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Effectiveness of nurse-led intervention on weight reduction among adults in urban Puducherry – A randomized controlled pilot trial

Vembu Krishnasamy¹, Kumari Manjini Jayaram², Venkatachalam Jayaseelan³, Ramesh Shanmugam⁴, Vathsala Sadan⁵

Abstract:

BACKGROUND: The recent spike in the incidence of type 2 diabetes is most likely caused by the obvious rise in the prevalence of overweight and obesity. The risk of developing noncommunicable illnesses can be prevented and reduced with even modest weight loss. This study was conducted with the aim of evaluating the effectiveness of a nurse-led intervention (NLI) strategy on weight reduction among adults in urban Puducherry.

MATERIALS AND METHODS: A two-arm, parallel-group, randomized controlled study with an open label was conducted with obese adults in urban areas of Puducherry, namely Nesavalar colony and Govindanpet, from November 2022 to February 2023. Totally, 88 obese adults were randomized using a simple random sampling method to either the NLI arm or the general care (GC) arm. WHO STEPS (version 3.2) questionnaire was adopted to gather baseline and end line data. NLI arm participants received NLI and GC arm participants received GC from urban primary health center. In statistical analysis, the proportion was used to summarize categorical variables. The parametric and nonparametric tests were applied based on the variable type and normality of the data. Multiple linear regressions were used with outcome changes in weight in the NLI arm.

RESULTS: At 16 weeks, the NLI arm lost a mean weight of – 2.58 kg and the GC arm gained 0.38 kg with a mean difference in weight of 2.96 between arms. A significant reduction was found ($P < 0.001$) in weight, waist circumference, body mass index, and also found significant improvement in cholesterol profile and thyroid stimulating hormone.

CONCLUSION: This community-based NLI study is effective for weight reduction in urban Puducherry and it lowers the risk of developing noncommunicable diseases among adults. Due to the larger size of the geographical area and the more number of clusters, a stringent follow-up plan and extra manpower must be created for the main study.

Keywords:

Effectiveness, nurse-led intervention, randomized controlled trial, weight reduction, WHO STEPS

Introduction

An improper or excessive deposit of fat that poses a risk to one's health is referred to as obesity. According to the global burden of illness, over 4 million people per year died as a result of being overweight or obese in 2017. Overweight and obesity,

formerly thought to be issues mainly in high-income nations, are now substantially on the rise in low- and middle-income countries, especially in metropolitan areas. In India over the past five years, obesity has increased by 4% among both men and women regardless of gender. The proportion of overweight or obese women

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¹Community Health Nursing, JIPMER, Puducherry, India,

²Medical Surgical Nursing, JIPMER, Puducherry, India, ³Department of Preventive and Social Medicine, JIPMER, Puducherry, India,

⁴Department of Adult Health Nursing, Bule Hora University, Ethiopia,

⁵College of Nursing, Christian Medical College, Vellore, Tamil Nadu, India

Address for correspondence:

Dr. Kumari Manjini Jayaram, College of Nursing, JIPMER, Puducherry - 605 006, India.

E-mail: kumari_mj@ymail.com

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in NFHS-5 is 24, up from 20.6% in NFHS-4 (2015–16). From 18.9% (NFHS-4), the prevalence in men climbed to 22.9% (NFHS-5).^[1] In Puducherry, 19.1% of individuals were overweight and 31.8% had generalized obesity. A considerable percentage of people were found to have prehypertension, and 45.1% of participants had central obesity, which highlights the need for early intervention.^[2] Urban areas have a higher prevalence of obesity. Some of the worst performers are Chandigarh, Delhi, and Puducherry, where nearly half the population is overweight. The pattern of the richest people being four times more likely to be overweight than the poorest people is also evident. The disparity in occupation and access to food can be partly blamed for this. Males in cities are about twice as likely to be overweight than males in rural areas. Women do not exhibit such a pronounced disparity between urban and rural areas.^[1] The high prevalence of obesity and overweight is associated with several health risks, including cardiovascular diseases, diabetes, and certain cancers. All of these illnesses have a negative impact on both mortality and quality of life.^[3] To treat obesity, a systemic approach, which is the key to obesity intervention, involves the simultaneous integration of lifestyle or behavioral training, diet modification to lower calorie consumption, and an increase in physical activity at both individual and environmental levels.^[4] In India, numerous weight loss studies in India have documented fast weight loss, harmful effects, and weight regaining consciousness across a range of demographics, including both men and women, people of all ages, and residents of both urban and rural areas. Even if the results of weight-loss intervention studies employing convenient sampling and a quasiexperimental design have shown a considerable change,^[5] there is still a lack of consistency in behavior to prevent weight rebound. However, a systematic review that compared the clinical effectiveness of combined behavioral weight management programs (BWMPs) targeting weight loss to single component programs found that weight loss was similar in the short term for diet-only and combined BWMPs, but weight loss was increased in the long term when diet and physical activity were combined. Physical activity-only programs are less successful than integrated BWMPs in both the short and long term.^[6] Nonetheless, additional nursing research is needed, particularly if it is to be community-based and culturally sustainable. To combat obesity and overweight, it is vital to create effective weight loss interventions. Randomized controlled trial (RCT) may evaluate the long-term effectiveness and safety of weight loss programs. A systematic review of 20 eligible studies to determine whether nurse-delivered weight management interventions improve weight outcomes across the lifespan found that three out of nine studies with longer-term follow-up assessments showed a significant loss in weight or body mass

