynaecological Nursing in Chennai .The study was conducted in Institute of Obstetrics and Gynaecological Nursing in gynaecology outpatient department.

Screening of menopausal women with the inclusion criteria for selection was done. Information about the study was given to the participants and informed consent obtained in the prescribed form. The investigator assured the confidentiality. Pre assessment was conducted using tools. Information was collected for the study by questionnaire. Samples were selected by Non-randomised convenient sampling technique was used to select the menopausal

women from the sample frame and totally sixty samples were taken from the gynaecology outpatient department. From that, thirty samples were assigned to experimental group, and thirty samples were assigned to control group.

Then the needed information for the researcher were gathered from the samples with the help of questionnaires and assessed the level of menopausal problems using the modified wiklund menopausal rating scale to both the experimental and control groups. Then per day 50gms of cooked soya bean was administered orally for 20 days only for the experimental group. Post-assessment level of menopausal problems was assessed in the experimental group and control group on 21st day .There was a significant difference between the experimental and control group.

3.14 PLAN FOR DATA ANALYSIS

After the data collection the collected data were organized, tabulated summarized and analyzed .The data were analyzed according to the objectives of the study using the descriptive and inferential statistics.

- Analysis of frequency and percentage for demographic data.
- Hypotheses related to the effectiveness of soya protein in reducing menopausal problems.
- Chi-square test of significance was used to find out the association between the level of menopausal problems and selected demographic variables such as age ,marital status ,occupation ,and income.

DESCRIPTIVE STATISTICS

1. Frequency and percentage distribution was used to analyze the demographic data for menopausal women.
2. Mean and standard deviation were used to assess the effectiveness of oral administration of soy protein in reduction of menopausal problems.

INFERENTIAL   STATISTICS

1. Student independent 't' test and mean difference with 95% CI was used to compare the pre and post-assessment level of menopausal symptoms for both the experimental and control groups.
2. Chi-square test was used to find out the association of the post- test level of menopausal symptoms with their selected demographic variables.

SUMMARY

This chapter dealt with the methodology undertaken for the study. It includes research approach ,research approach ,research design ,setting of the study , population ,sample and sampling technique ,selection and development of the tool , pilot study, data collection methods and plan for data analysis.

Fig No:2 SCHEMATIC REPRESENTATION OF RESEARCH DESIGN

Research Approach
Quantitative Research Approach

Research design
Quasi –experimental reseach design

Population
60 menopausal women in Institute Of Obstetrics and gynaecology

Study Setting
Gynaecology outpatient department

SAMPLING TECHNIQUE
Convenient Sampling Technique.

DEMOGRAPHIC DATA

- Age
- Educational status
- Religion
- Income
- Type of family
- Marital status
- Medical status
- Age at which menopause attained
- Duration of Menopausal symptoms

Sample size: 60 Menopausal women
Experimental group : 30
Control group : 30

PRE-ASSESSMENT
Assessment of menopausal problems

Experimental group

Control Group

Data collection procedure

Modified Wiklund menopausal rating scale

Intervention
Administration of soy protein 50gms-20 days

No intervention

POST-ASSESSMENT
Assessment of menopausal problems

Analysis and Interpretation
Descriptive and inferential statistics

Dissemination of findings

CHAPTER-IV
DATA ANALYSIS AND INTERPRETATION

This chapter deals with analysis and interpretation of the data collected from the menopausal women at the Institute of Obstetrics and Gynaecology, Egmore, Chennai -8, regarding the effectiveness of soya bean on menopausal symptoms among menopausal women.

Polit and Hungler (2007) defined data analysis as the method of categorizing, ordering, manipulating and summarizing of data to reduce the intelligible and interpretable form. So that research problem can be studied and tested including relationship between the variables. The data were collected complied analyzed and tabulated data are interpreted under the following sections.

Section – I : Distribution of demographic variables of Experimental group and control group.

Section –II : Distribution of Pre-assessment and comparison of Statistical value of pre-assessment level of menopausal symptoms score.

Section –III : Distribution of Statistical value of post-assessment and comparison of post-assessment level of menopausal symptoms score.

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Section–IV : Distribution of Statistical value of effectiveness of soya consumption to reduce the menopausal symptoms among the experimental group.

Section –V : Association between the level Of Menopausal Symptom Reduction Score and Demographic Variables in Experiment and Control group

SECTION -I

Table 1 : Distribution of demographic variables of Experimental group and Control group.

Demographic variables		Group			
		Experiment		Control	
		No. of women	%	No. of women	%
Age	46 -50 years	25	83.3%	22	73.3%
	51 -55 years	5	16.7%	8	26.7%
	55- 56 years	0	0.0%	0	0.0%
Educational Status	Illiterate	15	50.0%	13	43.3%
	Primary	11	36.7%	12	40.0%
	Middle school	4	13.3%	5	16.7%
Religion	Christian	5	16.7%	3	10.0%
	Hindu	25	83.3%	27	90.0%
Occupation	Sedentary worker	4	13.3%	4	13.3%
	Moderate worker	15	50.0%	15	50.0%
	Coolie	11	36.7%	11	36.7%
Income	Rs.2000 -3000	17	56.7%	18	60.0%
	Rs.3000 -6000	11	36.7%	11	36.7%
	> Rs.6000	2	6.7%	1	3.3%
Marital status	Married	30	100.0%	30	100.0%
	Unmarried	0	0.0%	0	0.0%

Type of Family	Nuclear family	21	70.0%	15	50.0%
	Joint family	7	23.3%	12	40.0%
	Extended family	2	6.7%	3	10.0%
Number of children	One	2	6.7%	4	13.3%
	Two	18	60.0%	19	63.3%
	Three	7	23.3%	5	16.7%
	Above three	3	10.0%	2	6.7%
Medical Problems	Blood pressure	18	60.0%	21	70.0%
	Diabetic Mellitus	12	40.0%	9	30.0%
Treatment taken	Yes	3	10.0%	6	20.0%
	No	27	90.0%	24	80.0%
Menopause attained	40 -45 years	3	10.0%	8	26.7%
	46 -50 years	23	76.7%	20	66.7%
	51 -56 years	4	13.3%	2	6.7%

Table-1 reveals   the demographic information of menopausal women those who are participated in the study on **"A Study to assess the effectiveness of soya bean on menopausal symptoms among menopausal women in the Institute of Obstetrics and Gynaecology, Chennai."**

In experimental group, regarding the age of menopausal women in which majority 25(83.3%) of them were comes under the age group of 46-50 years. And in control group majority 22(73.3%) were at the age group of 46-50 years.

In experimental group, regarding the education 15(50.0%) belongs to illiterate and in control group 13(43.3%) of them were illiterate.

In experimental group, regarding the religion majority of 25(83.3%) of them were following Hinduism and in control group majority 27(90.0%) of them were following Hinduism.

In experimental group, regarding the Occupation 15(50.0%) of them were moderate worker and in control group 15(50.0%) of them were moderate worker.

In experimental group , regarding the income 17(56.7%) of them were having the monthly income of RS.2000-3000 and in control group 18(60.0%) of them were having the monthly income of RS.2000-3000. In both the experimental and control group regarding the marital status 30(100%) of them got married.

In experimental group , regarding the type of family 21(70.0%) of them were under nuclear family and in control group 15(50.0%) of them were under nuclear family .In experimental group , regarding the number of children 18 (60.0%) of them were having two children and in control group 19(63.3%) of them were having two children .

In experimental group , regarding the medical problems 18 (60.0%) of them were having Blood pressure and in control group 21(90.0%) of them were having blood pressure In experimental group , regarding the treatment taken majority of 27 (90.0%) of them were not taken any treatment and in control group 24(80.0%) of them were not taken any treatment .

In experimental group , regarding the age at which menopause attained were 23(76.7%) under 46-50 years and in control group 20(66.7%) of them were attained menopause .

AGE DISTRIBUTION
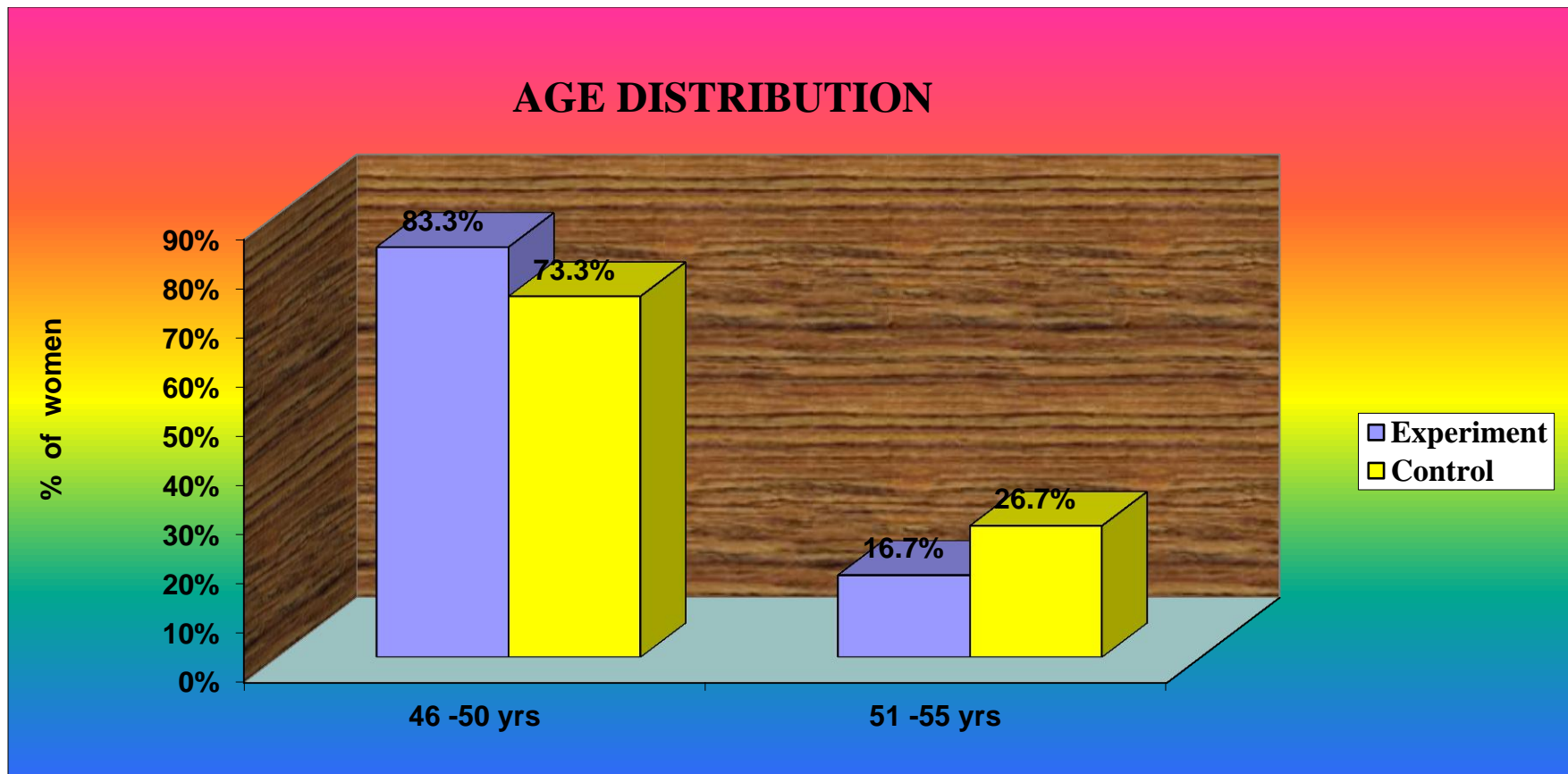
FIGURE : 3 Graphical representation of menopausal women according to age in experimental group and control group

EDUCATIONAL STATUS

% of women

70%
60%
50%
40%
30%
20%
10%
0%

50.0%
43.3%
36.7%
40.0%
13.3%
16.7%

Non literate   Primary   Middle school

■ Experiment
■ Control

FIGURE : 4 Graphical representation of menopausal women according to Education in experimental group

and control group

FIGURE : 5 Graphical representation of menopausal women according to religious status in experimental group and control group

