CHAPTER 5

SUMMARY AND CONCLUSION

The increased incidence and associated health risks has turned obesity into a serious health problem. The exact etiology of obesity still remains obscure. Genetic factors, inappropriate eating and reduced activity play a key role in the development of obesity. Dysregulation of various hypothalamic mechanisms controlling energy intake have also been implicated in its development and progression.

Recent advances made in the understanding of the body’s weight regulating mechanisms has helped to define novel sites for targeting and intervention, to result in reduced intake and enhanced expenditure.

Stimulating weight regulating mechanisms, through dietary supplements are currently considered effective and ideal. In this basis, indigenously prepared capsule containing Caralluma fimbriata (a cactus) extract and Soya (TVP granules) was chosen. Both Caralluma fimbriata and Soya are known to have the ability to control appetite, induce fat oxidation and prevent lipogenesis, which prevent fat accumulation and thus inhibit weight gain.

The present study was planned to determine the effect of Soya and Caralluma on selected anthropometric measurements, lipid profile, blood pressure measurements, nutrient intake and physical discomforts of obese post-menopausal women subjects.

Sampling procedure

Initially, 600 obese post-menopausal women were selected from various parts of Chennai from a population of 1350 (random sampling) and were subjected to a general survey, to collect information related to general background information, dietary habits, frequency of consumption of foods, physical discomforts, energy expenditure pattern and three day dietary recall. Height and weight measurements were taken and BMI was computed. Out of 600 subjects, 150 samples were selected based on the inclusion criteria of the study (purposive sampling) and was subjected to experimental research. Among them, 50 sub-samples were supplemented with Soya (n=50), another 50 sub-sample (n=50) were supplemented with Caralluma(n=50), and 50 sub-sample were not given any supplementation (control group)(n=50). All the groups were administered to pre-test initially and post-test at the end of ninety days of supplementation.
The assessments made were anthropometric measurements, lipid profile, blood pressure, nutrient intake and physical discomforts of obese post-menopausal women, initially and at the end of 30, 60 and 90 days for anthropometric measurements and at the end of 90 days for other parameters, for Soya, Caralluma and control groups.

**Tools employed**

The tools used for data collection were:

1. Interview schedule
2. Anthropometric measurements
3. Blood pressure measurements
4. Biochemical tests
5. Three day dietary recall schedule

After establishing the reliability and validity of the interview schedule and analyzing the problems encountered during the experimental work carried out by a pilot study, the investigation was conducted among post-menopausal obese women subjects who were in Soya, Caralluma and control group. The measurements obtained were classified, tabulated and subjected to the following statistical techniques: percentage analysis, mean and standard deviation, followed by t test, correlation coefficient tests and rank tests including Wilcoxon sign rank test and Mann Whitney test.

**Summary of findings**

Details pertaining to general information, case history, information regarding menstrual cycle, weight reduction regimen followed, psychological factors influencing food intake, dietary information, physical discomforts, complications associated with obesity, energy expenditure pattern, food frequency and nutrient intake of subjects obtained from general survey are summarised below:

- Half of the subjects belonged to the age group 51-60 years, had higher monthly family income, more than one-fourth of the respondents had up to middle school education. Many of them were housewives. Most of them lived in nuclear family.
Most of them had developed sudden, adult onset of obesity. Majority of the respondents had not reported of family history of obesity, heart attack and hypercholesterolemia.

Majority of the respondents had a BMI (body mass index) range of 25-29.9.

Most of the subjects were post-menopausal and if they had menstruation (peri-menopausal stage), it was irregular, for which many of them did not take any medicines.

Almost all the subjects were not on any weight reduction regimen like exercise, dieting, weight reduction pills and other activities.

Most of the subjects were not affected by external cues like, eating food while watching television, by the smell/sight of food, by frequent visits to social gatherings and others like advertisements, etc. Majority of them did not have the habit of eating under stress, while reading/studying, while preparing meals and when they were alone. Most of the respondents were not influenced by any eating disorder.