index (BMI) between the intervention and control groups at follow-up times ranging from 12 months to 2 years.^[7] Through intervention and nurse assistance, the nurse-led intervention (NLI) was created to modify the preventative method. Counselling and encouragement given repeatedly may assist obese people in sticking to a healthy diet and exercise routine. This study's major goal was to determine the effectiveness of nurse-led weight loss intervention strategies on weight reduction in urban adults. This pilot study's objective was to evaluate the effectiveness of a NLI strategy on weight loss among adults in urban Puducherry.

Materials and Methods

Study design and setting

This was a two-arm, parallel-group, randomized controlled experiment with an open label. Around half (50.6%) of residents live in rural regions, according to the Census of India 2011, while 49.22% live in urban areas.^[8] Obesity screening was conducted by collecting demographic information including age, sex, education, contact information, occupation, income, and other characteristics such as height and weight, regarding current health issues, any constraints on physical activity, any drug histories, treatment plans, or weight-loss programs and the availability of a smartphone in two randomly chosen urban localities that are served by urban health centers that are currently in operation. One individual has been chosen from each family by adapting the WHO Kish technique. A total of 230 individuals were evaluated for obesity; out of 114 obese adults, 88 (44 from each) were recruited using simple random sampling [Figure 1].

Study participants and sampling

The study participants were enrolled in October 2022 who measured a BMI of 25 or above, between the ages of 18 and 50 years, and had lived in Puducherry urban area for a year preceding the study or longer were eligible to participate in the trial. Adults with restrictions on physical activity, those engaged with other weight loss programs, those taking medications that impact weight reduction, those suffering from serious diseases, those with vision or hearing impairments, those who underwent bariatric surgery, those who were pregnant, and those with psychiatric issues have been excluded from this study. The sample size of 88 (20% of the main study), with 44 in each arm, was determined to adequately reflect the variety and characteristics of the target population while providing pertinent information and identifying possible problems without requiring an excessive amount of time and resources. A total of 88 obese people were randomly assigned, using a simple random sample procedure, to the NLI arm (Govindanpet) or the general care (GC) arm (Nesavalar colony).

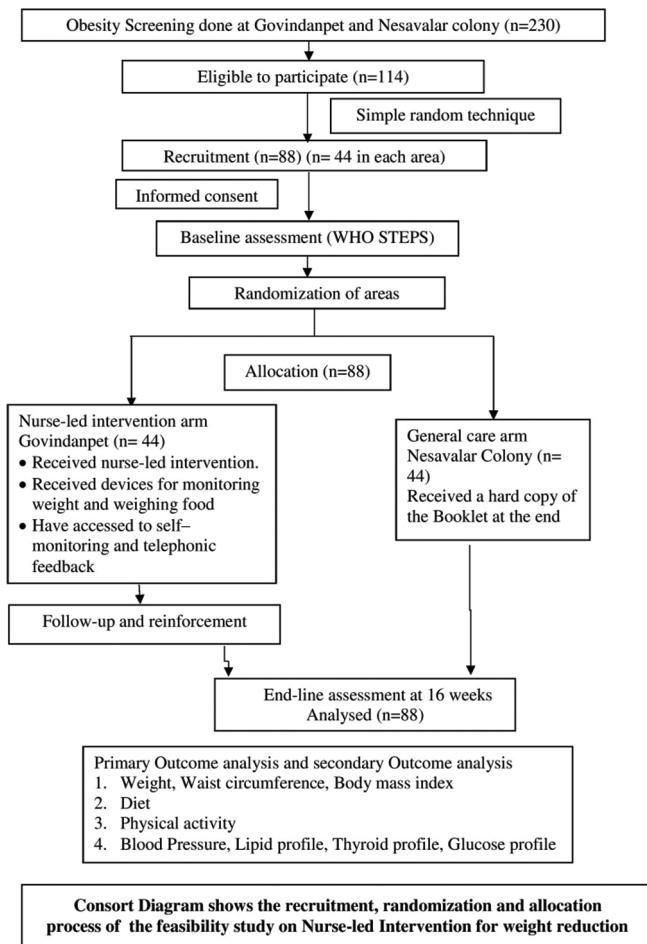


Figure 1: CONSORT diagram

Operational definition

Obesity ($\geq 25 \text{ kg/m}^2$) and overweight ($23\text{--}24.99 \text{ kg/m}^2$) were evaluated using Asian BMI categorization cutoffs. The criteria for abdominal obesity were WC $\geq 80 \text{ cm}$ for women and $\geq 90 \text{ cm}$ for males.^[2] Systolic blood pressure (SBP) 140 mmHg , diastolic blood pressure (DBP) 90 mmHg , and/or antihypertensive medication use were considered to be indicators of hypertension at the time of data collection. SBP of $120\text{--}139 \text{ mmHg}$ or DBP of $80\text{--}89 \text{ mmHg}$ was used to identify prehypertension.^[9,10]