OCCUPATION STATUS

% of women

	Experiment	Control
Sedentary worker	13.3%	13.3%
Moderate worker	50.0%	50.0%
Coolie	36.7%	36.7%
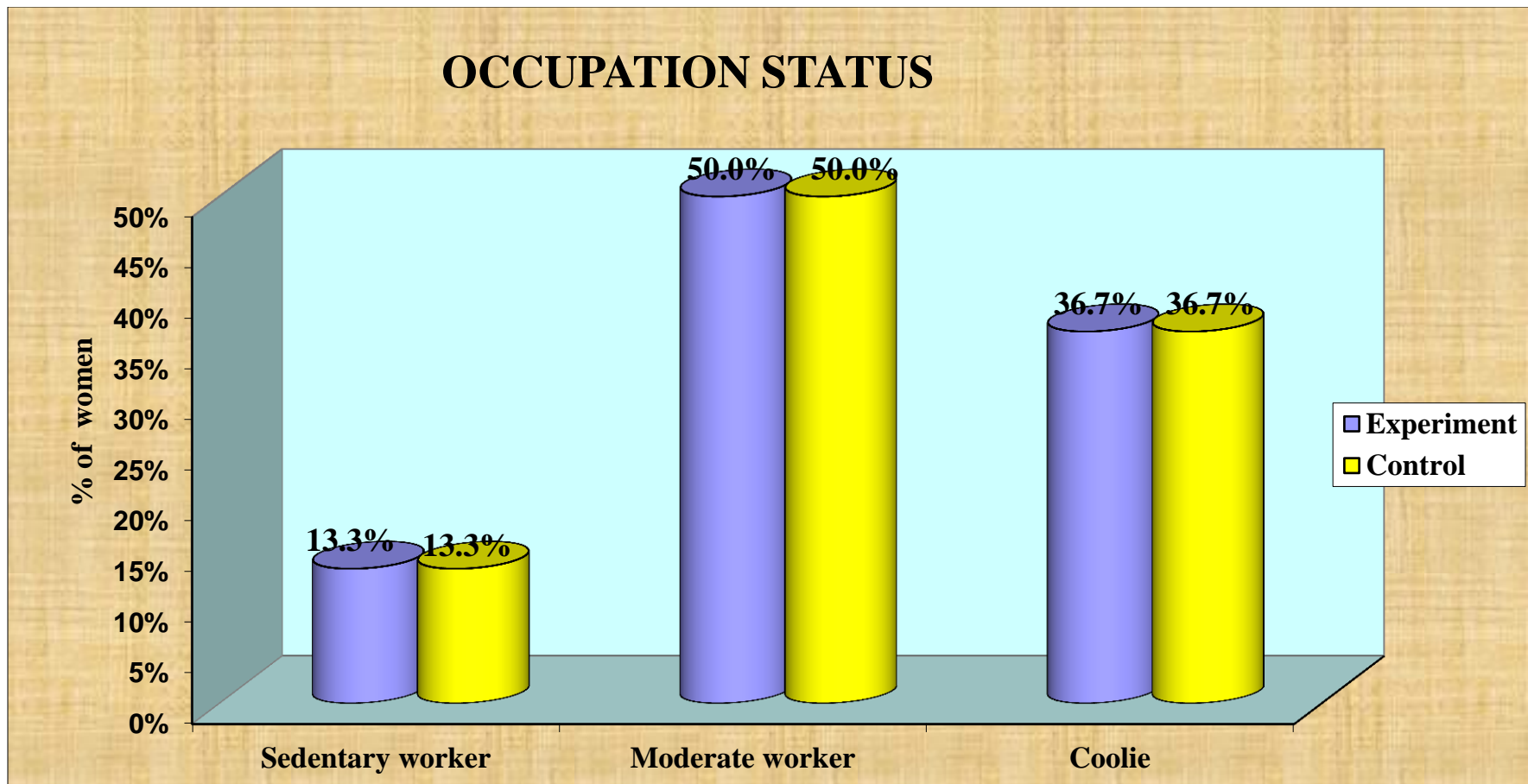
FIGURE : 6 Graphical representation of menopausal women according to Occupation status in experimental group and control group

MONTHLY INCOME STATUS
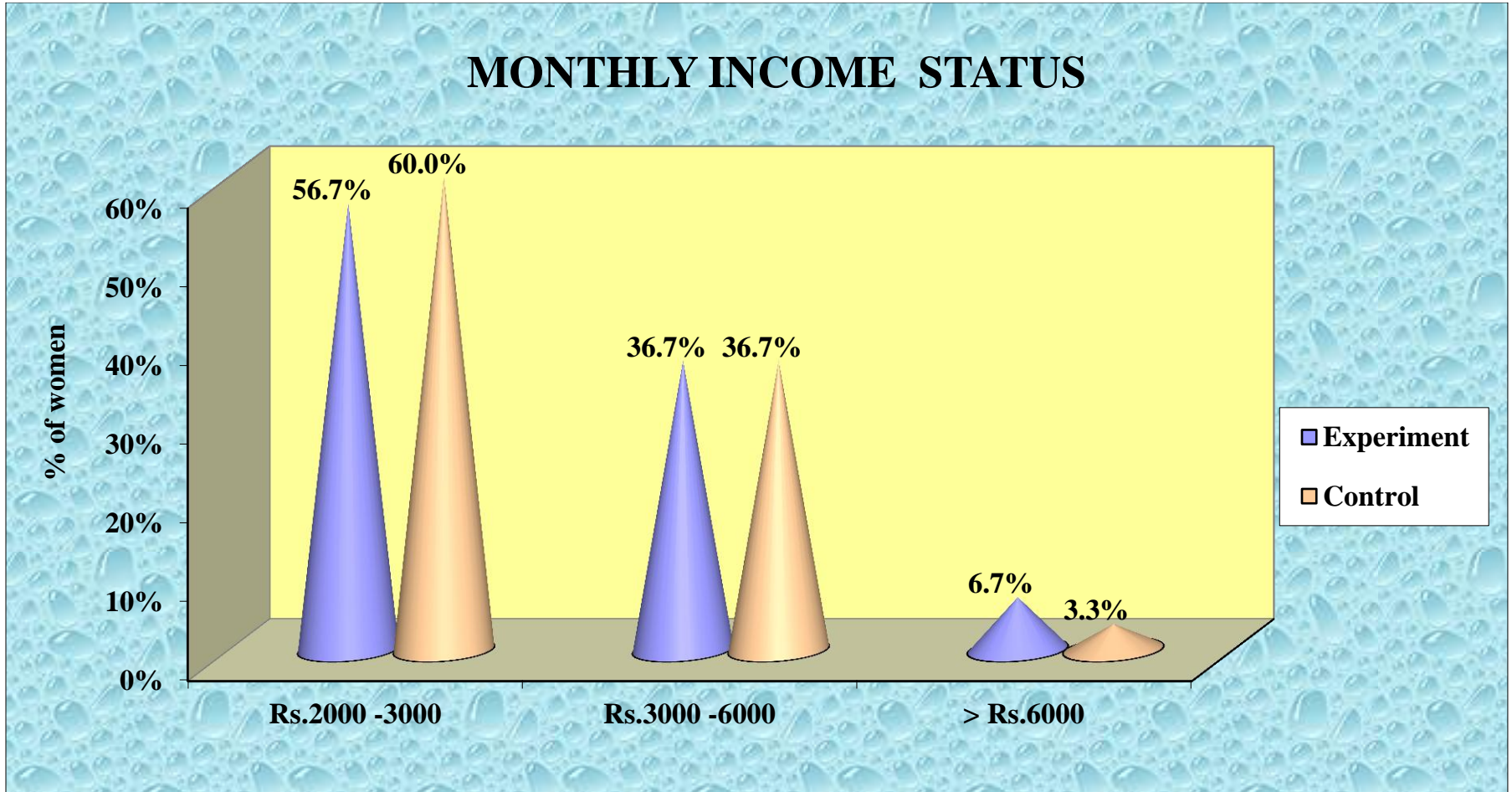
FIGURE : 7 Graphical representation of menopausal women according to monthly income in experimental group and control group
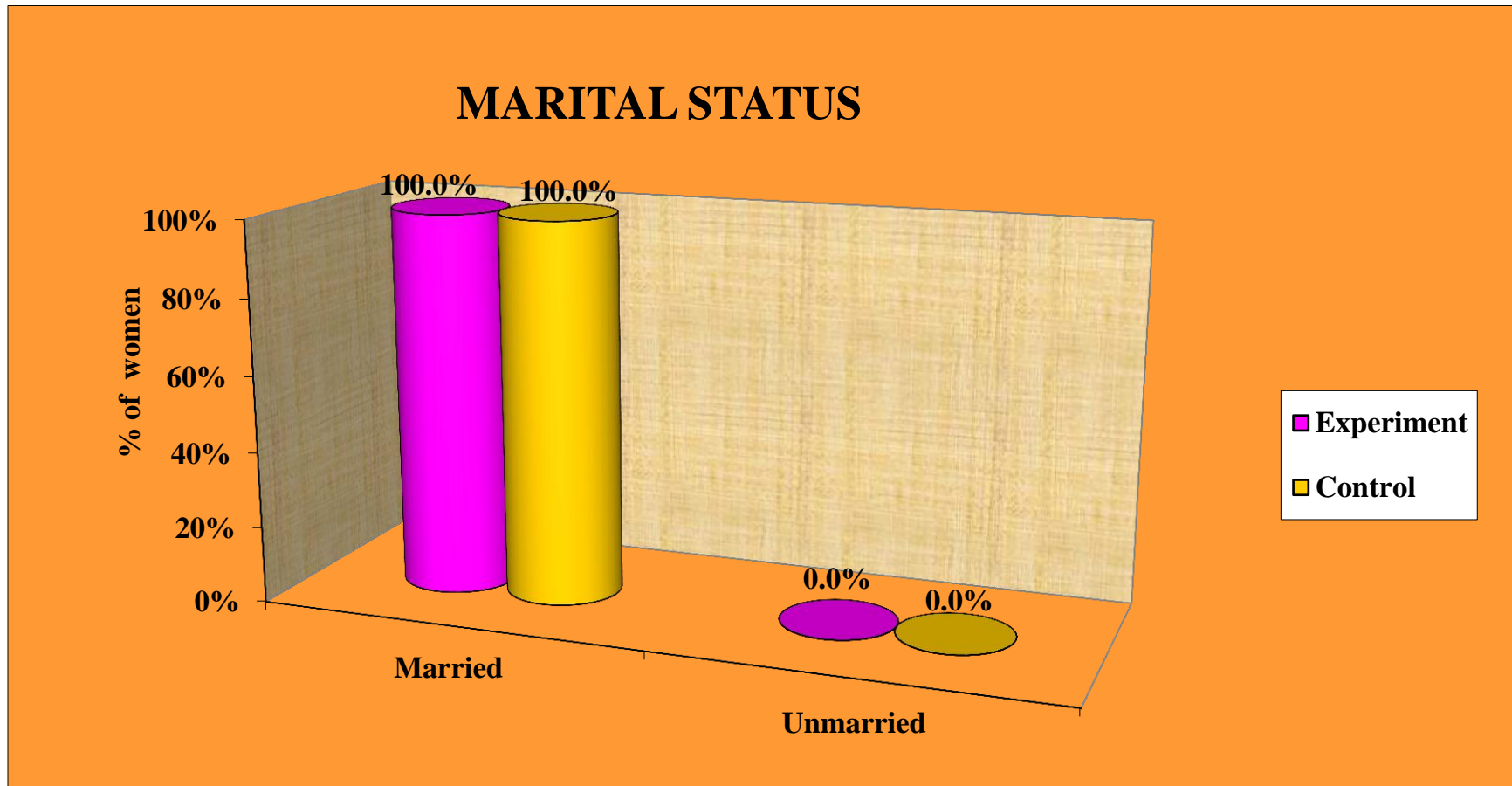
FIGURE : 8 Graphical representation of menopausal women according to marital status in experimental group and control group
