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Comparison of the effectiveness of lifestyle interventions and multi-interventional therapy on biochemical parameters of metabolic syndrome among women

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Abstract:

BACKGROUND: Metabolic syndrome is one of the emerging health issues in developing countries. It includes diabetes, high blood pressure, obesity, and elevated blood cholesterol. This study aimed to compare the effects of two different types of interventions: multi-interventional therapy (MIT) and lifestyle interventions (LIs) on high-density lipoprotein (HDL), triglycerides, and fasting blood sugar (FBS) among women with metabolic syndrome.

MATERIALS AND METHODS: The study used a quasi-experimental nonequivalent control group design with two experimental groups and one control group. This study was conducted among self-help group women from nine area development societies (ADS) in a selected area in South India from March 1, 2019, to February 28, 2020. Women (aged between 35 and 55 years) with metabolic syndrome were recruited by multistage sampling (N = 220) and randomly assigned into three groups: (a) control, (b) MIT (intervention 1), and (c) LIs (intervention 2). Reflexology foot massage, dietary modification, moderate-intensity exercise, and structured education were given to the MIT group and dietary modification, moderate-intensity exercise, and structured education were given to the LI group for 12 weeks. The control group received routine care. A demographic and clinical data sheet is used to collect the basic information. Biochemical variables (HDL, triglycerides, and FBS) were assessed before and after the intervention. The data obtained from the study were computed using a frequency distribution to describe the demographic characteristics, and a Chi-square (x^2) test was conducted to find the homogeneity. Both parametric and nonparametric tests were conducted for the comparison of the effectiveness of different methods of interventions on biochemical parameters of metabolic syndrome.

RESULTS: Women who received MIT and LI had significantly lower values of HDL, triglycerides, and FBS after the treatment from baseline and compared with the control group. The study found a significant improvement in the biochemical parameters in the MIT group as compared to the control group and the LI group (<0.001).

CONCLUSION: Paired *t*-test shows significant improvement in HDL, triglycerides, and FBS ($P < 0.001$) in both the LI and MIT groups. In case of triglycerides, MIT was found to be more effective ($P < 0.001$). Both MIT and LIs can be considered interventions for reducing triglycerides and FBS and increasing HDL.

Keywords:

Diabetes, dyslipidemia, hypertension

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Introduction

Raised total cholesterol is a major cause of disease burden in both the developed and developing worlds.[1] In 2008, the global prevalence of raised total cholesterol among adults (≥5.0 mmol/l) was 39% (37% males and 40% females).[1] Hypercholesterolemia involves an imbalance of cholesterol levels including low-density lipoprotein and high-density lipoprotein in the blood. The treatment mainly focused on treat to target approach and therapies based on expected response.[2] A study from Iran reveals that the prevalence of undiagnosed dyslipidemia was 16% as compared to 13.2% of diagnosed dyslipidemia and both were more prevalent in women.[3]

A review of population-based studies in India shows increasing mean total cholesterol levels. Recent studies reported that high cholesterol was present in 25 to 30% of urban and 15 to 20% of rural people.[4] The prevalence of metabolic syndrome increases in parallel with increasing obesity in the population.

The global prevalence of diabetic adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014, and it has been raising more rapidly in middle- and low-income countries. Diabetes was the seventh leading cause of death in 2016. A study on the prevalence of diabetes and its associated risk factors in India showed that the prevalence of diabetes was 6.4% and also found that age, waist circumference, hypertension, body mass index (BMI), total cholesterol, and smoking are significant in the prevalence of diabetes mellitus (DM).[5] Studies reported that reflexology foot massage has a significant effect on blood pressure (BP), lipoproteins, and blood sugar levels. It is done by stimulating various reflex zones in the foot. This is the first study to incorporate reflexology foot massage along with lifestyle intervention (LI) for metabolic syndrome. It is economical and safe to compare the two non-pharmacological interventions to improve the biochemical parameters.

Materials and Methods

Study design and setting

A quantitative research approach was used to compare the effectiveness of LI and multi-interventional therapy (MIT) on the physiological and biochemical parameters of metabolic syndrome. A quasi-experimental nonequivalent control group design was used in this study. The MIT group received reflexology foot massage sessions along with LIs, and the LI group received LIs alone. No intervention was given to the control group, which was instructed to follow the routine care advised by the healthcare provider. The main intention was to find out the benefit of adding reflexology to LI in the outcomes. By including three groups, the comparison was performed with the LI group and with the control group.