Most of them were non vegetarians, ate three meals a day. Majority of them did not eat outside home foods and raw vegetables and fruits. Many of them preferred fruit juice compared to whole fruit and fruit concentrate.

Majority of the respondents did not have nutrition knowledge, dietary restrictions, religious prohibitions and food allergies. Most of them did not skip their meals; and did not consume lot of water but chewed the food for a long time. More than half the respondents had regular consumption of beverages.

Majority of them suffered from increased sweating, joint pain and were not able to climb stairs.

Most of the subjects had no complications and other problems related to obesity (except hypertension). Majority of the respondents did not take any multivitamin or mineral supplement. Only few had reported of taking medicines for migraine, joint pain, etc.
• Majority of them were not doing exercise regularly. Most of the respondents were involved in sedentary activities like sitting, doing house-hold work, reading, writing and sleeping.

• Most of the subjects consumed high sodium containing foods like pickles, chips, egg, amaranth, bread and high caffeine foods like tea and coffee regularly. Their intake of calorie dense foods like refined sugar, oil, coconut, rice, bread were also high. Majority of them had milk, curd, greens, pulses and egg frequently which improved their nutrient intake quality.

• Most of the respondents aged 41-60 years had a slightly lesser caloric intake when compared with RDA, whereas among elderly women, the energy intake was almost similar to the energy RDA. When protein intake was compared with RDA the values were almost similar in both the groups. The carbohydrate intake was reduced and the fat intake was drastically increased when compared with RDA, among the subjects.

The anthropometric measurements of obese post-menopausal women subjects assessed including weight, BMI, waist circumference, hip circumference, waist to hip ratio and MUAC, initially before supplementation and at the end of 30, 60 and 90 days, within Soya, between Soya and Caralluma and between Soya and control groups are summarised below:

• A significant decrease in body weight was observed in the post intervention phase as compared with the pre-test values, with the mean decrease of about 2.64kg. There was also a significant reduction in body weight at the end of 30 and 60 days intervention when compared with initial weight. Similarly, when the body weight values between 30th and 60th day, 60th and 90th day were compared, a highly significant reduction was observed.

• A highly significant decrease in BMI was observed when the values obtained at the end of 30, 60 and 90 days were compared with initial and also from 30th to 60th day, from 60th to 90th day were compared.

• The reduction observed in waist circumference among the subjects at the end of 30, 60 and 90 days as compared with initial and between the 30th and 60th, between 60th and 90th day was highly significant.
• When the mean hip circumference obtained from 30th to 60th day and similarly from 60th to 90th day was compared, a highly significant decrease was observed. A significant reduction in hip circumference was also observed when the value obtained at the end of 30, 60 and 90 days were compared with initial value.

• There was a significant decrease in mean WHR from the 60th day to the 90th day, of supplementation.

• A significant decrease in MUAC value was obtained at the end of 90 days of supplementation as compared with initial value. Similarly there was a reduction in values obtained at the end of 30 and 60 days of Soya supplementation as compared to initial value. When the mean decrease, observed from 30th to 60th day and from 60th to 90th day was compared, it was highly significant.

• When the mean difference between the initial and at the end of 30days, 60days and 90days of supplementation period were compared a significant increase was observed, among control group.

• No significant difference between the pre-test values of Soya and control group was observed.

• A significant reduction in mean body weight was observed at the end of 60 days among Soya group when compared with control. When mean body weight obtained finally (post test value) among Soya group was compared with the control a highly significant decrease was observed.

• The decrease in BMI observed among Soya group at the end of 30, 60 and 90 days of supplementation was highly significant when compared with control.

• The waist circumference values of Soya group obtained at the end of 60 and 90 days showed a significant decrease as compared with control.

• There was a significant reduction in hip circumference values computed at the end of 60 and 90 days among Soya subjects when compared with the control.
A significant decrease in MUAC values were obtained at the end of 30, 60 and 90 days of Soya supplementation as compared to control.

When the differences between the initial values of the Soya and Caralluma groups for various anthropometric measurements were compared, no significant difference was obtained.

No significant difference was observed in anthropometric measurements between Soya and Caralluma group when their post-test values were compared.