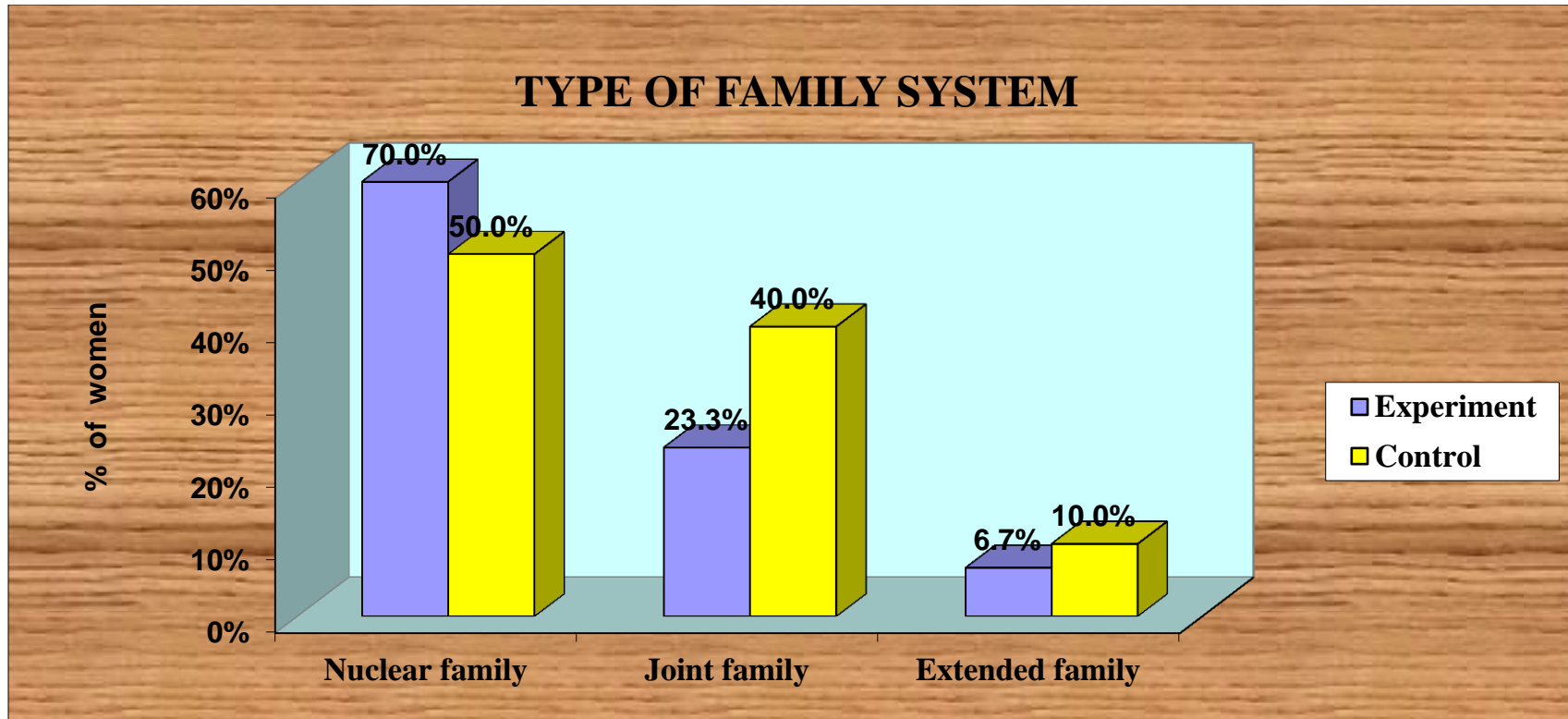
FIGURE : 9 Graphical representation of menopausal women according to type of family system in experimental group and control group
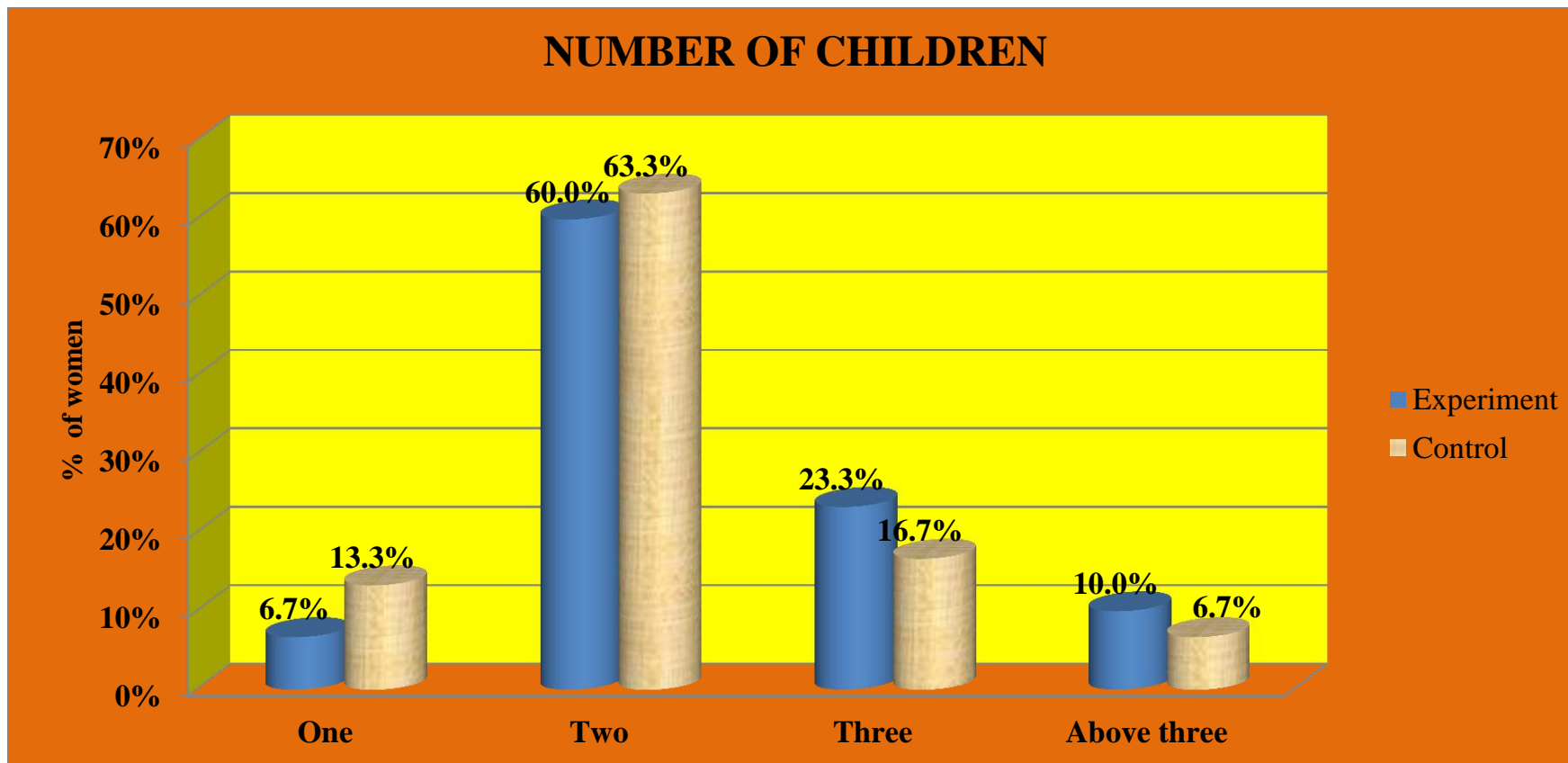
FIGURE : 10 Graphical representation of menopausal women according to number of children in experimental group and control group.
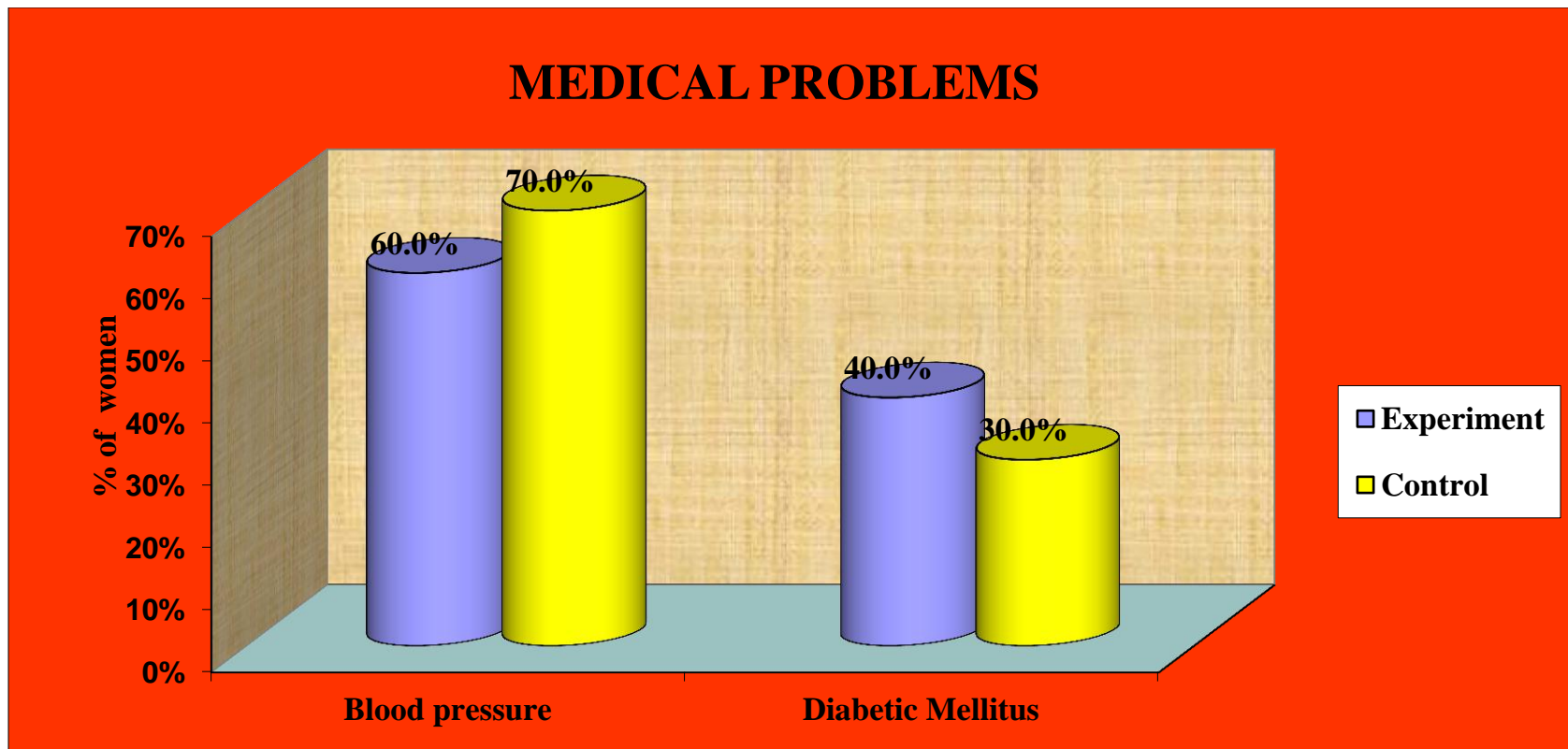
FIGURE : 11   Graphical representation of menopausal women according to medical problems in experimental group and control group
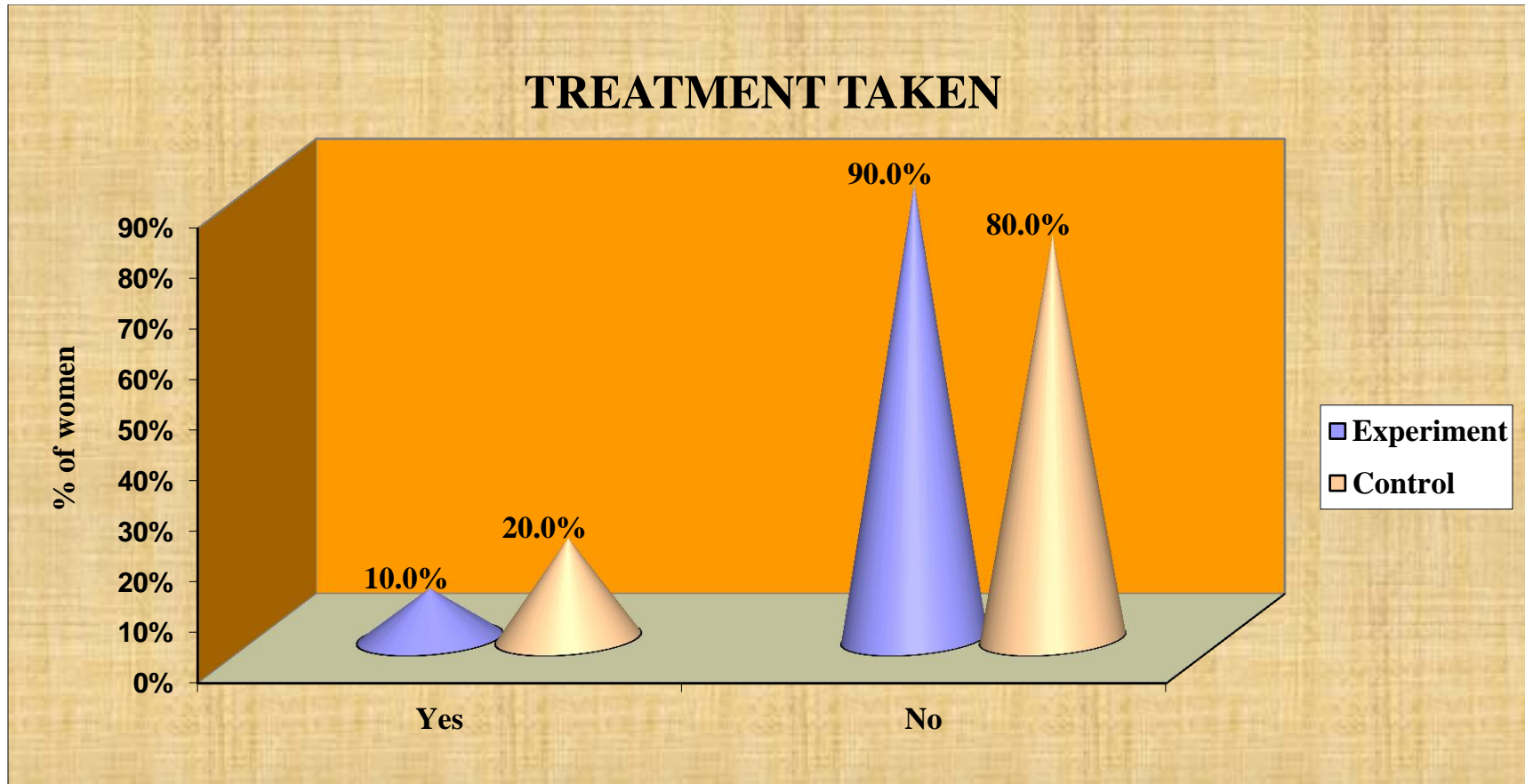
FIGURE : 12 Graphical representation of menopausal women according to treatment taken in experimental group and control group