Raised blood pressure (hypertension) was defined as having a systolic (SBP) or diastolic (DBP) reading of 140 mmHg or above, or as being currently taking medication to decrease hypertension. Hypercholesterolemia was defined as those whose total cholesterol levels were 200 mg/dl and above or who were on lipid-lowering medications at the time.^[10] Fasting blood glucose of $\geq 125 \text{ mg/dl}$ or current use of antidiabetic drugs was used to diagnose diabetes mellitus.^[11] Less than five servings of fruits and vegetables (or 80 g) consumed daily over the assessment week were determined to be an insufficient amount. Per capita salt consumption of more than 6 g per day was considered high. Less than 600

metabolic equivalents (METs), based on total physical activity (related to work, transportation, and leisure time) in the week before the evaluation, were used to determine physical inactivity.^[12]

The intervention's description: Adult health nursing, endocrinology, general medicine, dietetics, physiotherapy, and medical social work specialists' recommendations served as the foundation for the development and structuring of the NLI's content through focus group discussions that took into account the factors that help and hinder overweight residents in the same area from losing weight. The study framework Pender's health promotion model (HPM) is used to promote adherence to diet and exercise for leading NLI. The application of HPM emphasized more on individuals rather than on families and peer groups.^[13]

Data collection tool and technique

This pilot trial lasted from October 2022 until February 2023. After receiving consent, information was acquired using the WHO STEPS (version 3.2) questionnaire. A face-to-face interview using the WHO STEPS survey questionnaire and blood collection at the baseline and sixteenth week, respectively, were used to evaluate the primary and secondary outcomes. Measurements of height, weight, waist circumference (WC), and blood pressure (BP) were obtained by WHO STEPS standards. An overnight fasting blood sample was used for the evaluation of total cholesterol, thyroid, and fasting blood glucose profiles.^[14]

After completing the baseline assessment (time point 1), one area was randomly allocated to the intervention group using simple random allocation and one area to the control group. This was done to prevent intervention contamination. It was not possible to blind the researcher or the participants because the treatments included health education booklets, in-person home visits, mobile messaging, and calls. Participants in both arms had access to general healthcare throughout the entire 16-week experiment. It was advised that participants disclose their participation in the trial to their primary care physician (or general practitioner). At the Anganwadi centers located in each interventional region, participants allocated to the intervention arm received group-based educational treatments on good eating habits and physical activity, including weight reduction activities, during the first two weeks. The teaching methods employed throughout the educational sessions on healthy eating patterns included lectures, group discussions, posters, and displays of healthful foods. The instructional methods used in the sessions included lectures and discussions, posters and demonstrations, and a suryanamaskar return demonstration. BMI, optimal body weight, and calorie needs were calculated using

online health calculators (www.nin.res.in).^[14] A model meal plan (individually adjusted with a 200 Kcal calorie deficit) was developed based on calorie needs, biochemical characteristics, physical activity, and spending capacity on food. The initial stage of the intervention included a one-day recall using measuring spoons and cups, and it was reassessed after sixteen weeks. The investigator tracked the subjects' caloric intake using the Diet Cal program to determine the quantity of nutrients and food types ingested. Food values were accepted in the form of portions that could be eaten. Through fit-bit bands, the investigator randomly tracked their activity. In the first step of the WHO questionnaire, the MET minutes per week were used to measure the amount of physical activity. The fit band's data on steps combined with the Surya Namaskar's reps and sets in the same questionnaire. A booklet and self-monitoring tools (fit bit bands and nutritional measurement cups) were given to study participants. The usage of mobile communication, group activities, and counselling was strongly encouraged among the participants. After instruction, the investigator made voice and video calls to the intervention arm participants. A professional expert gave one motivational speech, which was videotaped and played for the audience. For their practice, participants saw recorded footage of the suryanamaskar. Through phone calls and text messages, members of the control group were notified that the research study's first stage had been completed (time point 1; baseline assessment), and the second stage would be finished in sixteen weeks (time point 2; end-line assessment). Following the conclusion of the two assessment phases,^[11] participants were given informational booklets, and nearby community health professionals were trained using the same curriculum.