The lipid profile parameters of obese post-menopausal women assessed in pre-intervention and post-intervention phase within Soya group, between Soya and control and between Soya and Caralluma are summarized below:

- A highly significant decrease in total cholesterol, triglyceride, HDL, LDL, VLDL, TC/HDL ratio, and LDL/HDL ratio was obtained at the end of 90 days of Soya supplementation as compared with the initial value.
- When the mean lipid profile values between pre-test and post-test values of control group were compared, a significant increase in all lipid profile values except VLDL and a decrease in HDL values were observed.
- There was no significant difference in mean values of lipid profile parameters like total cholesterol, triglyceride, HDL, LDL, VLDL, TC/HDL ratio and LDL/HDL ratio between initial values of Soya and control group.
- There was a highly significant decrease in post-intervention lipid profile values including total cholesterol, triglyceride, HDL, LDL, VLDL, TC/HDL and LDL/HDL risk ratios among Soya group when compared with the control group.
- The initial, lipid profile values between Soya and Caralluma group were not significant.
- A highly significant reduction was observed among Caralluma group in the post-test LDL values when compared with the Soya group.
Similarly, a significant decrease in the risk ratio LDL/HDL was deduced among Caralluma group when compared with Soya group.

The blood pressure levels of obese postmenopausal women subjects obtained initially and at the end of 90 days of supplementation within Soya group and between Soya and control group are summarized below:

- A highly significant decrease in systolic and diastolic pressure of the subjects were observed among Soya group at the end of 90 days of Soya supplementation as compared with their initial values.
- A significant increase in mean values of blood pressure at the end of 90 days as compared with initial values, was observed among control group.
- There was no significant difference between systolic and diastolic pressure of the subjects between Soya and control group in the pre-intervention phase.
- There was a highly significant reduction in systolic and diastolic pressure obtained in the post intervention phase of Soya group when compared with control.

The nutrient intake of obese post-menopausal subjects observed initially and at the end of 90 days of supplementation within Soya and between Soya and control group are summarized and given below:

- A significant decrease in energy, protein, fat and carbohydrate intake was observed among Soya group in the post intervention phase when compared with the pre intervention phase.
- No significant difference in mean energy, protein, and fat intake was observed at the end of supplementation period as compared with initial value, but there was a significant increase in carbohydrate intake in the post intervention phase as compared with the pre intervention phase, among control group.
- There was no significant difference in the mean nutrient intake (energy, protein, fat and carbohydrate) of obese post-menopausal subjects, initially, before supplementation, between Soya and control group.
A highly significant decrease was observed in protein and fat intake among Soya group when compared with control, in the post intervention phase.

The physical discomforts of the subjects initially before supplementation and at the end of supplementation period within Soya and between Soya and control group was summarized below,

- A significant improvement in physical discomforts like exhaustion, breathlessness, fatigue and excessive sweating, inability to climb stairs, joint pain, lethargic at work, gastritis, flatulence and constipation was observed at the end of 90 days of Soya supplementation as compared with initial value.

- No significant difference between initial and final values of physical discomforts were obtained among control group.

- Insignificant difference was observed between the mean rank scores of physical discomforts between Soya and control group, in the pre intervention phase.

- When mean rank scores of physical discomforts like, exhaustion, fatigue, excessive sweating, inability to climb stairs, joint pain, lethargic at work, gastritis, flatulence, indigestion and constipation, between Soya and control was compared, a significant improvement among Soya group was observed in the post intervention phase.

The anthropometric measurements of obese post-menopausal women subjects assessed including weight, BMI, waist circumference, hip circumference, waist to hip ratio and MUAC, initially before supplementation and at the end of 30, 60 and 90 days, within Caralluma, between Caralluma and control groups are summarised below:

- When mean body weight of Caralluma group (final value) was compared with the initial value, a significant reduction of about 2kg was observed. There was a significant decrease in mean weight values obtained at the end of 30 and 60 days when compared with initial. A significant reduction in mean weight was also observed at the end of 60th day as compared with 30th day and at the end of 90th day as compared with 60th day.
A significant decrease in mean BMI was observed at the end of 30, 60 and 90 days of Caralluma supplementation as compared with initial. There was also a significant reduction in BMI when 90\textsuperscript{th} day value was compared with 60\textsuperscript{th} day value and when 60\textsuperscript{th} day value was compared with 30\textsuperscript{th} day value.