MENOPAUSAL AGE

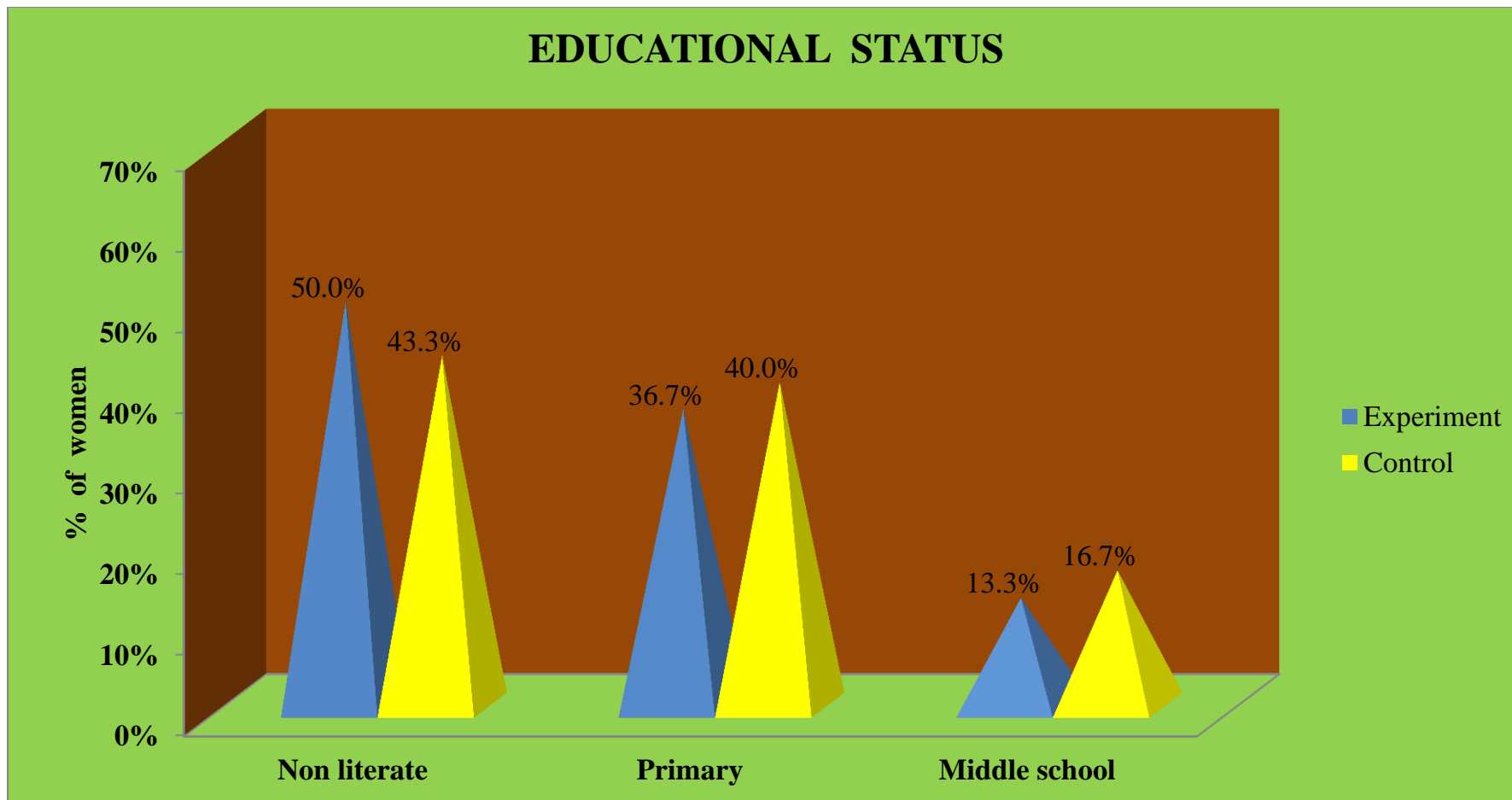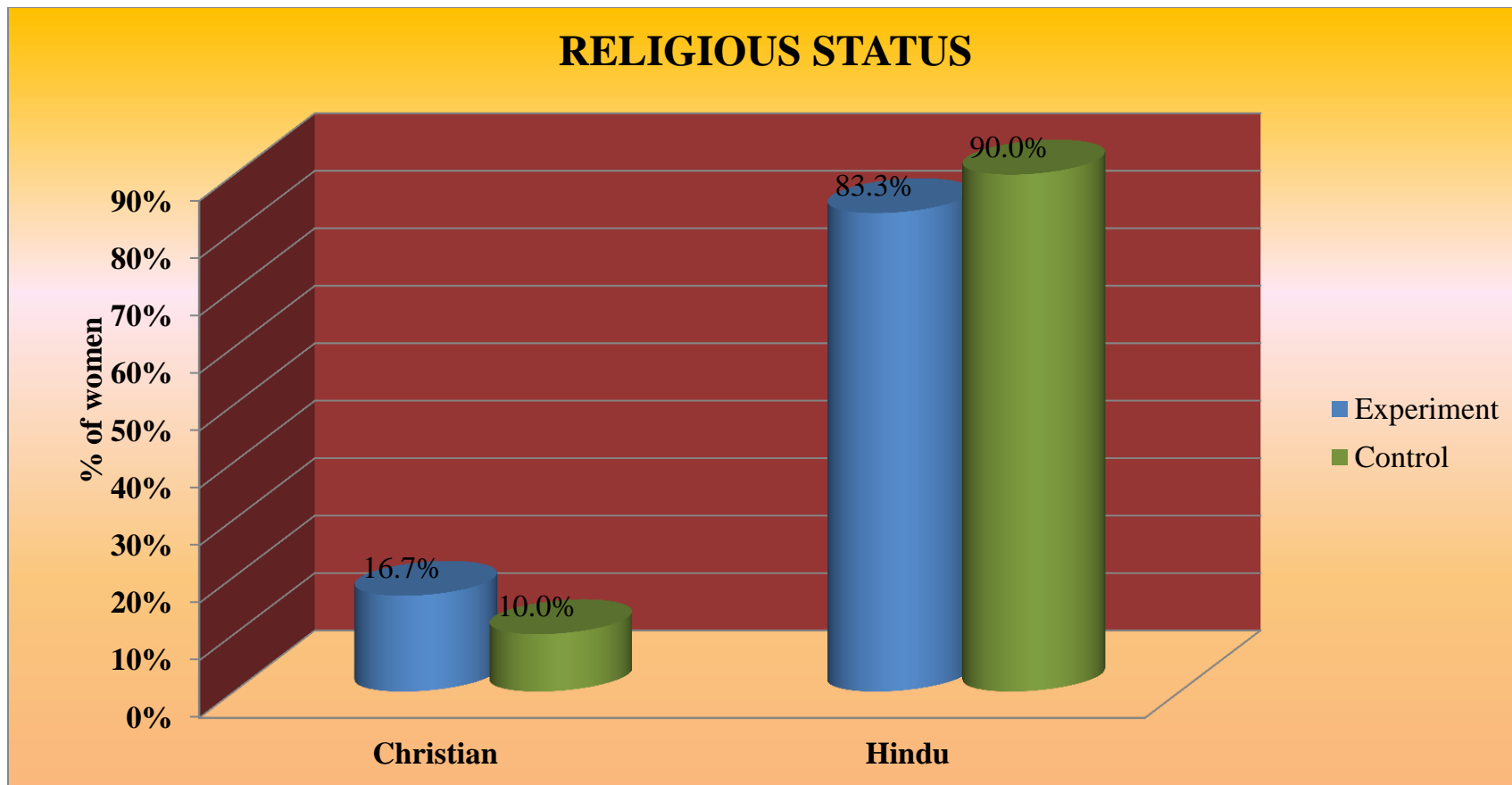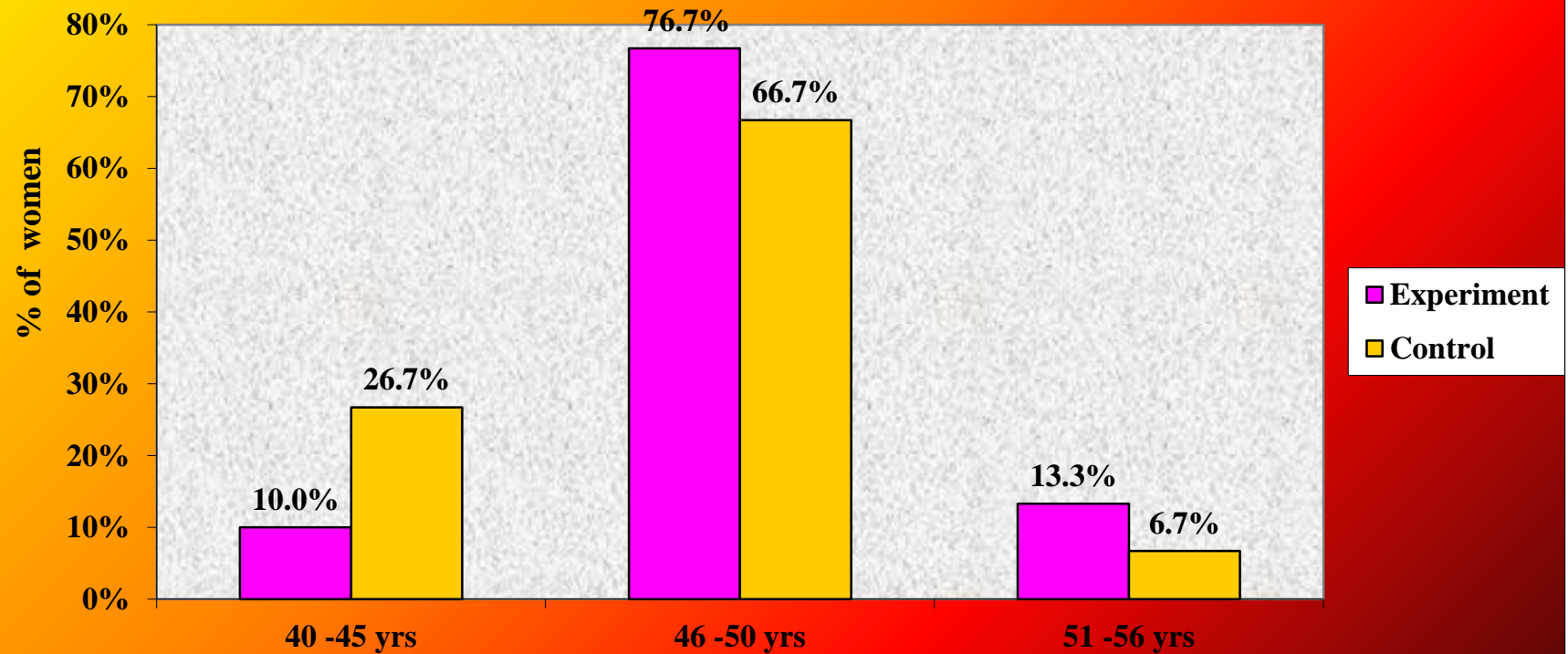*FIGURE : 13 Graphical representation of menopausal women according to Menopausal age in experimental group and control group*

SECTION –II

Table: 2   Distribution of Pre- assessment of menopausal symptom score (Wiklund Menopausal Symptom Scale).

MENOPAUSAL PROBLEMS	EXPERIMENT		CONTROL		TOTAL
Hot Flushes	2.33	.802	2.43	.935	t=0.44 P=0.65
Sleep Disturbances	2.50	.572	2.47	.571	t=0.22 P=0.82
Night sweats	2.10	.803	2.37	.814	t=1.43 P=0.15
Fatigue	2.31	.765	2.27	.583	t=0.56 P=0.57
Vaginal dryness	.67	.844	.50	.572	t=0.89 P=0.37
Headache	2.20	.887	2.30	.837	t=0.44 P=0.65
Irritability	1.43	1.223	1.03	.906	t=1.42 P=0.16
Joint pain	2.67	.711	2.43	.774	t=1.21 P=0.22
Breast tenderness	.53	.730	.90	1.029	t=1.59 P=0.11
Palpitation	.83	1.085	1.10	1.242	t=0.88 P=0.37

Table 4.2 reveals the distribution to assess the menopausal symptoms among women between 45-56yrs in experimental group and control before the soya bean consumption. Statistically there is **no significant difference** between experimental and control group women. Statistical significance was assessed using student independent t-test.

Table : 3 Distribution of Statistical value of comparison of pre-assessment level of menopausal symptoms score.

	Pre assessment		Student's independent t-test
	Mean	**SD**	
Experimental	17.57	3.08	t=1.29 P=0.21 not significant
Control	17.80	2.94	

* significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at   P≤0.001

Table 3 compares the menopausal symptoms score in experimental group and control group before the soya bean consumption .In Experiment group, in pre-assessment, menopausal women   were having 17.57 menopausal symptoms score and in control group 17.80 menopausal symptoms score . So the difference is 0.23. This difference is small and it is not statistically significant. Statistical significance was assessed using student independent 't'   test.

Fig 14: Box-plot compares the pre-assessment and post-assessment level of menopausal problems between experimental and control group

Table : 4   *Distribution of Statistical value of pre-assessment level of menopausal symptoms .*

LEVEL OF MENOPAUSAL SYMPTOMS	EXPERIMENT		CONTROL		CHI SQUARE TEST
	n	%	n	%	
Mild	7	23.3%	6	20.0%	$\chi2=0.10$
Moderate	21	70.0%	22	73.3%	P=0.95
Severe	2	6.7%	2	6.7%	Not significant

* significant at P≤0.05   ** highly significant at P≤0.01   *** very highly significant at   P≤0.001

Table :4 compares the experiment and control group level of menopausal symptoms score .

In experiment group, 23.3% of the women were having mild symptoms, 70% were having moderate symptoms and 6.7% of them were having severe menopausal symptoms.

In control group, 20.0% of the women were having mild symptoms, 73.3% were having moderate symptoms and 6.7% of them were having severe menopausal symptoms. This difference was small and it is not statistically significant difference. Statistical significance was calculated using chi square test.

SECTION –III

Table : 5 *Distribution of Statistical value of post-assessment of menopausal symptoms score.*

Menopausal problems	Experiment		Control		Total
Hot Flushes	1.60	.724	2.53	.819	t=4.67 P=0.001***
Sleep Disturbances	1.73	.691	2.53	.507	t=5.11 P=0.001***
Night sweats	1.30	.837	2.43	.774	t=5.44 P=0.001***
Fatigue	1.57	.711	2.30	.535	t=3.89 P=0.001***
Vaginal dryness	.40	0.68	.50	.572	t=0.60 P=0.54
Headache	1.53	.774	2.37	.718	t=4.84 P=0.001***
Irritability	1.10	.995	1.17	.986	t=0.26 P=0.79
Joint pain	1.60	.610	2.50	.731	t=4.02 P=0.001***
Breast tenderness	.47	1.006	1.30	1.291	t=2.77 P=0.01**
Palpitation	.63	1.033	1.10	1.242	t=2.80 P=0.001***

Table 5 shows the assessment of menopausal symptoms among women between 45-56years in control and experimental group after soya bean consumption. Statistically there was a significant difference between experimental and control group, except vaginal dryness and breast tenderness. Statistical significance was assessed using student independent t-test.

Table : 6   Distribution of Statistical value of comparison of post-assessment menopausal symptoms score.

	Post test		Student's
	Mean	**SD**	**independent t-test**
Experimental	12.07	3.19	**t=8.77 P=0.001*****
Control	18.73	2.89	**significant**

* significant at P≤0.05 ** highly significant at P≤0.01 *** very highly significant at   P≤0.001

Table :6 compares the menopausal symptoms score in experimental group and control group before soya bean consumption.