Statistical analysis

Version 14 of STATA was used to conduct statistical analysis. The mean, standard deviation (SD), and proportion of individuals were used to summarize the various variables. For comparisons between the intervention and control groups, categorical variables were evaluated using the Chi-square test or, when appropriate, Fisher's exact test, while continuous variables were evaluated using unpaired and paired *t*-tests, Wilcoxon rank-sum and Wilcoxon signed-rank tests, both of which had 95% confidence intervals. Statistical significance was defined as a *P* value of 5% or less (two-sided). Multiple linear regressions were used with outcome changes in weight in the NLI arm.

Ethical consideration

The clinical trial was registered with the Clinical Trials Registry India^[14] (CTRI/2021/12/038785) after receiving clearance from the Institute Ethics Committee, JIPMER (JIP/CON/IEC/2021, dated 20.10.2021). Following acceptance from the Puducherry

government (No. 08/2021/HRW/DHFWS, dated 23.09.2021), the Health Research Wing.

Results

Totally 88 from two urban localities were enrolled in the study and randomly assigned into two groups (geographical area wise). After frequent visits by the researcher and consenting with clear explanation, a good response to the participation was achieved from the nonresponders. The nutrition exhibition attracted the participants and their family members too. Involved community volunteers to organize nutritional exhibitions. The overall group allocation process worked well because the participants were from the same street within a 500-m radius. As the majority of participants' phones were either owned by or used by other family members, responses to direct face-to-face contact were better during intervention than responses to messages or phone calls. However, participants showed less interest in maintaining their nutrition and exercise records were needed a lot of reminders.

Participant's characteristics at baseline: Sample characteristics are reported in Table 1. Among the participants, the mean (SD) age was 38.04 (7.53) years, and more than a half 51.14% were in 40–50 years of age group. In the majority of the participants, 87.5% were female and 51.14% had in family income of \leq 10000 rupees. Baseline data did not differ between the two groups. Table 2 shows the baseline clinical characteristics of the study participants. The study participants' weight ranges from 66.6 to 108 kg with a mean (SD) of 79.08 (9.29). The weight of the GC arm and NLI arm study participants at the enrollment was 79.44 ± 10.4 and 78.72 ± 8.2 kg, respectively, with BMI of 32.5 ± 4.02 and 32.8 ± 3.35 kg/m². The baseline values of both groups were ($P > 0.05$) similar in blood pressure, fruit and vegetable intake, physical inactivity, glucose profiles, and thyroid profiles. The WC was 99.7 ± 8.8 and 99.31 ± 6.3 with GC arm and NLI arm, respectively [Table 3].

Differences in mean clinical parameters at 16 weeks: At 16 weeks, the NLI arm's mean weight reduced by -2.581 ± 0.9 (mean \pm SD) compared with 0.38 ± 0.14 in GC arm with a mean difference (SE) between arms 2.96 (0.19) with $P < 0.001$ with a mean difference (SE) in BMI of 1.22 (0.074) $P < 0.001$ and the WC with a mean difference (SE) of 2.5 (0.238) $P < 0.001$. Also found a significant reduction in DBP, sedentary behavior, low-density lipoprotein, and thyroid and cholesterol profiles. Also NLI arm participants showed a significant ($P < 0.001$) reduction in salt intake and significantly ($P < 0.001$) increased their fruit and vegetable intake to more than five servings per day with the increase in physical activity.

Table 1: Baseline sociodemographic characteristics of the enrolled study participants (n=88)