Study participants and sampling

This study was conducted among self-help group women from nine area development societies (ADS) in a selected area in South India from March 1, 2019, to February 28, 2020. Two hundred and seventy women, 90 in the control group, 90 in the LI group, and 90 in the MIT group, were taken for the main study. The sample size was estimated assuming 12% difference among the means with 20% standard deviation and 90% power at 5% level of significance. Adding 20% dropouts for three groups (control group, LI group, and MIT group), the estimated sample size was 86. It was rounded to 90 per group (total of 270 participants). The estimated sample size was 270: 90 in the control (routine care) group, 90 in the LI group, and 90 in the MIT group. The sample size was estimated using SigmaPlot 13.0 (Systat Software Inc., USA).

In phase 1, 1600 women from nine randomly selected ADS were assessed for eligibility by checking weight, height, waist circumference, and blood pressure. 762 women who did not meet any one of the criteria were excluded. In phase 2, the remaining 838 women were assessed for eligibility criteria by checking fasting blood sugar (FBS), high-density lipoprotein (HDL), and triglycerides. Five hundred and seventy-eight women met the criteria of metabolic syndrome. Nine ADS were randomly assigned into the control group (three ADS), the LI group (three ADS), and the MIT group (three ADS). Participants were assigned random numbers and drawn the numbers from 1 to 90 in each group using a computer-generated random table. 16 women from the control group, 16 from the LI group, and 18 from the MIT group dropped out at different stages of the study. The remaining 220 participants were taken for final analysis. Inclusion criteria for the study were women belonging to the age group of 35 to 55 years and meeting any three of the following five criteria of metabolic syndrome such as waist circumference >88 cm, high blood pressure: Systolic Blood pressure (SBP) >130 mmHg or Diastolic Blood pressure (DBP) >85 mmHg or on treatment for hypertension, high fasting blood sugar >100 mg/dl or on treatment for DM, HDL <50 mg/dl, and triglycerides >150 mg/dl. Women who reported a history of cardiac disease, renal disease, cancer, ligament injury, surgery in the leg, neurovascular problems, pregnancy, psychiatric disorders, and severe cognitive impairment were excluded from the study.

Data collection tools and technique

1) Socio-demographic and clinical information sheet: A structured questionnaire was used to collect the information regarding demographic and

clinical information from the participants. The data included the demographic and clinical variables of women consisting of age, marital status, education, occupation, monthly income, type of family, preferred food groups, lifestyle habits, menstruation, history of diabetes and hypertension during pregnancy, history of DM, history of hypertension, and dyslipidemia.

2) Biochemical parameters: It included FBS (mg/dL), HDL (mg/dL), and triglycerides (mg/dL). Biochemical measurements are performed by collecting 10 mL of blood from the participants at 9 am after 12 hours of overnight fast. Triglycerides and FBS were tested by the glycerophosphate oxidase-peroxidase (GPO-POD) method and HDL using a homogenous method.

Interventions

Intervention I. (LI group—diet, exercise, and education). Dietary modification: BMI was assessed. The dietary modification was given as per the BMI. One woman (BMI <18.5) received 1800 Kcal/day, 26 women (BMI: 18.5–24.99) received 1500 kcal/day, and 47 women (BMI ≥25) received 1200 kcal/day. A food exchange list was prepared as per the directions of the dietician and provided to the participants. Participants were instructed to maintain a dietary diary, and it was monitored weekly to ensure their intake. Moderate-intensity exercises: The women were instructed to walk 30 minutes per day (between 5 pm and 7 pm) for 5 days a week. Before beginning the exercises, the women were instructed to do warm-up exercises for 10 minutes followed by brisk walking for 30 minutes and cool down after the walking. A record of walking exercises including distance walked, duration, and walking speed was maintained by the participants. It was observed and monitored weekly. Structured health education**:** It was given regarding metabolic syndrome components, causes, and its control measures including diet, exercises, and regular follow-up. It emphasized the importance of dietary modification and recommended daily dietary intake of calories, salt, and fiber. It also emphasized the benefits of moderate-intensity exercises such as walking and steps to be followed while walking and warm-up exercises. An information booklet related to metabolic syndrome was given to the participants after the education.