In Experiment group, in post-assessment, menopausal women were having 12.07 menopausal symptoms score and in control group 18.73 were having menopausal symptoms score . So the difference is 6.66. The difference was large and it is statistically significant. Statistical significance was assessed using student independent t-test.
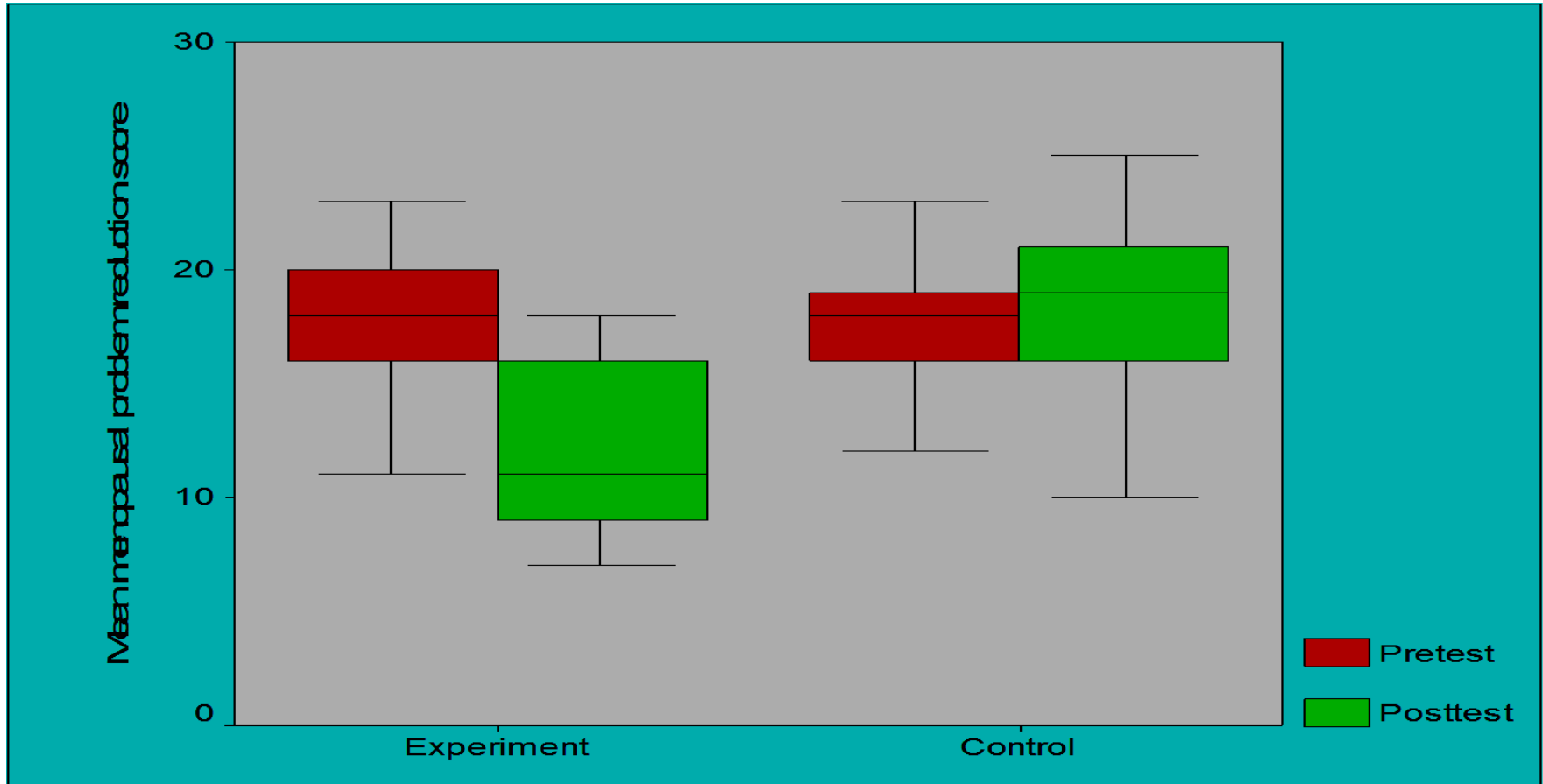
Table : 7   Distribution of Statistical value of post-assessment level of menopausal symptoms .

LEVEL OF MENOPAUSAL SYMPTOMS	EXPERIMENT		CONTROL		CHI SQUARE TEST
	N	%	n	%	
Mild	21	70.0%	5	16.6%	$\chi2=0.10$
Moderate	9	30.0%	23	76.7%	P=0.95
Severe	0	0.0%	2	6.7%	Not significant

* significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at   P≤0.001

Table : 7 compares the experiment and control group level of menopausal symptoms score .

In experiment group, 70.0% of the women were having mild menopausal symptoms, 30% are having moderate symptoms and none of them are having severe symptoms.

In control group, 16.6% of the women were having mild menopausal symptoms, 76.7% are having moderate symptoms and 6.7% of them are having severe symptoms.

This difference was small and it is not statistically significant difference. Statistical significance was calculated using **chi square test.**

POST-ASSESSMENT LEVEL OF MENOPAUSAL SYMPTOMS
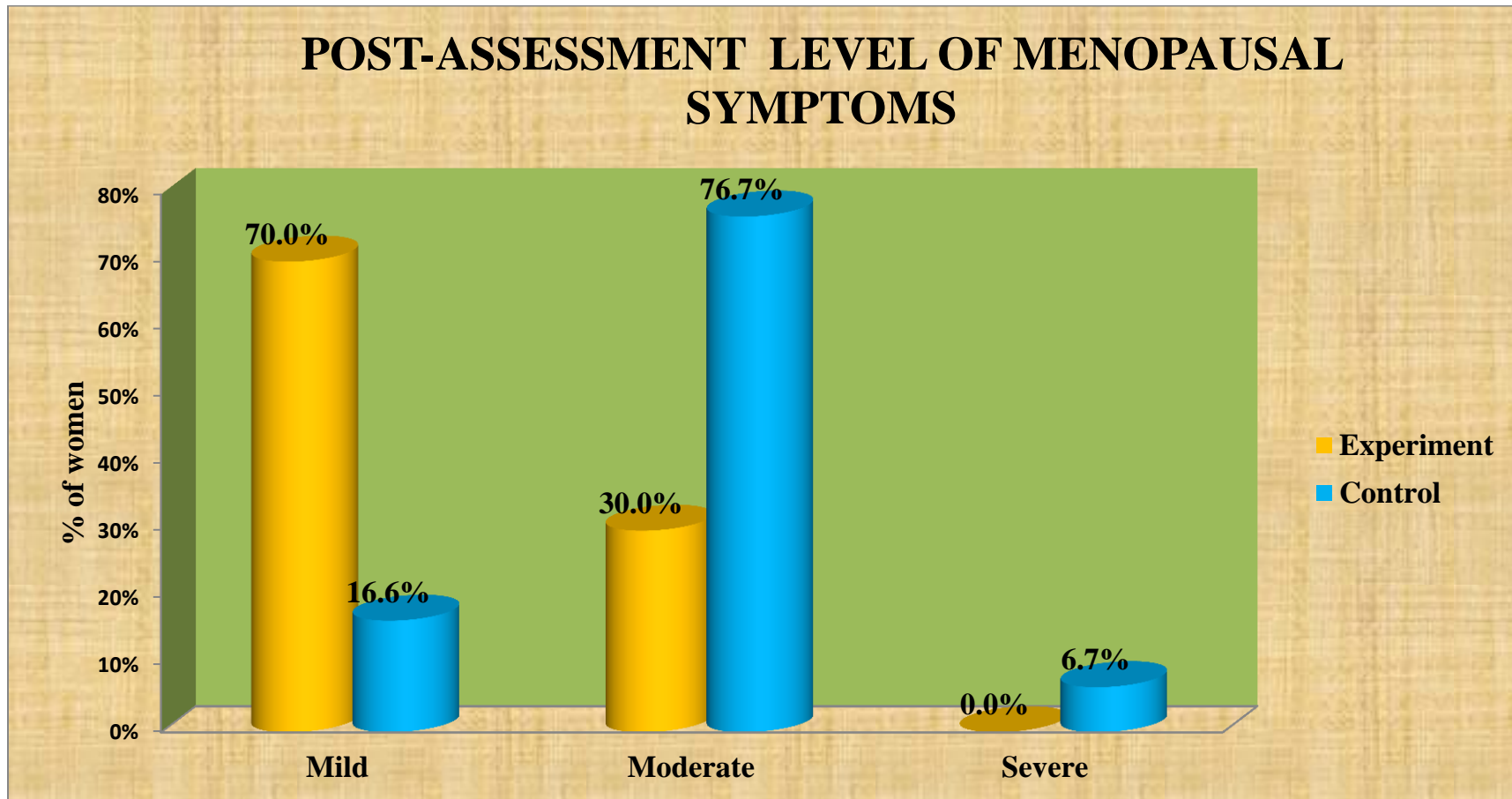
FIGURE : 15 Graphical representation of menopausal women according to post-assessment level of menopausal in experimental group and control group

<p align="center">SECTION –IV</p>

<p align="center">Table : 8 Distribution of Statistical value of effectiveness of soya consumption to reduce the menopausal symptoms among the experimental group.</p>

		Max score	Menopausal problem score	Mean difference with 95% CI	Percentage difference with 95%CI
Experiment	**Pre-assessment**	30	17.57	5.5(4.3-6.7)	↓**18.3%(14.3%-22.3%)**
	Post-assessment	30	12.07		
Control	**Pre-assessment**	30	17.80	-0.93(-2.01-0.15)	↑**3.1%(-6. 7%-5.0%)**
	Post-assessment	30	18.73		

Table no 8 shows the comparison of overall reduction of menopausal symptoms score between pre-assessment and post-assessment. On an average, in experimental group 18.3% of the symptom score were reduced and in Control group 3.1% of the symptoms were increased more after soya consumption. Difference between pre-assessment and post-assessment score was analyzed using Mean differenc with 95% CI and proportion with 95% CI and mean difference with 95% CI.

Table : 9 Distribution of Statistical value of effectiveness of soya consumption.

	Reduction score		Difference in knowledge gain
	Experiment	**Control**	
OVERALL	↓18.3%	↑-3.1%	21.4%

18.3% is the net benefit of this study.

SECTION -V

Table : 10 Association between level Of Menopausal Symptoms Reduction Score And Demographic Variables(Experiment)

Demographic variables		Level reduction score				Total	Chi square test
		Below Median(<5.5)		Above Median(>5.5)			
		n	%	n	%		
Age	46 -50 yrs	10	40.0%	15	60.0%	25	**χ2=6.00**
	51 -55 yrs	5	100.0%	0	40.0%	5	**P=0.01******
Educational Status	Non literate	11	73.3%	4	26.7%	15	
	Primary	3	27.3%	8	72.7%	11	**χ2=6.54**
	Middle school	1	25.0%	3	75.0%	4	**P=0.03***
Religion	Christian	2	40.0%	3	60.0%	5	χ2=0.24
	Hindu	13	52.0%	12	48.0%	25	P=0.62
Occupation	Sedentary worker	1	25.0%	3	75.0%	4	χ2=1.62
	Moderate worker	9	60.0%	6	40.0%	15	P=0.42

	Coolie	5	45.5%	6	54.5%	11	
Income	Rs.2000 -3000	6	35.3%	11	64.7%	17	χ2=4.28 P=0.11
	Rs.3000 -6000	7	63.6%	4	36.4%	11	
	> Rs.6000	2	100.0%	0	0.0%	2	
Marital status	Married	15	50.0%	15	50.0%	30	χ2=0.00 P=1.00
Type of Family	Nuclear family	11	52.4%	10	47.6%	21	χ2=2.19 P=0.33
	Joint family	4	57.1%	3	42.9%	7	
	Extended family	0	0.0%	2	100.0%	2	
Number of children	One	1	50.0%	1	50.0%	2	χ2=0.69 P=0.87
	Two	8	44.4%	10	55.6%	18	
	Three	4	57.1%	3	42.9%	7	
	Above three	2	66.7%	1	33.3%	3	
Medical Problems	Blood pressure	10	55.6%	8	44.4%	18	χ2=0.55 P=0.45
	Diabetic Mellitus	5	41.7%	7	58.3%	12	
Treatment taken	Yes	2	66.7%	1	33.3%	3	χ2=0.37 P=0.54
	No	13	48.1%	14	51.9%	27	
Menopause attained	40 -45 years	3	100.0%	0	0.0%	3	χ2=5.99 P=0.05*
	46 -50 years	9	39.1%	14	60.9%	23	
	51 -56 years	3	75.0%	1	25.0%	4	

Reduction score= pre-assessment score- post-assessment score

Table : 10 shows the association between level of reduction score and their demographic variables. Younger, more educated and menopausal women under 46-50 years has reduced menopausal symptoms than others. Statistical   significance was calculated using chi square test.