Variables	GC arm (n=44) (%)	NLI arm (n=44) (%)	Both arms (n=88) (%)	P
Age in years				
18–39	20 (45.45)	23 (52.27)	43 (48.86)	0.52
40–50	24 (54.55)	21 (47.73)	45 (51.14)	
Sex				
Male	4 (9.09)	7 (15.91)	11 (12.5)	0.52
Female	40 (90.91)	37 (84.09)	77 (87.5)	
Marital status				
Unmarried	2 (4.55)	3 (6.68)	5 (5.68)	1
Married	42 (95.45)	41 (93.18)	41 (94.32)	
Religion				
Hindu	36 (81.82)	41 (93.18)	77 (87.5)	0.16
Christian	7 (15.91)	2 (4.55)	9 (10.23)	
Muslim	1 (2.27)	1 (2.27)	2 (2.27)	
Education				
Uneducated	1 (2.27)	0	1 (1.14)	0.45
Primary education	11 (25)	15 (34.09)	26 (29.55)	
Secondary education	16 (36.36)	18 (40.91)	34 (38.64)	
Graduates	16 (36.36)	11 (25)	27 (30.68)	
Employment status				
Student	5 (11.36)	0	5 (5.68)	0.10
Housewife	29 (65.91)	30 (68.18)	59 (67.05)	
Unemployed	0	2 (4.55)	2 (2.27)	
Semiskilled	5 (11.36)	7 (15.91)	12 (13.64)	
Skilled	2 (4.55)	4 (9.09)	6 (6.82)	
Professionals	3 (6.82)	1 (2.27)	4 (4.55)	
Monthly income (Rupees)				
≤ 10000	24 (54.55)	21 (47.73)	45 (51.14)	0.43
10001–20000	19 (43.18)	19 (43.18)	38 (43.18)	
≥ 20001	1 (2.27)	4 (9.09)	5 (5.68)	
Baseline clinical parameters of study participants (n=88)				
Obesity class				
Obese I (BMI 25–29.9 kg/m ²)	19 (43.18)	12 (27.27)	31 (35.23)	0.12
Obese II (BMI ≥ 30 kg/m ²)	13 (56.82)	21 (72.73)	57 (64.77)	
Abdominal obesity				
Absent	0	1 (2.27)	1 (1.14)	0.31
Present	44 (100)	43 (97.73)	43 (98.86)	
Diabetes				
Absent	33 (75)	32 (68.18)	63 (71.59)	0.49
Present	11 (25)	12 (28.4)	25 (28.41)	
Fasting blood glucose				
<100 mg/dl	27 (61.36)	25 (56.82)	52 (59.09)	0.75
100–125.9 mg/dl	8 (18.18)	7 (15.91)	15 (17.05)	
126 mg/dl	9 (20.45)	12 (27.27)	21 (23.86)	
Hypertension				
No	4 (9.09)	7 (15.91)	11 (12.5)	0.61
Prehypertensive	26 (59.09)	25 (56.82)	51 (57.95)	
Hypertensive	14 (31.82)	12 (27.27)	26 (29.55)	
Triglyceridemia				
Absent	37 (84.09)	31 (70.45)	68 (77.27)	0.13
Present	7 (15.91)	13 (29.55)	20 (22.73)	
Metabolic syndrome				
Absent	27 (61.39)	25 (56.82)	52 (59.09)	0.67
Present	17 (38.64)	19 (43.18)	36 (40.91)	

Contd...

Table 1: Contd...

Variables	GC arm (n=44) (%)	NLI arm (n=44) (%)	Both arms (n=88) (%)	P
FV Intake				
<5 servings/day	22 (27.27)	11 (25)	23 (26.14)	0.81
≥5 servings/day	32 (72.73)	33 (73.86)	33 (73.86)	
Salt intake				
>6 grams per day	14 (31.82)	23 (52.27)	37 (42.05)	0.05
≤6 grams per day	30 (68.18)	21 (47.73)	51 (57.95)	
Physical activity/week				
<600 METs	36 (81.82)	35 (79.55)	71 (80.68)	0.79
≥600 METs	8 (18.18)	9 (20.45)	17 (19.32)	

GC=General care arm, NLI=Nurse-led intervention, FV=Fruit and vegetable intake

Table 2: Baseline characteristics of study participants (n=88)

Variable	Mean (SD)		P
	GC arm	NLI arm	
Weight (Kg)	79.44 (10.4)	78.72 (8.2)	0.72
WC (cms)	99.7 (8.8)	99.31 (6.3)	0.80
BMI (kg/m ²)	32.5 (4.02)	32.8 (3.35)	0.78
Systolic BP (mm Hg)	125.72 (12.9)	132.54 (19.8)	0.06
Diastolic BP (mm Hg)	83.09 (10.5)	85.84 (10.2)	0.21
Sedentary Behavior (min/day)	212.72 (119)	175.22 (53)	0.06
FV intake serving/day	7.6 (2.7)	7.3 (2.9)	0.62
Physical Activity (METs/wk)	485.5 (251.2)	457.27 (288.5)	0.63
Glucose (mg/dl)	130.93 (86.4)	114.59 (54.8)	0.29
Total Cholesterol (mg/dl)	190.4 (41.5)	204.84 (38.6)	0.09
LDL (mg/dl)	127.75 (32.7)	135.77 (27.8)	0.21
Triglycerides (mg/dl)	121.8 (49.06)	141.56 (68.6)	0.12
HDL (mg/dl)	45.90 (11.09)	45.18 (11.54)	0.76
VLDL (mg/dl)	24.34 (9.8)	29.22 (14.8)	0.07
FT3 (ulU/mL)	3.39 (0.42)	3.27 (0.42)	0.18
FT4 (ng/dL)	1.01 (0.2)	1.05 (1.2)	0.80
TSH (ulU/ml)	3.21 (2.2)	3.40 (2.9)	0.72

WC=Waist circumference, BMI=Body mass index, HDL=High-density lipoprotein, LDL=Low-density lipoprotein, VLDL=Very-low-density lipoprotein, FT3=Free triiodothyronine, free T4, or free thyroxine, TSH=Thyroid-stimulating hormone, GC=General care arm, NLI=Nurse-led intervention, FV=Fruit and vegetable

Differences in dietary intake: At 16 weeks, NLI participants showed a decline in the percentage of energy from carbohydrates ($P < 0.001$), fat ($P < 0.001$), and saturated fat ($P < 0.001$). On the other hand, the total percentage of prescribed calorie intake (200 Kcal deficit from calorie requirement of the individual) was not significant, $P = 0.67$. However, the percentage of energy from protein sources was found high (30.03%) compared to the baseline of 8.84% ($P < 0.001$). A significant increase in intake of 11.7 g ($P < 0.001$) was also found [Table 4].