Intervention II: (MIT group—reflexology foot massage, diet, exercise, and education). Reflexology foot massage has 10 stages: 1. preparation, 2. lungs, 3. thyroid, 4. liver, 5. gall bladder, 6. stomach from the right foot, 7. small and 8. large intestine from the left foot, 9. spinal cord, and 10. solar plexus, 11. Hypophysis from both feet. Every foot reflexology session began with the right foot and the whole foot, followed by the left. The duration of the procedure was 30 minutes in the specific points related to metabolic syndrome. It was provided once a week for 12 weeks in the home setting. Dietary modification: BMI was assessed. The dietary modification was given as per the BMI. One woman (BMI <18.5) received 1800 Kcal/day, 25 women (BMI: 8.5–24.99) received 1500 kcal/day, and 46 women (BMI ≥25) received 1200 kcal/day. A food exchange list was prepared as per the directions of the dietician and provided to the participants. Participants were instructed to maintain a dietary diary, and it was monitored weekly to ensure their intake. Moderate-intensity exercises: The women were instructed to walk 30 minutes per day (between 5 pm and 7 pm) for 5 days a week. Before beginning the exercises, the women were instructed to do warm-up exercises for 10 minutes followed by brisk walking for 30 minutes and cool down after the walking. A record of walking exercises including distance walked, duration, and walking speed was maintained by the participants. It was observed and monitored weekly. Structured Health Education**:** It was given regarding metabolic syndrome components, causes, and its control measures including diet, exercises, and regular follow-up. It emphasized the importance of dietary modification and recommended daily dietary intake of calories, salt, and fiber. It also emphasized the benefits of moderate-intensity exercises such as walking and steps to be followed while walking and warm-up exercises. An information booklet related to metabolic syndrome was given to the participants after the education.

Control group: The control group did not receive any intervention and was advised to continue routine care advised by the healthcare provider.

Data collection was performed from March 2019 to February 2020. Women who met the inclusion criteria were randomly assigned into two groups: experimental group and control group. A pretest was performed. After the assessment, MIT was given to the experimental group and the control group was advised to follow routine care advised by the healthcare provider. A posttest was conducted after 12 weeks of intervention among two groups. The primary author underwent training in reflexology before the study. We had clear written intervention protocols, which assisted in ensuring fidelity and adherence to the intervention protocol. Enactment of the intervention was assessed by weekly monitoring of the self-reported activity checklist and a daily diary of diet consumed. Reminder messages were given through the WhatsApp group. The individualized health education was given by the investigator herself and clarified the doubts of participants.

Data analysis

The data obtained from the study were computed using a frequency distribution to describe the demographic characteristics, and the Chi-square (x^2) test was conducted to find the homogeneity. Both parametric and nonparametric tests were conducted for the comparison of the effectiveness of MIT on the physiological

parameters of metabolic syndrome. One-way analysis of variance (ANOVA) and paired *t*-test were used for comparison between pre- and posttest scores of physiological variables. A probability of 0.05 or less was taken as statistically significant.

Ethical consideration

The approval for conducting the study was obtained from the Saveetha Medical College Hospital Human Ethics Committee (Approval No.: 003/02/2019/IEC/SMCH). Permission was obtained from the State Kudumbashree Mission and Community Development Society. The informed consent form was translated into the regional language. Participants were contacted and explained the purpose and usefulness of the study. The confidentiality of the information and the right to withdraw from the study were explained at their level of understanding in the regional language. Written consent was obtained.

Results

Demographic and clinical characteristics of the participants such as age, marital status, education, occupation, monthly income, type of family, preferred food groups, lifestyle habits, menstruation, history of gestational diabetes, pregnancy-induced hypertension, history of DM, and history of hypertension were assessed. The Chi-square test was conducted to find out the homogeneity of the participants. Homogeneity was observed in all characteristics of women ($P < .05$).

The mean HDL in the pretest of the control group, the LI group, and the MIT group was 39.2 mg/dL, 39.1 mg/dL, and 39.2 mg/dL, respectively. It was not found to be statistically significant ($P = 0.993$). The mean HDL in the posttest of the control group, the LI group, and the MIT group was 39.1 mg/dl, 45.6 mg/dl, and 45.6 mg/dl, respectively [Table 1]. It was found to be statistically significant ($P < 0.001$)*. The pretest and posttest of the respective control group, LI group, and MIT group were tested by paired *t*-test. In the case of the control group, it was significant ($P = 0.033$), whereas in the case of the MIT group and the LI group, it was statistically significant ($P < 0.001$). Even though there is a significant difference ($P < 0.001$) between the control group and both MIT and LI groups, no significant difference was observed between the LI group and the MIT group ($P = 0.998$).