ASSOCIATION BETWEEN LEVEL OF MENOPAUSAL SYMPTOM REDUCTION AND AGE

Below average(<5.5%)

Above average(≥5.5%)
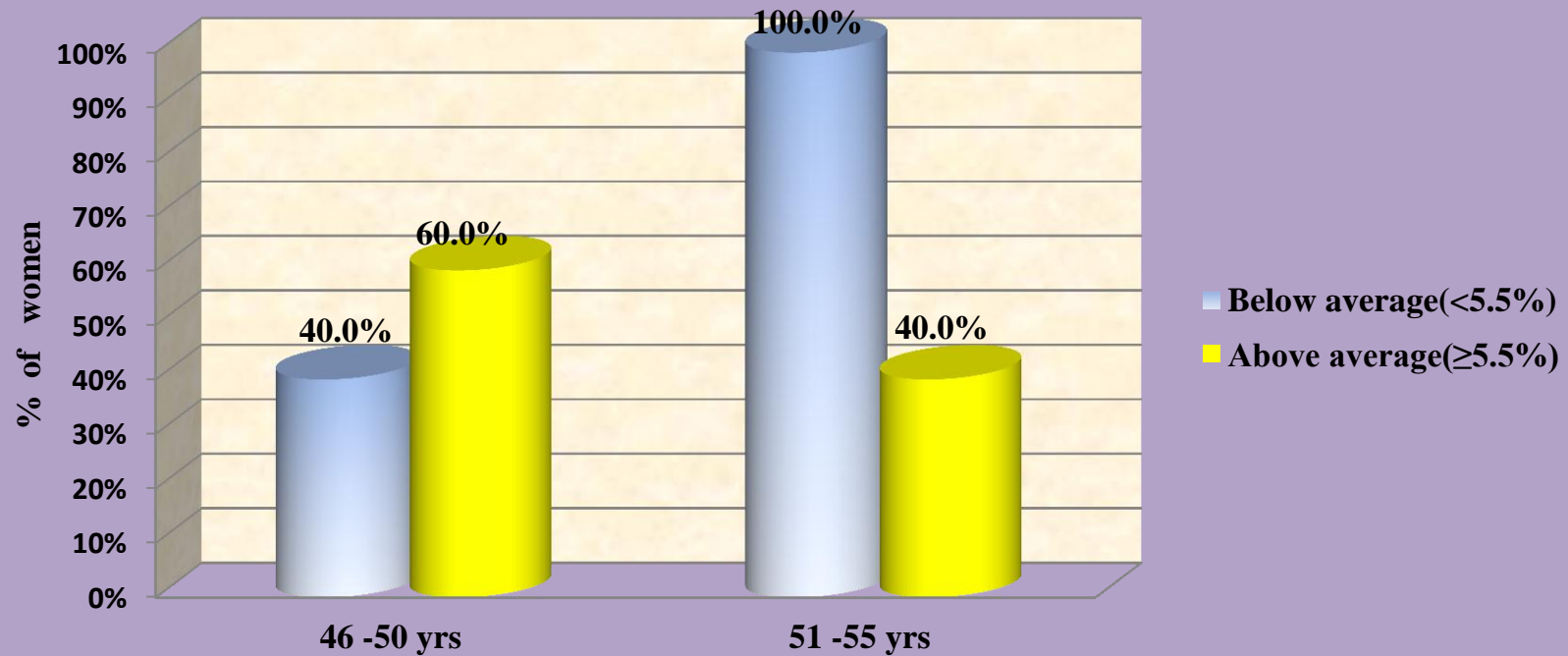
FIGURE : 16 Graphical representation of menopausal women according to association between level of Menopausal Symptom reduction and age in experimental group and control group

FIGURE : 17 Graphical representation of menopausal women according to association between level of
Menopausal symptom reduction and education in experimental group and control group

ASSOCIATION BETWEEN THE LEVEL OF MENOPAUSAL SYMPTOM REDUCTION AND MENOPAUSAL ATTAINED AGE

% of women

	40 -45 yrs	46 -50 yrs	51 -56 yrs

100.0%
75.0%
60.9%
39.1%
25.0%
0.0%

■ Below average(<5.5%)
■ Above average(≥5.5%)
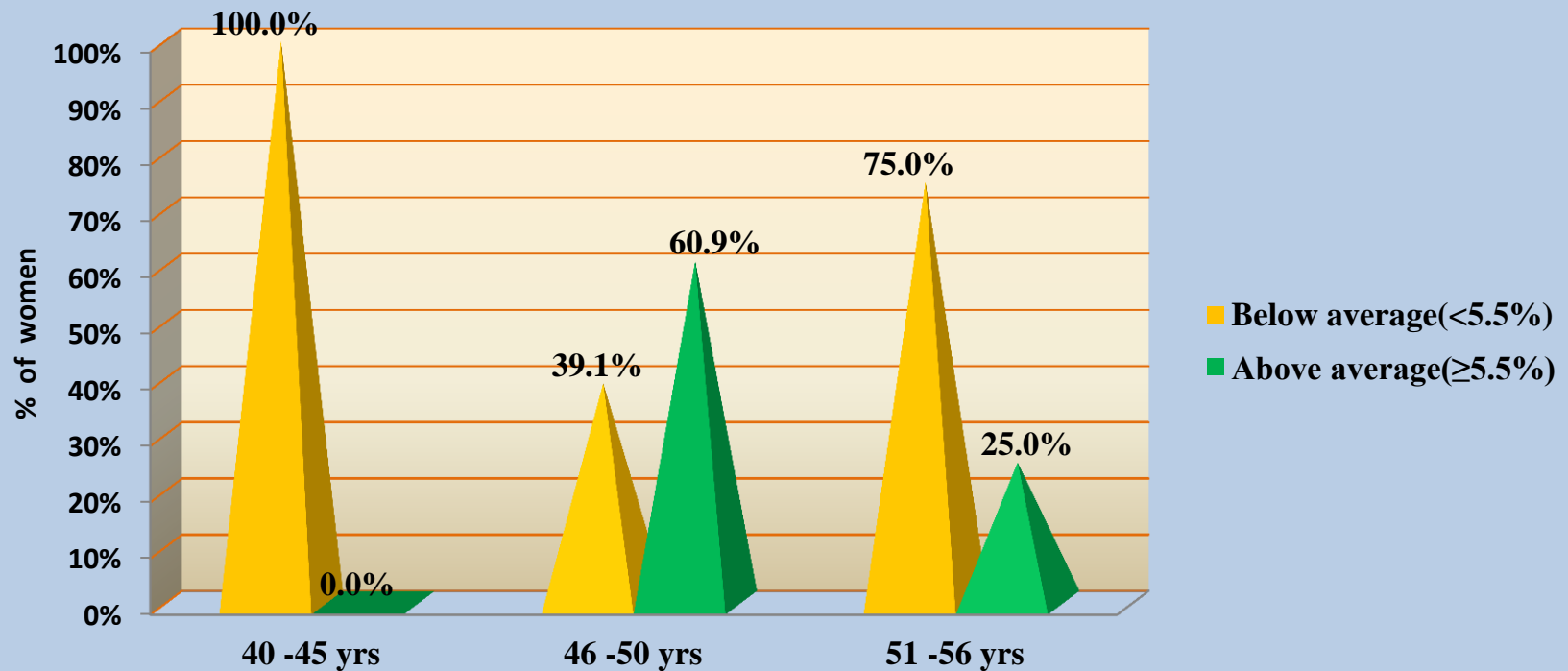
FIGURE : 18 Graphical representation of menopausal women according to association between level of menopausal symptom reduction and menopause attained age

Table : 11   Association between level Of Menopausal Symptoms Reduction
Score And Demographic Variables (Control)

Demographic variables		Level reduction score				Total	Chi square test
		Below Median(<0.93)		Above Median(>0.93)			
		n	%	n	%		
Age	46 -50 years	10	45.5%	12	54.5%	22	χ2=0.68 P=0.40
	51 -55 years	5	62.5%	3	37.5%	8	
Educational Status	illiterate	6	46.2%	7	53.8%	13	χ2=0.61 P=0.73
	Primary	7	58.3%	5	41.7%	12	
	Middle school	2	40.0%	3	60.0%	5	
Religion	Christian	3	100.0%			3	χ2=3.33 P=0.06
	Hindu	12	44.4%	15	55.6%	27	
Occupation	Sedentary worker	2	50.0%	2	50.0%	4	χ2=0.15 P=0.92
	Moderate worker	7	46.7%	8	53.3%	15	
	Coolie	6	54.5%	5	45.5%	11	
Income	Rs.2000 -3000	10	55.6%	8	44.4%	18	χ2=2.04 P=0.36
	Rs.3000 -6000	4	36.4%	7	63.6%	11	
	> Rs.6000	1	100.0%			1	
Marital status	Married	15	50.0%	15	50.0%	30	χ2=0.00 P=1.00
Type of Family	Nuclear family	6	40.0%	9	60.0%	15	χ2=0.26 P=0.96
	Joint family	7	58.3%	5	41.7%	12	

	Extended family	2	66.7%	1	33.3%	3	
Number of children	One	2	50.0%	2	50.0%	4	χ2=0.15 P=0.69
	Two	9	47.4%	10	52.6%	19	
	Three	3	60.0%	2	40.0%	5	
	Above three	1	50.0%	1	50.0%	2	
Medical Problems	Blood pressure	10	47.6%	11	52.4%	21	χ2=0.55 P=0.45
	Diabetic Mellitus	5	55.6%	4	44.4%	9	
Treatment taken	Yes	3	50.0%	3	50.0%	6	χ2=0.00 P=1.00
	No	12	50.0%	12	50.0%	24	
Menopause attained	40 -45 years	3	37.5%	5	62.5%	8	χ2=0.70 P=0.71
	46 -50 years	11	55.0%	9	45.0%	20	
	51 -56 years	1	50.0%	1	50.0%	2	

Reduction score= pre-assessment score- post-assessment score

Table :11 shows the association between level of Menopausal symptom reduction score and their demographic variables. None of the demographic variables are associated with reduction. Statistical significance was calculated using chi square test

CHAPTER –V

DISCUSSION

"Almost everybody is enthusiastic about the promise of biotechnology to cure disease and to relieve sufferings"

-Blain Lee

Natural menopause occurs with the conclusion of a woman 's final menstrual period ,it occurs normally between 40–56 years of age and is a complex phenomenon simultaneously encompassing physiological, psychological and social aspects of a women's life .Oestrogen deficiency has implicated in an increased risk for vasomotor symptoms, osteoporosis, cardiovascular disease, urogenital atrophy, cognitive decline and Alzheimer's disease. To reduce these menopausal symptoms this study was conducted.

The aim of the present study was to evaluate the effectiveness of soya bean in reducing the Menopausal symptoms among menopausal women. The study was conducted using Quasi experimental research design .The subjects selected for the study was women with Menopausal symptoms in the gynaecology outpatient department at the Institute Of Obstetrics And Gynaecology, Chennai .The sample size was 60.

Modified wiklund menopausal rating scale was used to assess the level of menopausal symptoms. The responses were analysed by using descriptive statistics (Mean, standard deviation, frequency, percentage) and inferential statistics and student independent't' test. Discussion on the findings was arranged based on the objectives of the study.

The first objective of the study was to assess the menopausal symptoms among menopausal women before the consumption of soya bean in experimental group and control group

The chi square test was performed to assess the menopausal symptoms among the women between 45-56 years in experimental group before the soya bean consumption. The pre-assessment mean value of menopausal symptom score for experiment group was 17.57 and in control group was 17.80 score respectively. The obtained 't' value in comparison of pre-assessment of menopausal symptom score for experimental and control group was 1.29 and P=0.21 respectively. Statistically this shows that there is no difference between pre-assessment score. It was confirmed by using the student independent t-test.

In the pre-assessment level of menopausal symptoms the calculated chi square value was 0.10 respectively at P= 0.95.The student independent t-test was performed to assess the mean and the SD Score .

The pre-assessment level of menopausal symptoms in experiment group, 23.3% of the women were having mild menopausal symptoms, 70% were having moderate symptoms and 6.7% of them were having severe symptoms.

The pre-assessment level of menopausal symptom in control group, 20.0% of the women were having mild menopausal symptoms, 73.3% were having moderate symptoms and 6.7% of them are having severe symptoms. The difference is small and it is not statistically significant.

The above findings are consisted with the **Shah Rashmi (2004)** conducted a population based cross sectional study on prevalence of menopausal symptoms in Mumbai among 500 women age of 40-56 years the study finding reports that over 64% menopausal women complaints of 37.4 % muscular and joint pain, 35.6% fatigue, the other symptoms reported were

19.4% hot flushes,18.6% sweating , 20.6% insomnia ,13.8% head ache and 7.6 % of urogenital problems. The study concluded that higher proportion of menopausal women suffers from vasomotor symptoms when compared to psychological and urogenital problems.

The second objective of the study was to assess the menopausal symptoms among menopausal women after the consumption of soya bean in experimental and control group .

The calculated mean value in comparison of soya bean consumption to reduce the menopausal symptoms among the experimental group was 12.07 and in control group was 18.73. So the difference is 6.66**.** The SD score in experimental group was 3.19 and in control group was 2.89. The calculated 't' value was 8.77 respectively at P=0.001***·This difference is large and it is statistically significant. Statistical significance was assessed using student independent t-test.

The level of post-assessment menopausal symptoms in the experiment group, 70.0% of the women were having mild menopausal symptoms, 30% were having moderate symptoms and none of them were having severe symptoms. In control group, 16.6% of the women were having mild menopausal symptoms, 76.7% are having moderate symptoms and 6.7% of them are having severe symptoms.

The chi square test was performed to assess the level of post-assessment menopausal symptoms were 0.10 respectively at P value 0.95. This difference is small and it is not statistically significant difference. Statistical significance was calculated using **chi square test.**

The above findings are consisted with the **J.Lissa (2010)** conducted an experimental study to evaluate the effectiveness of soya bean on menopausal problems in Madurai. The study results reveals that in experimental group the mean post-assessment status of the selected menopausal problems 13.5 is lower

than the mean pre-assessment status 18.3, the mean difference is 4.53 and the obtained 't' value 12.58 is significant at 0.05 level. The study concluded that there is a typical reduction in the level of menopausal symptoms after administration of soya bean .

The third objective was to compare the effectiveness of soya bean consumption in reducing the menopausal symptoms among the experimental group and control group.

The calculated percentage difference with 95% CI was performed to evaluate the effectiveness of soya bean consumption on menopausal symptoms among experimental group .The calculated percentage difference with 95% CI was in experimental group 18.3% of symptoms score were reduced after the soya bean consumption where as in Control group 3.1% of the symptoms were increased.

Differences between pre-assessment and post-assessment score was analysed using the Mean difference and proportion with 95% CI .18.3% of the menopausal symptom reduction is the net benefit of this study respectively. The difference in knowledge gain is 21.4%.

Hence the research hypothesis stated that there was a significant change in menopausal symptoms between experimental and control group.

The above findings are consisted with the **Radhakrishnan G ,Rashmi G 2010** conducted a randomized double blind study was conducted in 2010 at United states, to assess the efficiency and safety of a standardized compound based on extract of soya phytoestrogen in management of menopausal symptoms. Sample was 60 menopausal women who had symptoms. The result found that the menopausal women taking a soya supplement reported a 45% (p<0.001) reduction in the severity of their menopausal symptoms like hot flush ,joint

pain.However the control group also reported a no reduction in severity of symptoms. The study was concluded that soy isoflavone treatment was safe and effective alternative therapy for menopausal symptoms.

The forth objective was to find out the association between the experimental group and control group with selected demographic variables.

In association between level of reduction score and their demographic variables in the experimental group the reduction score of menopausal symptoms in the menopausal women at the age of 46-50 years was 60% and the chi square value was 6.00 respectively with the p value as P=0.01**.**

The reduction score of menopausal symptoms in the Menopausal women under the middle school was 75% and the chi square value was 6.54 respectively with the p value as P=0.003**.**

The reduction score of menopausal symptoms in the women attained menopause at the age of 46-50 years was 60,9% and the chi square value was 5.99 respectively with the p value as P=0.05**.** The association between the level of reduction score and their demographic variables in the control group , None of the demographic variables are associated with reduction.