Results of multiple linear regression analysis: We performed a multiple linear regression among 44 NLI arm participants using covariates (fruit and vegetable intake, fat intake including saturated fat, number of steps walked, practice of yoga, SBP, fasting blood glucose, triglycerides, high-density lipoprotein, very-low-density lipoprotein, (FT3) free triiodothyronine) that were found to be significant at $P \leq 0.2$ as the independent variable

and the weight difference at the end as the dependent variable. After adjusting with covariates, results showed that the P value of 0.25 had not statistically significant relationship with weight difference. However, this ($r^2 = 0.3125$) model explains 31.25% of the variation in weight difference [Table 5].

Discussion

The objective was to determine the effectiveness of NLI strategies for weight reduction among adults in urban Puducherry. At 16 weeks, the NLI arm had lost an average of 2.58 kg and the GC arm had gained 0.38 kg, indicating a mean weight difference (standard error) of 2.96 (0.19). Weight, WC, BMI, and a considerable improvement in thyroid-stimulating hormone and lipid profile were all reduced significantly ($P < 0.001$). According to a research, those who underwent an intensive lifestyle intervention lost $\geq 10\%$ of their body weight in the first year.^[15] The findings of this study suggest that a 16-week RCT on NLI to reduce weight in urban adults was working well. We were able to demonstrate that NLI strategies, facilitated weight loss at 16 weeks, found suitable to adults in urban Puducherry and support the practicality of a future study. Our findings demonstrated that NLI strategies are a good choice of nonpharmacological approach to losing weight due to the application of mobile technology in delivering intervention to people who are busy with their jobs. At 16 weeks, four (9.09%) NLI participants had lost at least 5% of their body weight. It was additionally found that mobile technology-enabled NLI for reducing weight is more affordable and accessible. The study, which was carried out in North India to determine the effectiveness of a nurse-led lifestyle modification intervention (NLLMI), revealed a high statistically significant difference ($P = 0.001$) between the study group and the control group as well as a significant reduction in BMI at the 12th and 24th weeks of the NLLMI.^[16] High intakes of carbohydrates and fats have been linked to obesity and cardiovascular illnesses, which are major public health concerns in India. Overweight and obesity are defined by BMIs exceeding 25.0 and 30.0, respectively, which are also signs of inadequate nutrition. Trans fats, in particular, have a negative impact on

Table 3: The comparison of variables after the intervention and the magnitude of changes in variables within and between groups n=88

Variable	GC arm (n=44)		NLI arm (n=44)		MD (SE)	P
	Mean (SD)	MD (SD)	Mean (SD)	MD (SD)		
Weight (Kg)	79.83 (10.44)	0.38 (0.14)	76.14 (8.16)	-2.581 (0.9)	2.96 (0.19)	<0.001
WC (cms)	99.92 (8.73)	0.18 (1.17)	97 (6.28)	-2.318 (0.95)	2.5 (0.23)	<0.001
BMI (kg/m ²)	32.69 (4.0)	0.15 (0.36)	31.69 (4.0)	-1.07 (0.34)	1.22 (0.07)	<0.001
Systolic BP	127.15 (16.23)	1.43 (10.95)	107.15 (26.21)	-25.38 (21.828)	26.81 (3.68)	<0.001
Diastolic BP	83.59 (1.52)	0.5 (3.44)	93.68 (5.18)	7.84 (34.69)	-7.34 (5.25)	0.169
Sedentary behavior (min/day)	205.22 (17.9)	-7.5 (77.94)	137.72 (8.15)	-37.5 (69.42)	30 (15.7)	0.0600
FV intake serving/ day	7.5 (3)	-0.09 (3.85)	11.77 (1.05)	4.477 (3.05)	-4.56 (0.74)	<0.001
Physical Activity (METs/wk)	586.38 (336.51)	100.9 (288.52)	1751.8 (697.81)	1294.5 (547.42)	-1193.63 (93.3)	<0.001
Glucose (mg/dl)	132.11 (86.87)	1.18 (6.7)	50.89 (52.75)	-63.69 (66.91)	64.87 (10.13)	<0.001
TC (mg/dl)	205.47 (41.07)	15.11 (14.6)	150.75 (44.18)	-54.09 (37.61)	69.204 (6.08)	<0.001
LDL (mg/dl)	129.97 (32.93)	2.22 (6.44)	66.36 (46.49)	-69.40 (49.34)	71.63 9 (7.5)	<0.001
Triglycerides (mg/dl)	125.88 (44.71)	4.06 (17.13)	132.34 (44.07)	-9.22 (42.37)	13.3 (6.89)	0.587
HDL (mg/dl)	45.227 (10.13)	-0.68 (3.21)	88.79 (60.72)	43.61 (62.41)	-44.29 (9.422)	<0.001
VLDL (mg/dl)	25.13 (8.945)	0.79 (3.44)	35.27 (15)	6.04 (19.28)	-5.25 (2.95)	0.082
FT3 (ulU/mL)	3.18 (0.54)	-0.21 (0.73)	2.21 (1.43)	-1.06 (1.68)	0.847 (0.276)	0.003
FT4 (ng/dL)	1.05 (0.21)	0.04 (0.26)	2.1 (1.66)	1.04 (1.97)	-1.00 (0.30)	0.001
TSH (ulU/ml)	3.26 (2.04)	0.05 (1.77)	2.52 (1.68)	1.04 (2.54)	0.93 (0.47)	0.051