There was a significant decrease in waist circumference obtained at the end of 30, 60 and 90 days (mean decrease was 2.29cm), when compared with initial. A significant reduction in waist circumference was also obtained at the end of 60 days as compared with 30\textsuperscript{th} day and at the end of 90 days as compared with 60\textsuperscript{th} day.

A highly significant decrease was observed at the end of 60 days of Caralluma supplementation when compared with 30\textsuperscript{th} day value, a similar decrease was observed at the end of 90 days as compared with 60\textsuperscript{th} day value. There was also a tremendously significant decrease in hip circumference obtained at the end of 30, 60 and 90 days as compared with initial.

When the mean MUAC values of 30\textsuperscript{th}, 60\textsuperscript{th} and 90\textsuperscript{th} day were compared with initial, a highly significant reduction was observed. A similar reduction was obtained at the end of 90\textsuperscript{th} day as compared to 60\textsuperscript{th} day value.

No significant difference was deduced between the initial values of Caralluma and control group.

There was a significant reduction in body weight at the end of 60 and 90 days of Caralluma supplementation as compared with the control.

When the BMI values obtained after 30, 60 and 90 days of Caralluma supplementation were compared with control, a significant decrease among Caralluma group was observed.

A significant decrease in waist circumference was observed among Caralluma subjects, at the end of 30, 60 and 90 days as compared with control.

There was a significant decrease in hip circumference values of Caralluma group obtained after 60 and 90 days of supplementation when compared with control.
A significant reduction in mean MUAC levels were obtained for Caralluma group at the end of 30, 60 and 90 days as compared with control.

The lipid profile parameters of obese post-menopausal women assessed in pre-intervention and post-intervention phase within Caralluma group, between Caralluma and control and between Soya and Caralluma are summarized below:

- There was a significant decrease in mean lipid profile values like total cholesterol, triglyceride, LDL, HDL, VLDL, TC/HDL and LDL/HDL risk ratios among Caralluma group at the end of 90 days of Caralluma supplementation as compared with the initial value.
- No significant difference between the mean lipid profile parameters of Caralluma and control group in the pre-intervention phase.
- A highly significant reduction in mean lipid profile measurements like total cholesterol, triglyceride, LDL, HDL, VLDL, TC/HDL ratio and LDL/HDL ratio respectively, were observed in Caralluma supplemented subjects at the end of 90 days when compared with the control.

The blood pressure values obtained in the pre and post intervention phase within Caralluma group, between Caralluma and control and between Soya and Caralluma are summarized and presented below:

- There was a significant reduction in both systolic and diastolic pressure levels observed in the post intervention phase when compared with pre intervention values, among Caralluma group.
- When the mean blood pressure values, both systolic and diastolic of Caralluma and control group were compared in the pre intervention phase, the values were insignificant.
- A highly significant decrease in systolic and diastolic pressure levels were observed among Caralluma group when compared with control in the post intervention phase.
- No significant difference in mean blood pressure values were observed between Soya and Caralluma group initially, before supplementation.
There was a significant reduction in diastolic blood pressure values among Caralluma group when compared with Soya, at the end of supplementation period, whereas no significant difference was observed in mean systolic pressure of the subjects in the post intervention phase between Soya and Caralluma groups.

The nutrient intake of obese post-menopausal subjects obtained in the pre and post intervention phase of Caralluma group, between Caralluma and control and between Caralluma and Soya are summarized and depicted below:

- There was a significant decrease in energy, protein, fat and carbohydrate intake of Caralluma subjects observed at the end of supplementation period as compared to their initial values.
- When the mean nutrient intake values of Caralluma and control groups were compared initially, before supplementation, no significant difference was observed.
- A highly significant decrease was observed in protein and fat intake of Caralluma subjects when compared with control in the post intervention phase.
- No significant difference in the pre-test values were obtained between Soya and Caralluma groups.
- A significant decrease in protein intake was observed among Soya subjects when compared with Caralluma, at the end of supplementation period.