The above findings are consisted with the **Kakkar V et .al (2007)** conducted a quasi - experimental study to find out the variation in menopausal symptoms with age , education and non-working status in north Indian sub population . The Menopausal Rating scale, a self-administered standardized questionnaire was applied with additional patient's related information for analysis. Data analysis revealed that statistically significant interactions were found for age, education, and working status with menopausal symptoms.

CHAPTER-VI

SUMMARY, CONCLUSION, IMPLICATIONS, RECOMMENDATION, AND LIMITATION

This chapter represents a brief account of the present study. Conclusions are drawn from the findings and the implications of the results are stated. It also includes recommendations, implications for the nursing practice, nursing education, nursing administration and nursing research.

6.1 SUMMARY OF THE STUDY

The study was conducted to evaluate the effectiveness of soya bean in reducing the menopausal symptoms among menopausal women in the Institute of Obstetrics and Gynaecology at Chennai .The Purpose of the study was to decrease the menopausal symptoms among the menopausal women and able to cope up with the discomfort they experienced during the menopausal period.

OBJECTIVES OF THE STUDY

1. To assess the menopausal symptoms among menopausal women before the consumption of soya bean in experimental group and control group.
2. To assess the menopausal symptoms among menopausal women after the consumption of soya bean in experimental group and control group.
3. To compare the effectiveness of soya bean consumption in reducing the menopausal symptoms between the experimental group and control group.
4. To find out the association between the experimental group and control group with selected demographic variables.

A formal permission was obtained from the director of the Institute of Obstetrics and Gynaecology at Egmore , Chennai-8 .The data was collected with the help of structured questionnaire and pre-assessment and post-assessment assessment method using Modified wiklund menopausal symptom scale.

The conceptual framework adopted for the study was Modified General system theory Model .The model helped the investigator in approaching the problem in a comprehensive and systematic manner. Review of research helped the investigator in the preparation of the conceptual model, Tool, and the methodology of the study.

The pilot study was conducted for six women for two weeks at gynaecology outpatient department, Institute of obstetrics and gynaecology Chennai, after getting formal permission was obtained from the director of Institute of obstetrics and gynaecology ,Chennai. The results revealed that soya bean is effective in reducing the menopausal symptoms among the experimental group. After pilot study reliability of the tool was assessed by using inter rater method and its correlation coefficient r –value is 0.82. This correlation coefficient is very high and it is good tool for assessing effectiveness of soya bean on menopausal symptoms among menopausal women in the Institute of Obstetrics and Gynaecology.

The experimental approach was utilized to achieve the overall purpose .The research design used for the Quasi experimental Study Design. Samples were collected for the study and this continued till the desired size was met. The study was conducted in the gynaecology outpatient department. Convenient sampling technique was used .The samples consists of 60 menopausal women , age group between 45-56 years.

6.2 MAJOR FINDINGS OF THE STUDY ARE AS FOLLOWS

❖ The pre-assessment mean value of menopausal symptom score for experiment group, 17.57 and in control group 17.80 score respectively.

❖ The post-assessment mean value of menopausal symptom score for experiment group 12.07 and in control group 18.73 score respectively.

❖ The level of pre-assessment menopausal symptoms in experiment group, 23.3% of the women were having mild menopausal symptoms, 70% were having moderate symptoms and 6.7% of them are having severe symptoms.

❖ The level of pre-assessment menopausal symptom score in control group, 20.0% of the women were having mild menopausal symptoms, 73.3% were having moderate symptoms and 6.7% of them are having severe symptoms.

❖ The level of post-assessment menopausal symptom in experiment group, 70.0% of the women were having mild menopausal symptoms, 30% were having moderate symptoms and none of them are having severe symptoms.

❖ The level of post-assessment menopausal symptom in control group, 16.6% of the women were having mild menopausal symptoms, 76.7% are having moderate symptoms and 6.7% of them were having severe symptoms.

❖ The obtained 't' value of comparison of pre-assessment menopausal symptom scores for experimental and control group was 1.29 respectively.

- ❖ The obtained 't' value of comparison of post t-test menopausal symptom score for experimental and control group was 8.77 respectively.
- ❖ In experiment group the reduction score in effectiveness of soya bean consumption was **18.3**% and in Control group it was **increased as 3.1% problems more.**
- ❖ The net benefit of this study in the effectiveness of soya bean consumption in reducing the menopausal symptoms was **18.3%**

6.3 CONCLUSION

The main conclusion drawn from this present study was that majority of the menopausal women had moderate level of menopausal symptoms. After the administration of soya bean, their menopausal symptoms are reduced significantly. The calculated mean difference was 6.66 .The obtained 't' value 8.77 shows statically significant .The subjects become familiar and found themselves comfort and express satisfaction. This ensured that administration of 50 grams of soya bean were effective in reducing the level of menopausal symptoms.

6.4 IMPLICATIONS

According to **Tolsma (1995),** the section of the research report that focuses on nursing implications usually includes specific suggestions for nursing practice, education, administration and nursing research.

a) Nursing education

Nursing curriculum is a means through which future nurses are prepared, the emphasis needs to be preventive and promotive health practice. The results of the study emphasis the learners to utilize the knowledge of soya bean in reducing the menopausal symptoms .As a nurse educator, we must strengthen the dietary method in reducing the menopausal symptoms among the menopausal women as an integral part of nursing curriculum for under graduate and post graduate programme. we must encourage the nursing students to learn about the accurate assessment of menopausal symptoms. The student nurses will update their knowledge regarding the method of reducing the menopausal symptoms among the menopausal women. Nursing curriculum has to focus on periodical screening programme of menopausal symptoms in hospitals and community.

b) Nursing practice

The nurses can encourage the use of soya bean as a form of nutrition supplementation among women with menopausal symptoms. As it is cost effective, locally available and has minimal side effects. The study findings will helps the Nurse to know the importance of soya bean intake in reducing the Menopausal symptoms and helps to motivate the women with menopausal symptoms to follow .The study findings will encourage the women to know the importance of reducing the Menopausal symptoms among the women. The nurse can plan for health programme on alternative and complementary treatment for menopausal symptoms.

c) Nursing administration

Nursing administrators or learners should take interest in formulating principles and adapting the various modalities of treatment for menopausal symptoms among the menopausal women. The nurse can take part in the health policy making, developing protocols, standing orders related to design the

health education programme and strategies. The nurse can explore their potential and encourage innovative ideas in preparation of appropriate teaching materials and usage of manpower for organizing the health education program me on menopausal symptoms. The present study proposes to help the nurse to plan for the awareness program me on reducing menopausal symptoms. The nurse can arrange for periodic mass health education programme in hospitals to create an awareness of menopausal symptoms.

d) Nursing Research

The study finding encourage ,further research studies on the effectiveness of soya bean in reducing Menopausal symptoms among women. The study findings helps to expand the scientific body of professional knowledge upon which further researchers are built upon these by increasing evidence based practice.

6.4 RECOMMENDATIONS

- ❖ A similar study can be replicated on large sample size.
- ❖ A similar study can be done with other type of soya products.
- ❖ Effectiveness of Soya bean can be compared with other complementary therapies to find its effectiveness.
- ❖ A similar study can be conducted in different settings.
- ❖ A comparative study can be conducted regarding Menopausal symptoms between rural and urban areas.
- ❖ A study can be conducted to compare effectiveness of soya versus hormonal replacement therapy among menopausal women.

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DATA COLLECTION TOOL

SECTION-1

DEMOGRAPHIC VARIABLE PROFORMA

PURPOSE:

This proforma is used to measure the demographic variables such as age, sex, education, occupation, religion, monthly income, number of years in the Gynaecology op Institute of obstetrics and gynaecology , Chennai , etc..

INSTRUCTION:

- o Choose the correct answer and write the number in the space provided.
- o Please be frank and feel in answering the questions.
- o All your answers will be maintained confidentially.

DEMOGRAPHIC PROFILE

SAMPLE NO :

1. Age in years

   a) 46-50 Years ☐

   b) 51-55 Years ☐

   c) 55-56 years ☐

   d) Above 56 ☐

2. Education status

    a)   Illiterate ☐

    b)   Primary ☐

    c)   Middle School ☐

    d)   High school and above ☐

3. Religion

    a)   Christian ☐

    b)   Hindu ☐

    c)   Muslim ☐

    d)   Others ☐

4   Occupation

    a)   Sedentary worker ☐

    b)   Moderate worker ☐

    c)   Heavy worker ☐

    d)   Coolie ☐

5. Income

    a)   2000-3000 ☐

    b)   3000-6000 ☐

    c)   Above 6000 ☐

    d)   Below 3000 ☐

6. Marital status

    a) Married ☐

    b) Unmarried ☐

    c) Widow ☐

    d) Divorce ☐

7. Type of family

    a) Nuclear family ☐

    b) Joint family ☐

    c) Extended family ☐

    d) Separated family ☐

8. Number of children

    a) One ☐

    b) Two ☐

    c) Three ☐

d) Above three ☐

9. Do you have any medical problems

   a) Blood Pressure ☐

   b) Diabetes Mellitus ☐

   c) Asthma ☐

   d) Cardiac diseases ☐

10. Whether or taken treatment for menopause

   a) Yes ☐

   b) No ☐

11. Menopause attained at the age of

   a) 40-45 years ☐

   b) 46-50 years ☐

   c) 51-56 years ☐

   d) 60 above ☐

MODIFIED WIKLUND MENOPAUSAL SYMTOM SCALE

S.NO	MENOPAUSAL PROBLEMS	3 FREQUENTLY	2 OCCASIONALLY	1 RARELY	0 NEVER
1.	How often do you experience Hot Flushes?				
2.	How often do you experience sleep disturbances?				
3.	How often do you experience Night sweat?				
4.	How often do you experience Fatigue?				
5.	How often do you experience Vaginal dryness?				
6.	How often do you experience Headache?				
7.	How often do you experience Irritability?				
8.	How often do you experience Joint Pain ?				
9.	How often do you experience Breast Tenderness ?				
10.	How often do you experience palpitation?				

SCORE

0-15 $\longrightarrow$ 0% -50% $\longrightarrow$ Mild

15-22 $\longrightarrow$ 50 %-76% $\longrightarrow$ Moderate

23-30 $\longrightarrow$ 76%-100% $\longrightarrow$ Severe

நேர்காணல் படிவம்

1.வயது வருடங்களில்

    அ) 46-50 வயது ☐

    ஆ) 51-55 வயது ☐

    இ) 55-56 வயது ☐

    ஈ) 56 இக்குமேல் ☐

2.கல்வித் தகுதி

    அ) கல்வியறிவு அற்றவர் ☐

    ஆ) ஆரம்பக்கல்வி ☐

    இ) உயர்நிலைகல்வி ☐

    ஈ) மேல்நிலை கல்வி மற்றும் பட்டபடிப்பு☐

3. மதம்

    அ) கிறிஸ்டியன் ☐

    ஆ) இந்து ☐

    இ) முஸ்லிம் ☐

    ஈ) மற்றமதம் ☐

4. தொழில்

    அ)சுலபமான தொழில் ☐

    ஆ) மிதமன தொழில் ☐

    இ) கடினமான தொழில் ☐

    ஈ) கூலி ☐

5. குடும்பமாத வருமானம்

    அ) ரூ 2000- 3000 ☐

    ஆ) ரூ 3000- 6000 ☐

    இ) ஆராயிருயித்துக்கு மேல் ☐

    ஈ) முவாயிரத்துகுல் ☐

6. திருமணநிலை

    அ) திருமணமாகாதவர் ☐

    ஆ) திருமணமானவர் ☐

    இ) விதவை ☐

    ஈ) விவாகரத்தானவர் ☐

7. குடும்பவகை

    அ) தனிக் குடும்பம் ☐

    ஆ) கூட்டுக் குடும்பம் ☐

    இ) விரிவான குடும்பம் ☐

    ஈ) பிரிந்த குடும்பம் ☐

8. குழந்தையின் எண்ணிக்கை

    அ) ஒன்று ☐

    ஆ) இரண்டு ☐

    இ) மூன்று ☐

    ஈ) மூன்றிற்குமேல் ☐

9. உங்களுக்கு வேறு ஏதேனும் நோய் உள்ளதா?

    அ) உயர் இரத்த அழுத்தம் ☐

    ஆ) சர்க்கரை நோய் ☐

    இ) ஆஸ்த்துமா ☐

    ஈ) இருதய நோய் ☐

10. நீங்கள் மாதவிடாய் சம்மந்தமான நோய்களுக்கு

    அ) ஆம் ☐

    ஆ) இல்லை ☐

11. மாதவிடாய் எந்த வயது வரம்பில் அடைந்தீர்கள்

    அ) 40-45 வயது ☐

    ஆ) 46-50 வயது ☐

    இ) 51-56 வயது ☐

    இ) 60 வயதிற்குமேல் ☐

மாற்றி வடிவமைகபட்ட விக்லண்ட்மாதவிடாய் சுலர்ச்சி நிற்றல் அளவுகோள்

வ.எ.ண்	மாதவிடாய் நின்ற காலத்தில் வரும் பிரச்சனைகள்	3 அடிக்கடி நிகழும்	2 அவ்வப்போது நிகழும்	1 எப்போழு தவது	0 எப்போழுதும் இல்லை
1.	உங்களுக்கு உடல் உஷ்ணமாக இருப்பதாக உணர்கிறீர்களா?				
2.	உங்களுக்கு இரவு நேரம் தூக்கம் தடைபடுவதாக உணர்கிறீர்களா?				
3.	உங்களுக்கு இரவு நேரங்களில் வியர்கிறதா?				
4.	உங்களுக்கு உடற்சோர்வு எற்படுவதுண்டா?				
5.	உங்களுக்கு பிறப்புறுப்பு வரண்ட தன்மையுடன் இருப்பதாக உணர்கிறீர்களா?				
6.	உங்களுக்கு தலைவலி வருவதுண்டா?				
7.	உங்களுக்கு மனளரிச்சல் இருப்பதாக உணர்கிறீர்களா?				
8.	உங்களுக்கு மூட்டுவலி இருக்கிறதா?				
9.	உங்களுக்கு மார்பை தொடும்பொது வலி இருக்கிறதா?				
10.	உங்களுக்கு படபடப்பு ஏற்படுவதுண்டா?				

