SPECIMEN FORMAT FOR THESES OF MONTH

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Abstract within 300 words:

The current study establishes the framework for extensive research in the field of Metabolic syndrome and Body composition and the underlying causes, prevalence rate, Knowledge, Attitude and Practice (KAP) towards a healthy lifestyle with a comprehensive lifestyle education awareness. The study's objectives were to: evaluate the prevalence of metabolic syndrome, analyse body composition, evaluate the subjects' KAP and educate on a healthy lifestyle. A total of 1359 participants, both males and females at 20-50years, residing in Bengaluru, visiting the Preventive Health Checkup of Sakra World Hospital, Bengaluru were enrolled. Validated assessment tools, InBody 770 equipment and lifestyle education counselling materials were used in the study. Metabolic syndrome was prevalent at 13.2%. The physical inactivity, smoking, alcohol habit, high calories consumption and low BMR were found to be the risk factors for metabolic syndrome and statistically significant $p<0.001$. The metabolic syndrome criteria (NCEP ATP III 2002, revised in 2005) were significantly high in metabolic syndrome subjects. Out of 180 metabolic syndrome subjects 150 participated in further study. Body composition analysis was done for these subjects. Central obesity was observed in 11.9%, high blood pressure among 15.4%, high triglycerides in 26.0%, low HDL-cholesterol among 31.9% and high fasting glucose in 3.7% of the metabolic syndrome subjects. The lifestyle intervention was given for these subjects and the data was compared pre-and postintervention. Postinterventional data showed statistical significance for the reduction in waist circumference, fasting blood sugars, triglycerides, systolic blood pressure , calories consumed to attain weight loss goals, body fat%, visceral fat area. There was statistically significant increase, post-intervention in exercise habit, physical activity level, knowledge, attitude and practice regarding healthy diet, physical activity, body composition and healthy lifestyle. Thus, a combination of diet, physical activity and healthy habits improved the overall health status of the subjects.

Key words : Metabolic syndrome, NCEP ATP III, Body composition, InBody 770, KAP, Lifestyle.

i) Major objectives :

- Evaluate prevalence of metabolic syndrome in the selected adults residing in Bengaluru
- Assess the metabolic syndrome participants' body composition parameters of the sub-sampled research subjects
- Assess the relation between metabolic syndrome, body composition and lifestyle adaptations in the enrolled sub-sampled research subjects
- Develop and educate on a healthy lifestyle about diet, exercise and social habits of the subjects to prevent/ cure metabolic syndrome
- Evaluate the subjects' Knowledge, Attitude, and Practice (KAP) regarding metabolic syndrome, body composition and lifestyle

Hypothesis: The null hypothesis (H_0) framed in the study:

- H_0 1. Developing and framing questionnaires to determine the Metabolic Syndrome's prevalence and KAP of the subjects is not possible.
- H_0 2. It is difficult to associate Metabolic Syndrome and Body composition parameters.
- H_0 3. There is no relation between Metabolic syndrome and body composition parameters with lifestyle habits like diet, exercise, physical activity level and social habits- smoking and alcohol of an individual.

ii) Methodology :

The study design is cross-sectional and longitudinal study wherein the subjects were selected from Sakra World Hospital, Bengaluru. The research subjects were screened (2250), for those visiting Preventive Health Checkups in Sakra World Hospital, Bengaluru, in the period in which the study was carried out during July 2021 to February 2023. Initially the approval was obtained from the Institutional Human Ethical Committee (IHEC) of Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore, IHEC Approval No: IHEC17-18/FSN/50. Later the approval was also obtained from Institutional Ethical Committee (IEC), Sakra World Hospital, Bengaluru; Approval No: IEC/SWH/CN/26619. The study was enrolled in the Clinical Trials Registry- India (CTRI) (CTRI/2021/07/035254) of ICMR.

