Original Article

Protocol of Randomized Controlled Trial to Evaluate the Effectiveness of Nurse-Led Intervention on Weight Reduction among Adults with Obesity in Urban Areas of Puducherry

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Abstract

Background: A large percentage of non-communicable diseases are preventable through the reduction of behavioral risk factors which is due to physical inactivity and unhealthy diet. Reducing the burden of obesity is likely to make a substantial impact on mitigating the mortality and morbidity due to non-communicable diseases. This study aims to evaluate the effectiveness of a nurse-led intervention on weight reduction among urban adults. **Methods:** This trial is a two-arm parallel group randomized controlled trial comparing the intervention arm-nurse-led intervention (NLI, n = 219) with the control arm-general care (GC, n = 219). Participants randomized to the NLI group will receive the interventional package for 12 months which includes health education and motivational strategies during follow-up. Baseline, 6-month and 12-month follow-ups will be conducted to assess primary and secondary outcomes for both arms using the WHO Steps questionnaire. The analysis will use an intention-to-treat approach to examine the change in behavioral and physical and biochemical parameters. **Conclusion:** The nurse-led intervention aims to provide an evidence-based acceptable and flexible support strategy for weight reduction in obese adults. This will impart healthy life skills to adults and also improve their health status and enable an adult to take charge of their health and this will ultimately prevent or delay non-communicable diseases. **Trial Registration:** Clinical Trials Registry India, CTRI/2021/12/038785. Registered prospectively with CTRI on 21/12/2021.

Keywords: Effectiveness, non-communicable disease, nurse-led intervention, obesity, randomized controlled trial, weight reduction

Introduction

Obesity is defined as abnormal or excessive fat accumulation that presents a health risk. The issue has grown to epidemic proportions, with over 4 million people dying each year as a result of being overweight or obese in 2017 according to the global burden of disease. Once considered a problem only in high-income countries, overweight and obesity are now dramatically on the rise in low- and middle-income countries, particularly in urban settings.[1]

Reducing the burden of these common risk factors is likely to make a substantial impact on mitigating the mortality and morbidity due to NCDs. Positive changes were observed in the community-based healthy lifestyle intervention program among adults with pre-diabetes.[2] As a contribution of population growth and aging together with economic transition resulted from changes in risk factors profile, non-communicable diseases (NCDs), and the attributed number of related deaths are expected to increase substantially in the future; particularly in low- and middle-income countries and this increase is most marked in the urban population.[3] High burden of NCD risk factors in the urban population of Puducherry and the burden was particularly higher among males. This typically emphasizes the need to address these issues comprehensively as a part of the NCDs prevention and

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control strategy.[4] Moore *et al*.[5] examined African women's perception of their risk of obesity-related co-morbid illness by using anthropometric measurements and self-reported demographics. This study reveals that >80% of the women were either overweight or obese. Overweight women reported having a higher risk of each disease.

A larger proportion of adults were found to have pre-hypertension and obesity shows the need for early intervention and clinically, significant weight loss was achieved in various clinical stings among obese clients with lifestyle intervention.[6-10] There are plenty of studies available to assess the burden of NCDs. But limited studies are only available on NCDs risk factors reduction and randomized control in weight reduction, especially in community settings. The objective of this study is to evaluate the effectiveness of a nurse-led intervention on weight reduction among urban adults. The nurse-led intervention will be designed to adapt the prevention approach through intervention along with nurse support. In addition to addressing obesity, this intervention will give the participants the strategies they need to shift smoothly and overcome any obstacles. Such research will benefit not just the study population but also other regions of India, and it will undoubtedly set the stage for future public health studies on NCDs. The primary objective of this study is to compare the effectiveness of a nurse-led intervention on weight reduction (5% or greater from the baseline weight) among adults with obesity.

Methodology

Study design, setting, and participants

This is an open-label two-arm, parallel-group, and randomized controlled trial**.** One of the four districts that make up the South Indian union territory of Puducherry is the Puducherry district, also referred to by its former name Pondicherry district. According to the Census of India 2011, 49.22% people of Puducherry reside in urban areas and 50.6% in rural ones.[11]

Randomly selected urban areas from currently functioning urban health facilities (Odiansalai, Kosapalayam, Muthialpet, Dubrayapet I, Lawspet I, Reddiarpalayam, Mettupalayam, and Gorimedu) in Puducherry were screened for obesity. WHO Kish method will be adapted to select a single person from each household.