மதிபீடு:

0-15 ----------   0%-50% $\longrightarrow$ குறைவாக

15-22 ---------   50%-76% $\longrightarrow$ மிதமாக

23-30 ---------   76%-100% $\longrightarrow$ கடுமையாக

INTERVENTION PROTOCOL

The soya bean (Glycine max) belongs to the legume family. Legumes features phytonutrients that lend some unique benefits to women in menopause. The soya bean is especially rich in isoflavones, the most widely studied class of phytonutrients.

PURPOSES

- ❖ Soy is a good source of protein and has been consumed by Asian populations for thousands of years.
- ❖ Soy isoflavones are sometimes referred to as phytoestrogens and have the most potent estrogen –like activity of all common phytoestrogens.
- ❖ The effects of soy isoflavones observed on mood and cognitive performance in post-menopausal women have been positive – particularly with verbal memory –and this may be of revelance to thinking in perimenopause.
- ❖ Soy isoflavones help to promote better bone health and have positive effects bone density.
- ❖ Soy isoflavones may helps to reduce hot flashes and night sweats that many women have during menopause.
- ❖ Soy isoflavones helps in Prevention of menopausal symptoms ,osteoporosis ,coronary heart disease, cancer.
- ❖ Isoflavones are phytoestrogen –chemicals that act like the harmone estrogen.

50 gms of Soya Beans contains :

- ➔ Phytoestrogen 20mg.
- ➔ Energy -223k .cal,Carbohydrate-10.45 gm
- ➔ Dietary fiber -5gm,Fat -9.75 gm ,Protein -21.6 gm
- ➔ Vitamin A-1moq, Vitamin B6-0.133 mg, Vitamin C-3mg.
- ➔ Vitamin K-2.7mg ,Calcium-120 mg,Mg-140 mg,Fe-5.2mg,Na-1mg,Z-2.45 mg

Daily soy consumption may support substantial health benefits--
(Revival food, 2010)

- ♣ Menopause and perimenopause discomforts support
- ♣ Weight loss support
- ♣ Beautiful hair, skin and nail appearance support
- ♣ Energy and workouts support
- ♣ Promotion of normal cholesterol and heart health
- ♣ Promotion of normal bone health
- ♣ Maintenance of normal blood sugar health
- ♣ Promotion of better antioxidant health
- ♣ Support of colon and digestive tract health
- ♣ Support for normal kidney health
- ♣ Thyroid and fertility health

PREPARATION:

- ❖ Take 50gms of soya bean .
- ❖ Rinse soyabean ,a few minute to remove the dust .
- ❖ Soak it in the 100ml of water through out the night .
- ❖ Then boil it in water for 15 to 20 minutes .
- ❖ Then the cooked soya bean is given to the samples.

PROCEDURE

- ❁ Formal permission from concerned authorities is taken after which samples are identified as per inclusion criteria.

- ❁ Subjects are then selected for control and experimental groups by convenient sampling.

- ❁ Baseline information is collected through structured interview schedule.

- ❁ Wiklund menopausal symptom scale is administered. If subjects present with two or more symptoms per day in the scale, they are included for the study.

- ❁ Subjects in the experimental group are asked to consume the soya bean 50gms per day in the presence of the investigator for 20 continuous days.

- ❁ At the end of third week subjects in both groups are again assessed to rate the Wiklund menopausal symptom scale and the effectiveness are evaluated.

EC RegNo.ECR/270/Inst./TN/2013
Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
 M.Kalaivani,
 M.Sc.,(N) II year,
 College of Nursing,
Madras Medical College, Chennai-3.

Dear Kalaivani

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled "A study to assess the effectiveness of soya bean on menopausal symptoms among menopausal women in the institute of Obstetrics and Gynaecology Chennai—08". No.19072013.

The following members of Ethics Committee were present in the meeting held on 06.07.2013 conducted at Madras Medical College, Chennai -3.

1. Dr.G.SivaKumar, MS FICS FAIS --- Chairperson
2. Prof. R. Nandhini MD -- Member Secretary
   Director, Instt. of Pharmacology ,MMC, Ch-3
3. Prof. Shyamraj MD -- Member
   Director i/c , Instt. of Biochemistry , MMC, Ch-3
4. Prof. P. Karkuzhali. MD -- Member
   Prof., Instt. of Pathology, MMC, Ch-3
5. Prof. Kalai Selvi -- Member
   Prof of Pharmacology, MMC, Ch-3
6. Prof. Siva Subramanian, -- Member
   Director, Instt. of Internal Medicine, MMC, Ch-3
7. Thiru. S. Govindsamy. BABL -- Lawyer
8. Tmt. Arnold Saulina MA MSW -- Social Scientist

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

R Nandhini

Member Secretary, Ethics Committee

From

Ms. M. Kalaivani,
M.Sc(Nursing) II year student,
College of Nursing,
Madras Medical College,
Chennai-03.

To

The Director & Superintendent,
Institute of Obstetrics and Gynaecology,
Egmore,
Chennai-08.

Through the proper channel

Respected Madam,

Sub : Requesting permission to conduct a research study - reg.

I, Ms. M. Kalaivani, studying M.Sc(Nursing) II Year in College of Nursing, Madras Medical College, Chennai-03, kindly request you to grant me permission for the study proposed to conduct on the topic titled **" A study to assess the effectiveness of soya bean on menopausal symptoms among menopausal women at Institute of Obstetrics and Gynaecology, Chennai-08",** to fulfill the requirement of data collection. I assure you that it will not interfere with the routine activities of the study settings.

Thanking you,

Place: chennai

Date: 11 / 07 / 13

Yours obediently,

(M.Kalaivani)

CERTIFICATE OF TOOL VALIDATION

This is to certify that the tool constructed by Ms.M.Kalaivani, M.Sc Nursing II year, College of Nursing, Madras Medical College which is to be used in her study titled **"A Study to assess the effectiveness of soya bean on menopausal symptoms among menopausal womens in the Institute of Obstetrics and Gynaecology, Chennai."** has been validated by the undersigned. The suggestions and modifications given by me will be incorporated by the investigator in concern with their respective guide. Then she can proceed to do the research.

SIGNATURE WITH SEAL

NAME   : Dr. M.S. MANICKA DEVI

DESIGNATION   : SENIOR ASSISTANT PROFESSOR

INSTITUTION   : IOG, EGMORE CHENNAI

PLACE : CHENNAI

DATE : 4|9|13.

CERTIFICATE OF TOOL VALIDATION

This is to certify that the tool constructed by Ms.M.Kalaivani, M.Sc Nursing II year, College of Nursing, Madras Medical College which is to be used in her study titled "**A Study to assess the effectiveness of soya bean on menopausal symptoms among menopausal womens in the Institute of Obstetrics and Gynaecology, Chennai.**"has been validated by the undersigned. The suggestions and modifications given by me will be incorporated by the investigator in concern with their respective guide. Then she can proceed to do the research.

SIGNATURE WITH SEAL

NAME : Mrs. KANAGAVALLI.P

DESIGNATION : READER

COLLEGE : MADHA COLLEGE OF NURSING

PLACE : KUNRATHUR, CHENNAI-69

DATE : 16/08/2013

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

"சோயா பயறு கொடுப்பதன்மூலம் மாதவிடாய் சுழற்சி நிற்றல் தொடர்புள்ள அறிகுறைகளை குறைய்பது பற்றிய ஓர் ஆய்வு"

பங்கு பெறுபவரின் பெயர்: வயது: தேதி: உள் நோயாளி எண்:

.... என்பவராகிய நான் இந்த ஆய்வின் விவரங்களும் அதன் நோக்கங்களும் முறையாக அறிந்து கொண்டேன். எனது சந்தேகங்கள் அனைத்திற்கும் தகுந்த விளக்கம் அளிக்கப்பட்டது. இந்த ஆய்வில் முழு சுதந்திரத்துடன் மற்றும் சுயநினைவுடன் பங்கு கொள்ள சம்மதிக்கிறேன்.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்துகொண்டு நான் எனது சம்மதத்தைத் தெரிவிக்கிறேன். இச்சுய ஒப்புதல் படிவத்தை பற்றி எனக்கு விளக்கப்பட்டது.

இந்த ஆய்வினை பற்றிய அனைத்து தகவல்களும் எனக்கு தெரிவிக்கப்பட்டது. இந்த ஆய்வில் எனது உரிமை மற்றும் பங்கினை பற்றி அறிந்து கொண்டேன்.

இந்த ஆய்வில் பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின்பேரில் தான் பங்கு பெறுகிறேன் மற்றும் நான் இந்த ஆராய்ச்சியிலிருந்து எந்நேரமும் பின்வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொண்டேன்.

இந்த ஆய்வில் கலந்து கொள்வதன்மூலம் என்னிடம் பெறப்படும் தகவலை ஆய்வாளர் இன்ஸ்டிட்யூசனல் எத்திக்ஸ் கமிட்டியினரிடமோ, அரசு நிறுவனத்திடமோ தேவைப்பட்டால் பகிர்ந்து கொள்ளலாம் என சம்மதிக்கிறேன்.

இந்த ஆய்வின் முடிவுகளை வெளியிடும்போது எனது பெயரோ, அடையாளமோ வெளியப்படாது என அறிந்து கொண்டேன். இந்த ஆய்வின் விவரங்களைக் கொண்ட தகவல்தாளைப் பெற்றுக் கொண்டேன். இந்த ஆய்விற்காக சோயா பயறு உட்கொண்டு பரிசோதனை செய்துக் கொள்ள சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கேற்கும்பொழுது ஏதேனும் சந்தேகம் ஏற்பட்டால், உடனே ஆய்வாளரை தொடர்பு கொள்ள வேண்டும் என அறிந்து கொண்டேன்.

இச்சுய ஒப்புதல் படிவத்தில் கையெழுத்திடுவதன்மூலம் இதிலுள்ள அனைத்து விஷயங்களும் எனக்கு தெளிவாக விளக்கப்பட்டது என்று தெரிவிக்கிறேன். இச்சுய ஒப்புதல் படிவத்தின் ஒரு நகல் எனக்கு கொடுக்கப்படும் என்று தெரிந்து கொண்டேன்.

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ஆராய்ச்சியாளர் கையொப்பம்   பங்கேற்பாளர் கையொப்பம்
தேதி:   தேதி:

ஆய்வு தகவல் தாள்

பங்கேற்பாளர் பெயர்   :

ஆராய்ச்சியாளர் பெயர்   :   மு.கலைவாணி

ஆய்வு தலைப்பு   :   சோயா பயறு கொடுப்பதன்மூலம் மாதவிடாய் சுழற்சி நிற்றல்
தொடர்புள்ள அறிகுறைகளை குறைப்பது பற்றிய ஓர் ஆய்வு.

இந்த ஆய்வு சென்னை அரசு தாய் சேய் குழந்தை நல மருத்துவமனையின் புறநோயாளிகள் பிரிவில் மேற்கொள்ளப்பட உள்ளது.

நீங்கள் இந்த ஆய்வில் பங்கேற்க அழைக்கிறோம். நீங்கள் இந்த ஆய்வில் பங்கேற்கலாமா அல்லது வேண்டாமா? என்பதை முடிவு செய்ய இந்த ஆவணத்தில் உள்ள தகவல் உதவியாக இருக்கும். உங்களுக்கு ஏதேனும் சந்தேகம் இருந்தால் நீங்கள் எங்களிடம் வெளிப்படையாக கேட்கலாம்.

எங்களுடைய அடிப்படை தகுதிகளில் நீங்கள் திருப்தியாக இருப்பதால் உங்களை இந்த ஆய்வில் பங்கேற்க அழைக்கிறோம்.

ஆய்வின் நோக்கம் மற்றும் செயல்பாடு:

சோயா பயறு கொடுப்பதன்மூலம் மாதவிடாய் சுழற்சி நிற்றல் தொடர்புள்ள அறிகுறைகளை குறைப்பது பற்றிய ஓர் ஆய்வு.

இந்த ஆய்வில் உங்கள் பெயர், வயது, பரிந்துரைக்கப்பட்ட மருந்து களின் பெயர், சிகிச்சை கால அளவு ஆகிய தகவல்கள் பெற்றுக் கொள்வோம்.

சில தகவல்கள் உங்களிடம் பெறப்படும்:

உங்களுக்கு உங்களுடைய மருத்துவத் தகவலை இரகசியமாக வைக்க உரிமை உண்டு. நீங்கள் இந்த ஆய்வில் கையொப்பமிடுவதால் நீங்கள் உங்களுடைய தகவலை ஆய்வு குழு மற்றும் நிறுவனத்திடம் காட்ட வேண்டும். இந்த ஆராய்ச்சியின் தகவல்கள் விஞ்ஞான இதழ்கள் மற்றும் விஞ்ஞான கூடத்தில் வெளியிடப்பட்டாலும் உங்களுடைய அடையாளங்கள் காட்டப்படமாட்டாது.

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ஆராய்ச்சியாளர் கையொப்பம்   பங்கேற்பாளர் கையொப்பம்

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TO WHOM SO EVER IT MAY CONCERN

This is to certify that the dissertation titled "**A Study to assess the effectiveness of soya bean on menopausal symptoms among menopausal women in the Institute of Obstetrics and Gynaecology, Chennai .**" done by Ms.M.Kalaivani, M.Sc (Nursing) II year, student of College of Nursing, Madras Medical College, Chennai-3 is edited for language appropriateness by _C·NAKKEERAN_

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