The study was conducted in six phases. In the first phase, the selection of subjects and development of research tools to collect the data, develop and standardize the counselling materials and validating the Inbody 770 was carried out. There was a total of 2250 who visited Preventive Health Checkup (PHC) in Sakra World Hospital, Bengaluru. By considering the inclusion and exclusion criteria, 1359 were enrolled into the research study after obtaining a consent. In the second phase, collection of socio- economic status including, age, education, social economic scale, family structure, marital status from the research subjects was carried out. The subjects between 20 to 50 years males and females were enrolled into the study.

In phase three, Anthropometric measures such as height, weight, waist circumference, and hip circumference were used to determine whether the research subjects had metabolic syndrome. Additionally, the waist-hip ratio and body mass index were computed. According to conventional procedure, biochemical markers such as blood pressure, triglycerides, HDL cholesterol, and fasting blood sugar were examined. Lifestyle habits of dietary preference, physical activity level, exercise, smoking and alcohol habits of the research subjects were collected. By using NCEP ATP III criteria (2002 revised in 2005) the prevalence of metabolic syndrome among the research subjects was assessed.

In phase four, after assessing the prevalence of metabolic syndrome among the subjects, the consent was obtained for subsample of subjects for continuing for the further study. Metabolic syndrome existed in 180 among 1359 subjects. By using

Daniel (1999) sample size formula; based on the prevalence; the sample size required was calculated as 153. Written consent was obtained from 150 subjects for continuing in the research study. InBody 770 was validated against DEXA using

Cronbach‘s alpha. InBody 770 was found to be valid and reliable for analysing the body composition. Body composition analysis was carried out for these metabolic syndrome subjects. Knowledge, Attitude and Practice (KAP) questionnaire and lifestyle education modules were also validated using Cronbach‘s alpha and conducting a pilot survey. The developed KAP questionnaire was used as a tool to collect the information from the metabolic syndrome subjects. Later, the lifestyle intervention on the diet to be followed, exercise protocol, increasing the physical activity level, relaxing technique, encouraging for the smoking and alcohol cessation were counselled.

In the fifth phase, the impact of the intervention of lifestyle counselling among the metabolic syndrome subjects was carried out. Impact of lifestyle education counselling intervention on metabolic syndrome subjects was studied. The impact of the intervention on anthropometric measures and BCA parameters, the impact of the intervention on calorie intake, physical activity level, exercise, smoking and alcohol habits, the impact of the intervention on metabolic syndrome criteria, the impact of intervention on Knowledge, Attitude, and Practice (KAP) were also studied.

In the sixth phase, the data obtained in the research study was statistically analysed using _R‘ software version 4.3.1 (R Core Team, Vienna, Austria, 2021). Descriptive statistics, Shapiro-Wilk test, paired sample T-test , Stuart-Maxwell marginal homogeneity test, Mann-Whitney U tests, Chi-Square test, Univariate and multivariate logistic regression analysis were done.

iii) Findings:

- Reliability and validation of DEXA with InBody 770 was tested and statistically analysed. The Cronbach‘s alpha obtained for DEXA and InBody 770 body composition analysis were 0.821 and 0.818 respectively. This states that the InBody 770 BCA analyser is validated for performing body composition analysis in comparison with DEXA scan body composition analysis.
- The Knowledge, Attitude and Practice (KAP) questionnaire was validated by conducting a pilot study. The Cronbach‘s alpha obtained for healthcare subjects and non- healthcare subjects for KAP questionnaire were 0.81 and 0.83 respectively. KAP questionnaire

developed had a significant correlation with a p value <0 .001 in KAP of both healthcare and non- healthcare pilot study subjects. This states that the KAP questionnaire developed is effective and can be used in the research study.