The physical discomforts of the subjects initially before supplementation and at the end of supplementation period within Caralluma, between Soya and control group and between Soya and Caralluma are summarized below:

- There was a significant improvement in physical discomforts like exhaustion, breathlessness, fatigue and excessive sweating, inability to climb stairs, joint pain, lethargic at work, and indigestion was observed at the end of 90 days of Caralluma supplementation as compared with initial value.
No significant difference between mean ranks of physical discomforts, among Caralluma and control groups were observed, initially before supplementation.

The subjects were able to conquer the physical discomforts like exhaustion, breathlessness, fatigue, excessive sweating, joint pain, lethargic at work, flatulence, constipation and indigestion among Caralluma group when compared to control, which was significant.

When the mean rank scores related to physical discomforts were compared between Soya and Caralluma in the pre intervention phase, an insignificant difference was obtained.

A better impact of Soya was observed in physical discomforts like sweating, fatigue, inability to climb stairs and gastritis, when compared with Caralluma, which was highly significant, in the post intervention phase.

There was a significant improvement in breathlessness and indigestion problem among Caralluma subjects when compared with Soya group, at the end of 90 days of supplementation period.

The correlation coefficient matrix was used to determine the relationship that exists in anthropometric measurements obtained in the post-intervention phase of Soya group and are summarized as follows:

- There was a significant positive correlation between body weight and BMI.
- A significant direct relationship was observed between weight and waist circumference.
- When weight was correlated with hip circumference, a significant positive correlation was obtained.
- The correlation between weight and MUAC was positive and highly significant.
- There was a significant positive correlation between BMI and hip circumference.
A significant positive correlation was obtained between BMI and MUAC.

When waist circumference and hip circumference were correlated, a significant positive correlation was obtained.

A significant direct relationship was obtained between waist circumference and WHR.

The correlation coefficient matrix was used to determine the relationship that exists in anthropometric measurements obtained in the post intervention phase of Caralluma group and are summarized as follows:

- There was a significant positive correlation between weight and BMI.
- A significant direct relationship was observed between body weight and hip circumference.
- When body weight was correlated with MUAC a highly significant positive correlation was obtained.
- There was a significant positive correlation between waist circumference and hip circumference.
- When waist circumference was correlated with WHR a significant direct relationship was observed.
- A highly significant negative correlation was obtained between hip circumference and WHR.
- There was a significant direct relationship between hip circumference and MUAC.

The correlation coefficient matrix showing relationships within the lipid profile parameters among Soya group in the post-intervention phase is summarized below:

- There was a significant positive correlation between total cholesterol and triglyceride.
- When total cholesterol and LDL values were correlated, there was a highly significant positive correlation.
A significant direct relationship between total cholesterol and HDL was observed.

A highly significant positive correlation was obtained between total cholesterol and risk ratios like TC/HDL and LDL/HDL ratio.

There was a highly significant positive correlation between triglyceride and HDL.

A significant direct relationship was obtained between triglyceride and TC/HDL ratio.

There was a highly significant positive correlation between LDL and risk ratios including TC/HDL and LDL/HDL ratio.

A highly significant direct relationship was observed between TC/HDL ratio and LDL/HDL ratio.

The correlation coefficient matrix showing correlations within lipid profile values of Caralluma group in the post-intervention phase was summarized and given below:

When total cholesterol and triglyceride values were compared, there was a highly significant positive correlation.

A highly significant direct relationship was observed between total cholesterol and HDL, LDL, TC/HDL and LDL/HDL risk ratios.

There was a significant positive correlation between triglyceride and HDL, triglyceride and TC/HDL ratio.

An inverse relationship was observed between HDL and TC/HDL ratio, HDL and LDL/HDL ratio, respectively, which was highly significant.

LDL showed a direct relationship with TC/HDL and LDL/HDL ratio and the correlation was highly significant.