The mean triglycerides in the pretest of the control group, the LI group, and the MIT group were 174.3 mg/dl, 176.2 mg/dl, and 174.7 mg/dl, respectively. It was not found to be statistically significant ($P = 0.932$). The mean triglycerides in the posttest of the control group, the LI group, and the MIT group were 174.5 mg/dl, 155.3 mg/dl, and 135.1 mg/dl, respectively. It was found to be statistically significant ($P < 0.001$)* [Table 1]. The pretest and posttest of the respective control group, LI group, and MIT group were tested by the paired *t*-test. In the case of the control group, it was significant ($P = 0.040$). Similarly, in the case of the LI group and the MIT group it was statistically significant ($P < 0.001$). Control, MIT, and LI showed statistically significant ($P < 0.001$). It was observed that compared to LI MIT was more effective in reducing the triglycerides ($P < 0.001$).

Table 1: Homogeneity verification of dependent variables (*n*=220)

Variable	CO (*n*=74) (M 72)	LI (*n*=74) (M 72)	MIT (*n*=72) (M 72)	*F*	*P*
HDL (mg/dl)	39.19±0.7	39.1±0.7	39.2±0.8	0.007	0.993
Triglycerides (mg/dl)	174.3±3.6	176.1±3.6	174.7±3.7	0.070	0.932
FBS (mg/dl)	138.7±8.0	135.6±7.9	140.3±8.3	0.087	0.917

CO=control, MIP=multi-interventional package, M=mean, SD=standard deviation

The mean FBS in the pretest of the control group, the LI group, and the MIT group was 138.7 mg/dl, 135.6 mg/dl, and 140.3 mg/dl, respectively. It was not found to be statistically significant ($P = 0.917$). The mean FBS in the posttest of the control group, the LI group, and the MIT group is 138.9 mg/dl, 124.2 mg/dl, and 124.1 mg/dl, respectively. It was found to be not statistically significant ($P = 0.325$) [Table 2]. The pretest and posttest of the respective control group, LI group, and MIT group were tested by the paired *t*-test. In the case of the control group, it was not significant ($P = 0.403$). In the MIT group and the LI group, it was statistically significant ($P < 0.001$). No significant difference was found between the control, LI, and MIT groups.

Discussion

The present study was intended to compare MIT and LI with the control group. The current study found that the HDL in the LI group was significantly increased after three months of LIs with diet, exercise, and education as compared to the control group. A study on exercises combined with a diet low in saturated fat and exercise combined with nutritional supplements showed that exercise and a low saturated fat diet reduced the LDL by 7 to 15% and triglycerides by 4 to 18% and increased the HDL by 5 to 14%. Exercise and nutritional supplement reduced the LDL by 8 to 30% and triglycerides by 12 to 39% and increased the HDL by 2 to 8%.[6]

A review on lifestyle modification in the management of hypercholesterolemia found that target cholesterol level could be achieved by lifestyle changes such as diet, weight reduction, and increased physical activity. Various dietary constituents such as green tea, plant sterols, and soy protein have a significant influence on total cholesterol.[7] Another review on LIs for hypertension

Table 2: Mean, SD, one-way ANOVA, and paired *t*-test of biochemical parameters among control (CO), lifestyle intervention (LI), and multi-interventional therapy (MIT) groups (*n*=220)

Variable	Time	CO (*n*=74)		LI (*n*=74)		MIT (*n*=72)		*F*	*P*
		M±SD	Paired "*t*" (*P*)	M±SD	Paired "*t*" (*P*)	M±SD	Paired "*t*" (*P*)		
HDL (mg/dl)	Pretest	39.19±0.7	2.174	39.1±0.7	22.167	39.2±0.8	32.052	0.007	0.993
	Posttest	39.0±0.7	(0.033)	45.6±0.7	(0.001)	45.6±0.7	(0.001)	28.651	0.001
Triglycerides (mg/dl)	Pretest	174.3±3.6	2.089	176.1±3.6	34.499	174.7±3.7	31.258	0.070	0.932
	Posttest	174.5±3.6	(0.040)	155.3±3.4	(0.001)	135.1±3.3	(0.001)	32.802	0.001
FBS (mg/dl)	Pretest	138.7±8.0	0.841	135.6±7.9	27.348	140.3±8.3	24.468	0.087	0.917
	Posttest	138.9±7.9	(0.403)	124.2±7.9	(0.001)	124.1±8.3	(0.001)	1.131	0.001

M=mean, SD=standard deviation, one-way ANOVA=one-way analysis of variance

and dyslipidemia among women of the reproductive age group found that LIs improved lipid levels in 10 of 18 studies and blood pressure in 4 of 9 studies.[8]