- The 1359 research subjects were categorized based on age and sex. Age of 20- 50 years, comprised of 60.9% (827) male and 39.1% (532) female subjects.
- In the current study, the majority were graduated (53.9%). The technical/ diploma/ certificate courses were done by 26% of subjects. In the current study, 54.7% of subjects were in intermediate occupations and 27.2% were small employers and own account workers. In the present study, the majority belonged to the lower middle socio-economic class (88.1%). The majority belonged to nuclear families, around 79.8% of subjects. and 67.5% of subjects were married and 30.5% were unmarried subjects.
- The males had a mean height of 171 ± 6.9 cm and the females had 159.1 ± 6.6 cm. The mean weight of the subjects was 73.7 ± 14.3 kg. The males' mean weight was 77.1 ± 13.3 kg and the females had a mean weight of 67.6 ± 13.6 cm. NIN reference range height 171 cm males and 152 cm females and weight 65 kg males and 55 kg females.
- The mean BMI of males was 26.6 ± 4.2 kg/m^2 and among females mean BMI was 26.7 ± 5.2 kg/m^2. Majority of the subjects were overweight/ obese as per Asian adult body mass index classification (2000).
- The waist circumference of males was 92.5 ± 8.1cm and females had a waist circumference of 88.7 ± 10.3 cm. Most of the enrolled subjects were having abdominal obesity (>90 cm males and >80cm females is considered as abdominal obesity as per IDF, 2021). The mean hip circumference of males was 108.1 ± 12.3 cm and of females 104.9 ± 15.2 cm.
- The waist-hip ratio (WHR) among males was 0.86 ± 0.1 and for females, 0.85 ± 0.1. The subjects' mean values indicated the waist-hip ratio was normal in males and high in females. As per WHO (2008), the normal WHR is ≤ 0.9 for males and females ≤ 0.85.
- The mean of fasting blood sugar in males was 105.6 ± 37.5 mg/dL and among females the fasting blood sugar was 99.7 ± 28.2 mg/dL. As per NCEP ATP III

(2002 revised in 2005) criteria, the mean FBS values were higher in both males and females. The triglycerides among males were higher with a mean of 154.9 ± 104.5 mg/dL, than, 119.3 ± 68.6 mg/dl in females. The high-density lipoproteins (HDL) among males was 41.5 ± 9.1 mg/dL and 44.2 ± 9.7 mg/dL in females. The mean LDL of males was 110.7 ± 35.7 mg/dl and for females was 112.7 ± 36.6 mg/dl. As per NCEP ATP III (2002 revised in 2005); the males had higher triglyceride mean values and higher mean values of LDL cholesterol. The mean

HDL values were normal. In females the triglycerides were normal, but the mean LDL values were higher and mean HDL values were lower.

- Low dietary diversity was observed in 203 subjects due to non- availability or low-affordability.
- When the food frequency questionnaire was used to observe the consumption pattern, it was observed that Rice (63%) and wheat (63.9%) and its products were the staple food of the subjects. They have included millet-based products (52.8%) after the Covid -19 pandemic. But the fruit (52.1%) and green leafy vegetable (14.9%) consumption was found to be low. Sweetened options were consumed by most of the subjects in the form of sugar (75.6%), jaggery (62.7%) or honey (45.3%) base products. Saturated fat, ghee was included by most of the research subjects (40.5%). Nuts (60.4%), oily seeds (32.7%) and dry fruits (52.9%). The sprouts consumption was sparingly found (5.2%). Non- vegetarian consumption of eggs (63.6%), chicken (66.1%), fish (40.5%) and red meat (39%) was consumed daily among the subjects.
- The average calories consumed per day by males was normal and the females had higher calorie consumption and values were 2244 ± 260.9 kcal and 2070 ± 276.2 kcal respectively. As per ICMR, NIN (2020) for sedentary and moderate activity men and women, the recommended dietary allowances of energy were 2110-2710 kcal and 1660-2130 kcal per day respectively. The Basal Metabolic Rate (BMR) of the subjects were 1730 ± 5.2 kcal and 1423 ± 134 .9 kcal in males and females respectively. As the physical activity level of males was higher than that in females, the total energy expenditure in males was 2200 ± 341.7 and in females 1787 ± 236.2 kcal.
- Research subjects 1010 (593 males and 417 females) never attempted any exercise. The exercise habit and physical activity levels were lower than the standards recommended [NIN (ICMR) Dietary guidelines for Indians, A Manual, 2011].
- In the current study, 83.3% never consumed alcohol. In the current study, 94.7% subjects did not have a smoking habit.
- The prevalence of metabolic syndrome in the currently enrolled subjects was 13.2%. The metabolic syndrome prevalence was 15.6% and 9.6% among males and females respectively. The waist circumference was higher in females (67.9%) than in males (46.8%). High triglyceride values were observed in males (37.2%) compared to females (15%). Low-density lipoproteins were higher in females (70.9%) than in males (56.3%) (NCEP ATP III, 2002, revised in 2005).