There was a significant positive correlation between VLDL and TC/HDL ratio.
When TC/HDL ratio was correlated with LDL/HDL risk ratio, there was a positive correlation, significant at one percent level was obtained.

The correlation coefficient showing correlation between anthropometric measurements and lipid profile, blood pressure and nutrient intake of Soya group in post-intervention phase are summarized below:

- There was a significant positive correlation between weight and diastolic pressure.
- A significant negative correlation was obtained when weight and energy intake was related.
- When the body weight and protein intake was correlated there was a significant inverse relationship.
- There was a significant negative correlation between BMI and VLDL.
- A significant positive relationship was observed between waist circumference and diastolic pressure.
- When waist circumference was correlated with protein intake, a significant negative correlation was observed.
- There was a significant positive correlation between hip circumference and diastolic pressure.
- A significant inverse relationship was obtained between WHR and systolic pressure.

The correlation coefficient showing correlation between anthropometric measurements and lipid profile, blood pressure and nutrient intake of Caralluma group in post-intervention phase are summarized below:

- There was a significant negative correlation between weight and total cholesterol.
- There was a significant negative correlation between weight and LDL.
- The correlation observed between weight and TC/HDL ratio was a highly significant inverse correlation.
- When weight and LDL/HDL ratio was correlated, it was observed that a significant negative correlation was obtained.
- There was a significant positive correlation, between BMI and energy.
- A significant positive correlation was observed between BMI and carbohydrate.
- A significant direct relationship was obtained between waist circumference and triglyceride.
- A significant positive correlation was obtained between waist circumference and energy.
- There was a significant positive correlation between waist circumference and protein intake.
- A significant positive correlation was deduced between waist circumference and fat intake.
- There was a significant positive correlation between hip circumference and triglyceride level.
- There was a highly significant direct correlation between hip circumference and HDL.
- There was a significant positive correlation, between hip circumference and energy.
- A significant positive correlation was revealed between hip circumference and protein intake.
- There was a significant direct correlation between hip circumference and fat.
- A significant positive correlation was obtained between WHR and LDL/HDL ratio.
- There was a significant negative correlation between MUAC and fat intake.
The results revealed that supplementation of Soya and Caralluma fimbriata had effected significant changes in anthropometric measurements and physical discomforts of obese post-menopausal subjects. A pronounced effect of the intervention was also observed in lipid profile parameters, blood pressure and nutrient intake, among both experimental groups.

Caralluma had shown a marked improvement in serum LDL level, LDL/HDL risk ratio, diastolic pressure and in physical discomforts like breathlessness and indigestion, when compared with Soya. Soya had a better impact on certain physical exertion, disabilities and gastritis problems as compared to Caralluma.

Thus, both Soya and Caralluma proved to be an effective antiobesogenic, hypolipidaemic, hypotensive, physical health promoting and appetite suppressing supplement.

LIMITATIONS OF THE STUDY

1. Biochemical parameters like blood sugar, homocysteine levels, C reactive protein, antioxidant status were not assessed, due to financial constraints.
2. Duration of the study was less (3 months), as it was difficult to get the compliance of the subjects towards experimental work, for a longer duration.
3. Obese subjects with BMI >29.9 were not included, because it was difficult to obtain morbidly obese people without any disorders/complications.
4. Triceps skin fold thickness was not measured, since fat accumulation is seen mainly in abdominal region, in post-menopausal women.

SUGGESTIONS FOR FURTHER RESEARCH

1. The effect of Soya and Caralluma fimbriata can be studied on obese pre and peri-menopausal subjects.
2. Antioxidant status, C reactive protein and homocysteine levels can be assessed on obese post-menopausal subjects with soya and caralluma supplementation.
3. Effect of Soya and Caralluma fimbriata on obese diabetic subjects can be studied.
4. Comparative study of pre and post-menopausal subjects using Soya and Caralluma fimbriata can be studied.
5. Comparison of anti obese effect of Soya and Caralluma fimbriata with other dietary supplements like Hoodia gordoni, Garcinia cambogia can be done.