In this study, a significant reduction in triglycerides was found in the LI group and the MIT group. Therapeutic LIs are effective in managing dyslipidemia to reduce cardiovascular risk. The difficulties associated with maintaining a healthy lifestyle in the long term often mean that dyslipidemia requires additional therapeutic intervention.[9] A systematic review and meta-analysis of clinical trials on LIs for type 2 DM found that comprehensive LIs include dietary changes and exercise. At least one component is effective in decreasing the incidence of type 2 diabetes in high-risk individuals.[10] In this study, a significant reduction in triglycerides was found in the LI group and the MIT group. A review on combination of diet and exercise intervention for the treatment of dyslipidemia found that the combination of lifestyle treatments such as exercise and diet found more advantageous. Diet primarily lowers the total cholesterol and LDL cholesterol concentration, and exercise intervention increases HDL cholesterol while decreasing triglyceride levels.[11] A systematic review of 35 studies showed positive relations between theory-based interventions and educational, clinical, and practical outcomes among patients with cardiovascular disease (CVD).[12]

A systematic review of the economic evaluation of LIs to prevent type 2 diabetes was analyzed in 20 studies. It was found that type 2 diabetes prevention by physical activity or diet or both proved cost-effective according to accepted thresholds.[13] Another review was conducted on the clinical impact of LIs for the prevention of DM from April to December 2015. 19 reviews were identified for inclusion. Almost all analyses reported that interventions were associated with a net reduction in diabetes incidence, measures of glycemia, and adiposity at follow-up to 23 years.[14]

In this study, most of the women were unemployed. The majority are from low socioeconomic status. A study on the assessment of socioeconomic status of diabetic patients and their complications found that those with low socioeconomic status face more challenges in their social environment together with less psychological support.[15]

A six-month observational study to assess the effect of the multicomponent outpatient group-based nutrition and LI program on glycemic control and use of glucose-lowering medications in type 2 diabetes people found that compared to baseline mean HbA1c levels at 6 months were 5 mmol/L lower and the number of patients with HbA1c levels ≤53 mmol/L after the interventions increased (from 36% to 60%). After 6 months, 49% had reduced their medication or eliminated it completely. Significantly lower fasting glucose levels, body weight, BMI, and waist circumference were also observed in the study groups.[16]

This study focused on the importance of diet, exercise, education, and reflexology foot massage to modify metabolic syndrome parameters. This is similar to the study of Mohebbi B *et al*., which clarified predictors of nutrition and cognitive factors to enhance Hypertension (HTN) management. They emphasized appropriate strategies to promote the quality of HTN management approach in nutrition knowledge, disease perceptions, and diet adherence among hypertensive middle-aged women.[17]

A study was conducted to translate a research lifestyle modification curriculum of diabetes prevention program into a community-based program and to determine whether the delivery approach is effective in lowering risk factors of type 2 diabetes in risk adults. The study found that at 6 and 12 months 39% and 56% of individuals had lost ≥5% of their weight. Significant improvement was noted in total cholesterol, LDL, and diastolic and systolic BP at 6 months. FBS and diastolic BP were significantly improved in a subgroup of participants with at least 5% weight loss. Glycosylated Hemoglobin (HbA1c) levels were associated with the percentage of weight loss.[18] In this study, the MIT group received reflexology foot massage along with LIs. The results showed a significant change in HDL, triglycerides, and fasting blood sugar. In case of triglycerides, a significant reduction was observed as compared to the LI group. A similar study was conducted to assess the effect of reflexology on lipoprotein in women with type 2 diabetes,

and a decrease in Low Density Lipoprotein (LDL) by 7.37%, HDL by 0.61%, and triglycerides by 12.95% was observed.[19]

A review aimed to revisit the concepts of reflexology and examine its effectiveness, practice, and training for reflexology practitioners, and the professional association had advocated that reflexology is effective for general well-being, maintenance, and treatment of chronic illnesses such as stroke, musculoskeletal disorders, and stress.[20] A randomized controlled trial was conducted among 62 type 2 diabetes patients to assess the effect of foot reflexology on the quality of life of diabetic patients. It was found that after foot reflexology therapy quality of life, functional capacity, and pain were significantly improved in the reflexology group.[21] All the above studies strongly support the findings of the present study and prove that LIs and MIT are effective in improving the biochemical parameters of metabolic syndrome.

Conclusions

The present study focused on clinical outcomes, which can be a study strength. The study results added more evidence to support the use of MIT and LIs for reducing triglycerides and FBS and improving HDL among women with metabolic syndrome. As an important predictor of CVDs, paying more attention to education and non-pharmacological interventions to prevent complications and setting tangible educational and clinical outcomes of metabolic syndrome should be considered. Further studies based on several health education and promotion theories/models are suggested to achieve positive outcomes of metabolic syndrome.

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Conflicts of interest

There are no conflicts of interest.

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