- In the current study, as per NCEP ATP III (2002, revised in 2005); 5.4%, had three metabolic syndrome criteria. Four metabolic syndrome criteria were present in 5.7% subjects. All five metabolic syndrome criteria were observed in 2.1% subjects. Two criteria were observed in 50.9% of subjects. If healthy lifestyle is not followed by these 692 subjects there is more chance of developing metabolic syndrome. About 26% of subjects had one of the metabolic syndrome criteria. Only 133 subjects did not have any of the metabolic syndrome criteria.
- As described by NCEP ATP III 2002, revised in 2005), low levels of high density lipoproteins were observed in 56.3% subjects, high waist circumference was observed in 55% subjects, high triglycerides were observed in 28.6% subjects. High FBS values were seen in 27% subjects. Systolic blood pressure was high in 151 subjects (11.1%) and high diastolic blood pressure in 47 subjects (3.5%) subjects. Overall, 180 subjects had metabolic syndrome of which 129 were males and 51 were females.
- The socio-economic profile of age, sex, level of education, occupation, socioeconomic class, family structure and marital status of the person were statistically significant at <0.001 among the research subjects with metabolic syndrome and those without metabolic syndrome.
- When age grouping is done as 21-30 years; 31-40 years and 41-50 years among metabolic syndrome present and metabolic syndrome absent groups it was statistically significant at <0.001, showing with age, the risk of Metabolic syndrome is increasing too.
- When metabolic syndrome and non-metabolic syndrome subjects were compared the physical inactivity, smoking, alcohol habit, high calories consumption and low BMR were found to be the risk factors for metabolic syndrome and statistically significant.
- The waist circumference, weight, body mass index and waist-hip ratio were statistically significant at <0.001 among the research subjects with metabolic syndrome and those without metabolic syndrome. The waist circumference, weight, BMI and waist-hip ratio were higher in the metabolic syndrome subjects than in non- metabolic syndrome subjects. But hip circumference had no statistical significance among metabolic syndrome subjects and non-metabolic syndrome subjects.
- The metabolic syndrome criteria of NCEP ATP III (2002 revised in 2005), the waist circumference, fasting blood sugars, triglycerides, HDL cholesterol, diastolic blood pressure and systolic blood pressure were statistically significant at <0.001 among the research subjects with metabolic syndrome and without metabolic syndrome, stating that, the above measured values were increasing the metabolic risk for the subjects.

- Among the 1359 research subjects enrolled into the study initially, 180 subjects had metabolic syndrome. A total of 150 subjects gave their consent to further continue in the study. Metabolic syndrome subjects had the mean age, height and weight were 40 ± 5.9 years, 167.3 ± 9.3 cm and 80.9 ± 15.1 kg respectively. Majority 50% subjects were graduates and 36.7% did technical or diploma or certificate courses. Majority were 53.3% subjects were small employers and own account workers, 39 (26%). Around 92 (61.3%) belonged to lower-middle socioeconomic class, 32 (21.3%) belonged to upper- lower socio-economic class and 26 (17.3%) were of upper middle socio-economic class. Subjects belonged majorly to nuclear family 17.3% subjects 14.7% were single members Most of them were married 76%subjects and unmarried were 20%.
- A majority of 94% (141) subjects had come for Preventive Health Checkup without any prior medical history. Family history had no statistical correlation with the disease condition of the subjects in the current study.
- The age grouping was done for easy understanding of the sub-sample subjects. The males were taller than the females in the current study. The males and females had the reference height. But the weight of females was comparatively higher than the males and higher than the reference weight. All the subjects were overweight and obese. The waist and hip circumference of females was higher than the males, and the waist-hip ratio of both males and females was found to be high. This shows abdominal obesity is more prevalent among the subjects.
- Most of the subjects 64.7% had predominantly vegetarian diet and at times were consuming non-vegetarian food.
- Smoking was never done by 78.7% of the subjects. Alcohol habit was stopped by 1.3% of the subjects. Around 49.3% subjects had never consumed alcohol and 49.3% of them were currently consuming alcohol. The smoking and alcohol habits were observed more in males than in females.
- The exercise was never done by 21.6% males. Around 76.7% males and 97.1% stopped the exercise habit for more than three months. The low exercise habit and sedentary activity was observed in the research subjects when compared with Guideline 9: Exercise regularly and be physically active to maintain ideal body weight. [NIN (ICMR) Dietary guidelines for Indians: A manual 2011, 2015].