WC=Waist circumference, BMI=Body mass index, HDL=High-density lipoprotein, LDL=Low-density lipoprotein, VLDL=Very-low-density lipoprotein, FT3=Free triiodothyronine, free T4, or free thyroxine, TSH=Thyroid-stimulating hormone, GC=General care, NLI=Nurse-led intervention, SD=Standard deviation, MD=Mean difference, SE=Standard error, Mean (SD)=Estimates of variables after the intervention, MD (SD) = Differences in variables between end line and baseline within group, MD (SE)=Magnitude of changes in variables between groups, GC=General Care arm, NLI=Nurse-led intervention, FV=Fruit and vegetable

Table 4: Comparison of dietary intake before and after NLI with nurse-led intervention arm (n=44)

Variable	Mean	SE	SD	95% CI	P
Total percentage calorie intake (Kcal)					
Baseline	93.84	0.73	4.86	92.36, 95.32	0.6661
End line	92.27	3.65	24.22	84.91, 99.64	
Energy from carbohydrate (%)					
Baseline	68.52	1.00	6.68	66.49, 70.55	<0.001
End line	55.01	0.52	3.45	53.96, 56.06	
Energy from fat (%)					
Baseline	18.73	0.70	4.65	17.31, 20.14	<0.001
End line	14.23	0.65	4.32	12.91, 15.55	
Energy from protein (%)					
Baseline	8.84	0.39	2.63	8.04, 9.65	<0.001
End line	30.03	0.54	3.60	28.94, 31.13	
Saturated fat intake (g)					
Baseline	13.93	0.74	4.96	12.42, 15.44	<0.001
End line	6.95	0.39	2.61	6.16, 7.75	
Dietary fiber (g)					
Baseline	11.77	0.48	3.19	10.8, 12.74	<0.001
End line	21.04	0.36	2.41	20.31, 21.77	

NLI=Nurse-led intervention

Note: The percentage of total calorie intake was calculated using formula, Total % calorie intake= (Calorie in/ Calorie requirement)*100

Percentage of energy from macronutrients was calculated for all participants by using the following formula:

Percentage of energy from macronutrients = (Amount of energy obtained from macronutrient (Kcal) / Calorie in)*100

Dietary intake was calculated from 24 hours recall during baseline and end line assessments from each subject. DietCal software was used to analyze client dietary intake.

health when consumed in excess.^[17] Our findings that saturated fat consumption was greater than protein intake (13.93%) were consistent with those of earlier studies conducted in India, which suggests that the Indian diet’s substantial dependence on cereal may be in part to blame.^[18] Wilson (2020) makes the suggestion and recommends lifestyle changes as the very first

phase of action for those who are overweight or obese, which is consistent with the outcomes of our study.^[19] Additionally, Thiabpho C *et al.*(2018) reported that a tailored modification to lifestyle consisting of 16 weeks of fitness training, dietary counselling, and health education led to healthy weight reduction and lowered the risk of metabolic syndrome in young obese women.^[20]

Table 5: Unadjusted and adjusted mean differences (95% CI) of nurse-led intervention arm (Dependent variable: Changes in weight after intervention)

Variables	Unadjusted mean difference			Adjusted mean difference		
	β	P	95% Conf. interval	β	P	95% Conf. interval
Fruit and vegetable intake/day	-0.1742	0.169	-0.4257, 0.0772	-0.1801	0.197	-0.4588, 0.0984
Fat	-0.0257	0.032	-0.0491, -0.0023	-0.0205	0.215	-0.0535, 0.0125
Saturated fat	-0.0340	0.151	-0.0809, 0.0128	0.0115	0.711	-0.0515, 0.0746
Steps walked	-0.0002	0.042	-0.0005, -0.0000	-0.0001	0.232	-0.0004, 0.0001
Yoga (suryanamaskaram poses/day)	0.0165	0.144	-0.0058, 0.0389	-0.0028	0.921	-0.0603, 0.0547
Systolic BP (mm Hg)	0.0076	0.135	-0.0024, 0.0176	0.0021	0.833	-0.0188, 0.0232
Glucose (mg/dl)	0.0039	0.120	-0.0010, 0.0089	0.0032	0.572	-0.0084, 0.0150
Triglycerides (mg/dl)	-0.0065	0.029	-0.0123, -0.0006	-0.0106	0.108	-0.0237, 0.0024
HDL (mg/dl)	0.0045	0.038	-0.0087, -0.0002	0.0015	0.730	-0.0077, 0.0108
VLDL (mg/dl)	-0.0117	0.187	-0.0294, 0.0059	0.0300	0.188	-0.0154, 0.0755
FT3 (uIU/mL)	0.1138	0.202	-0.0714, 0.2992	0.1578	0.261	-0.1233, 0.4390