- Central obesity was observed in 11.9%, high blood pressure among 15.4%, high triglycerides in 26.0%, low HDL-cholesterol among 31.9% and high fasting glucose in 3.7% of the metabolic syndrome subjects.
- When the metabolic syndrome parameter mean values were observed after grouping the age, it is found that waist circumference was highest among females 41 -50 years (106.7 ± 13.6 cm) and 21-30 year females (104.4 ± 11.7 cm) among males the waist circumference was highest among 31-40 years (103.6 ± 12.9 cm) compared to the other age groups. The fasting blood sugar values were higher in males 41-50 years (151.2 ± 62 mg/dl) and females 4150 years (146.4 ± 71.9 mg/dl). The males in 21-30 years and 31-40 years had higher FBS than females of the same age group. The triglycerides are very high among 21 to 30 years males (306.2 ± 199.1 mg/dL) and 31-40 years males (282.3 ± 229.1 mg/dL). The HDL cholesterol was low in 21-30 years males (34.5 ± 4.2 mg/dl) and females (31.2 ± 4 .3 mg/dL). The systolic and diastolic blood pressures were high in 41-50 years males and females compared to other age groups. In the current study, the younger adults between the age of 21 to 40 had higher risk factors for metabolic syndrome.
- Once Inbody 770 was validated against DEXA, the BCA was done for the subsampled metabolic syndrome subjects, the mean values when compared between males and females, the total body water, protein minerals, skeletal muscle mass, basal metabolic rate and whole body phase angle was high in males. Females had higher body fat mass, body mass index, body fat % and visceral fat area. They were statistically significant also. The BCA parameters of weight, body mass index and waist-hip ratio when compared in males and females, they were not statistically significant.
- When mean body composition parameters for the enrolled research subjects were analyzed age group-wise also.
- The Basal Metabolic Rate is on an average 227 calories higher while calculating using Harris Benedict Equation than that analysed in InBody 770.
- When mean body composition analysis measurements were statistically compared with the occupations of the research subjects it was found that total body water, protein, minerals, skeletal muscle mass, body fat percentage, visceral fat area, basal metabolic rate and whole-body phase angle had $p < 0.001$ and was highly statistically significant. The occupation of the subjects had a role to play on the body composition of the subjects. The body fat mass, weight, body mass index, and waist-hip ratio when compared to the occupation were not statistically significant among research subjects of various occupations.

- The physical activity level and body composition analysis measurements were statistically compared among the research subjects. The body fat percentage was significantly associated with physical activity levels of the MS subjects ($p<0.001$). The visceral fat area also had p-value 0.001 which was statistically significant. The body fat mass and whole-body phase angle had p value 0.004 which was also statistically significant. The body fat percent, visceral fat area and body fat mass was high in sedentary physical activity levels than in the subjects who had light or very active physical activity level. The whole-body phase angle was higher in research subjects those who were active than the sedentary subjects.
- The Knowledge, Attitude and Practice (KAP) scores pre-intervention when recorded were lower and indicated the need of intervention through lifestyle awareness modules.
- The validity and reliability of ten lifestyle education modules were tested and found to be valid and reliable with Cronbachs alpha test 0.81 and 0.85 for healthcare and non-healthcare subjects.
- The pre and post-interventional data of waist circumference and waist-hip ratio were significantly different at $p<0.001$, suggesting a significant reduction post intervention.
- Post intervention; as intended; the body fat mass, body fat percentage, visceral fat area, weight to control and fat to control decreased and there was an increase in Inbody score and obesity degree, which were statistically significant too.
- The pre and post values of protein, skeletal muscle mass, weight and basal metabolic rate were not statistically significant.
- The average calories consumed pre and post-intervention were statistically significant at $p<0.001$. The average calorie consumption of the subjects decreased and they were in par with the set weight loss goals.
- The physical activity level of the subjects when observed pre and post intervention. The physical activity level pre and post-intervention was found to be statistically significant at <0.001. The subjects included exercise as a part of their daily routine and they also increased their physical activity level after the lifestyle counselling intervention.
- When research subjects metabolic syndrome criteria was analysed; it was found that number of metabolic syndrome criteria were high among sedentary PAL.
- Post- intervention, the metabolic syndrome criteria like waist circumference, fasting blood sugars, triglycerides, and systolic blood pressure showed a significant reduction and were statistically significant with $p<0.001$.

- Out of 150 subjects, 35 subjects could become non-metabolic. The pre and post-metabolic syndrome criteria had a highly significant correlation of <0 .001. The lifestyle counselling intervention helped the subjects to reduce the number of metabolic syndrome risk factors and even got them to a nonmetabolic syndrome state.
- Research subjects 35 (23.3%) recovered from metabolic syndrome. These 35 subjects had significantly lesser fasting blood sugar, triglycerides diastolic blood pressure, and systolic blood pressure compared to those who still had metabolic syndrome post-intervention. This states that early intervention during the new onset of metabolic syndrome itself if the lifestyle education intervention is given can bring in statistically significant reduction in the metabolic syndrome risk factors.
- The impact of lifestyle counselling on four knowledge aspects: knowledge regarding healthy diet/ general nutrition, knowledge regarding benefits of exercise and weight loss, knowledge regarding body composition and knowledge regarding metabolic syndrome and the lifestyle to be followed had a high statistical significance at <0.001 proving that the intervention improved the overall knowledge of the metabolic syndrome subjects.
- Post-intervention in metabolic syndrome subjects the attitude score increased and was statistically significant with a p-value <0.001. here was a clear shift from being neutral on the attitude to being positive and strongly positive postintervention.
- Post-intervention in metabolic syndrome subjects the practice score increased and was statistically significant with p-value <0.001.
- The socio- economic profile except level of education (p <0.001) the rest other parameters like age, occupation, socioeconomic class, family structure and marital status had no statistical significance on the influence of knowledge about healthy diet/ general nutrition. This helps us to state, the level of education or the awareness brought in through counselling intervention can help the subjects to gain knowledge on healthy diet/ general nutrition.
- With increasing age, and education level; the knowledge regarding body composition was observed to be high and nuclear family subjects had good knowledge than others on BCA in the present study and had high statistical significance with p-value <0.001. The small employers and own account owners and intermediate/ higher managerial occupation subjects and subjects who were married had statistical significance at <0.05. It is observed that their exposure towards the health awareness was a reason for this finding. The parameters like socioeconomic status and diet habit had no statistical significance with knowledge about benefits of exercise and weight loss.

- Socio-economic profile influence on the attitude of lifestyle modifications had no statistical significance.
- Socio-economic profile influence on the practice of lifestyle modifications when analysed; except those who were married (significant correlation with $p<0.05$); no other parameter of socio- economic profile showed statistical correlation with practice of lifestyle modifications.
- The KAP scores when analyzed pre and post lifestyle counselling intervention, Post intervention the good knowledge regarding healthy diet/ general nutrition increased by 23%, knowledge on benefits of exercise and weight loss knowledge increased by 29%, knowledge regarding body composition increased by 57% and knowledge regarding metabolic syndrome and lifestyle to be followed increased by 43%. The attitude and practice score for lifestyle modification increased by 16% and 37% respectively.

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