Multiple linear regression using covariates (fruit and vegetable intake, fat intake including saturated fat, number of steps walked, performing yoga, systolic blood pressure, fasting blood glucose, triglycerides, high-density lipoprotein, very-low-density lipoprotein (FT3) free tri-iodo thyronine) as independent variable and the weight difference at the end as dependent variable. β – Coefficient

Repetition in habit formation plays a major role which can be achieved by providing patients with opportunities to practice, engage in, and build strong habits for long-term weight control behaviors.^[21-23] According to this study, keeping the participants motivated and engaged over time may be crucial to the success of NLI strategies. On weight, fasting glucose, triglycerides, total cholesterol, LDL cholesterol, end-line clinical parameters showed a significant reduction ($P < 0.001$) that was consistent with earlier research.^[24] According to one study, HDL cholesterol levels may rise with just a 1–3% weight loss. According to another study, T3 concentration closely links to a person's nutritional state, and mild weight loss causes a drop in T3 with minimal impacts on other thyroid hormone homeostasis parameters. These results supported our study's findings that weight loss of merely 1.28–5.83% improved lipid, thyroid, and glucose profiles.^[25]

Lean mass loss is halted by a high protein diet, which is known to preserve resting energy expenditure (REE). According to Wycherley TP *et al.*'s meta-analysis of 24 RCTs, subjects in both the high protein diet (1.250.17 g/kg body weight/day) and standard protein diet (0.720.09 g/kg body weight/day) groups had reduced REE, but the REE was higher in the HPD subjects (142 kcal/day, 95% CI, 16–269 kcal/day). A significant contributing factor to weight loss in the NLI arm was the average percentage of total energy that our study participants got through protein sources, which was 30.03%.^[26] Saturated fat intake should be kept to under 7% of total calories and cholesterol intake should be kept to under 200 mg per day. Additionally, polyunsaturated fats should make up no more than 10% and monounsaturated fats no more than 20% of total calories.^[27] The high-unsaturated/low-saturated fat diet (LC) group achieved weight loss and a significant reduction in cardiovascular disease risk factors, whereas the NLI arm's consumption of

low saturated fat of 6.95 percent of total calorie intake resulted in weight loss.^[28] The study that showed reduced carbohydrate diets were connected with considerable weight loss at 3–4 (MD 2.59 [3.93, 1.25] kg) supports the fact that our study participants consumed 55.01% of their total calories from carbohydrates.^[29] Sedentary time or sedentary behaviors, such as watching television, have been correlated with metabolic syndrome, according to published research.^[30-33] NLI of this study insisted on multiple short bouts when the patient is convenient made increase physical activity. Jakicic JM *et al.* looked at the outcomes of prescribing planned exercise in a series of brief bouts rather than one long bout.^[34] According to another study, patients who were told to exercise at home rather than in a controlled environment reported significantly more weekly minutes of physical activity. Similar to lifestyle exercise,^[35-37] home exercise appears to reduce obstacles to physical activity such as travel time, cost, the need for child care, or shame over being seen in public.

Apply to preventive practice

The results of the study identified that NLI is effective in urban settings in reducing weight, and it is proved that the involvement of community health nursing personnel in lifestyle modification is more effective not only in weight reduction but also in controlling blood pressure, diabetes, and improving the profiles of cholesterol and thyroid.

Limitation and strengths

Before the trial began, we had established nurse-led interventional strategies that the National Program for the Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases, and Strokes did not regularly offer to their obese patients. It also suggests that dropout rates may be reduced by giving participants more freedom in their way and place of their follow-up.

However, medical treatment for obesity is not widely practiced in India; therefore, changes in lifestyle have the biggest impact on weight loss. This study also had a small sample size, which cannot be extrapolated to a larger population, a short-term evaluation, and was only conducted in urban Puducherry. The duration of the study is less (16-week follow-up). Increased follow-up visits would yield better outcome evaluation.

Conclusion

Through this study we inferred that NLI strategies significantly reduce weight and make improvements in glucose, thyroid, and cholesterol profiles. Manpower may be increased during the follow-up process to motivate participants consistently. Additionally, the authors recommend carrying out a similar study at the national level comparing populations in rural and urban areas. In the same way, qualitative research can be carried out in the future to identify the variables that lead to long-lasting behavioral change in obesity therapy.

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Conflicts of interest

There are no conflicts of interest.

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