This study will recruit those who reside in urban areas of Puducherry for the past year or longer, with a BMI of 25 or more and aged between 18-50 years. After obtaining informed consent from the eligible adults from all villages 55 adults will be randomly selected for each. This study will exclude adults with limitations for physical activities, medications that can affect weight loss, a severe form of any diseases, visual, and hearing impairments, and who are currently on a weight loss program, bariatric surgery, pregnant, and psychiatric disorders.

Sample size calculation

Based on an existing literature search (done clinical setting), the calculated sample size was low and could not find similar community-based trials on weight reduction. With the assumption of the mean difference in the percentage of body weight reduction of 7% in the interventional group versus1% in the control group with 95% CI, 80% power, and the ratio between intervention and control arm as 1:1 by using Open Epi Version 3.01 the sample size estimated at 398. Totally, 438 samples (219 in each arm) have been estimated to recruit for this trial which allows for an anticipated dropout rate of 10%

Development of nurse-led intervention (NLI) in the weight reduction program

The nurse-led intervention (NLI) program content was developed and designed based on the recommendations made by experts from various fields namely Preventive and Social Medicine, endocrinology, general medicine, adult health nursing, Dietetics, Physiotherapy, and Medical social work through focus group discussion considering the enablers and barriers on weight reduction of the obese people from the same community.

The NLI program consists of two modules [Table 1] covering a broad range of topics "Education on Lifestyle Changes and Motivational Strategy during Follow-Up." Each module is divided into three portions to promote participation in the program [Table 2]. The NLI on weight reduction focuses on offering a variety of attainable strategies, including a minimal calorie deficit with a more

Table 1: Content of educational session

Session	Topics	Duration/Teaching method/AV aids
Week-1 Healthy dietary pattern		
Module 1	Importance of maintaining healthy weight, Obesity- Causes, Body mass index, Waist circumference, complication, Calorie Balance Calorie deficit	Lecture cum discussion with Posters/PPT
Module 2	Foods to be included, Foods to be restricted, Foods to be avoided. Limiting portion sizes, Use of Food Diary	Lecture cum discussion with Posters/PPT
Module 3	Healthy food exhibition (Food groups Healthy plate, Foods to be included, restricted and avoided for healthy weight loss, Portion sizes, Method of cooking for weight loss, Choices for breakfast, lunch, snacks, and dinner-game)	Fun—veggie game, Creating their healthy plate for breakfast. lunch, dinner-game
Week-2 Physical activity—Exercises		
Module 1	Walking on weight loss, Use of fit bit bands	Lecture cum discussion Posters/PPT
Module 2	Suriya namaskaram on weight loss	Demonstration and return demonstration
Module 3	Avoiding regaining lost weight	Lecture cum discussion Posters/PPT

The intervention will be given group-wise for 2 weeks at the Anganwadi center located in each interventional area.

balanced diet, incorporating millets into a daily routine diet, reducing fat and sugar intake, increasing fiber through locally available vegetables and fruits, better portion control (my plate), incorporating walking or suryanamaskar or both as per recommended protocol in daily routine, and avoiding regaining of lost weight. The education will be delivered directly group-wise at Anganwadi centers located in the respective areas.

Application of health promotion model

The main idea of this study is the creating impact of an individual's cognitive-behavioral aspect, and Pender's HPM is utilized as a research framework to encourage adherence to food and exercise to lead NLI. The application of HPM will primarily focus on individual clients rather focus on families and peer groups[12] [Figure 1].

Procedures

This trial has been approved by the Institute Ethics Committee (No. JIP/CON/IEC/2021, dated 20.10.202) and registered with the Clinical Trials Registry India (CTRI/2021/12/038785). The permission was obtained from Govt. of Puducherry, DHFWS, and Health Research Wing (No. 08/2021/HRW/DHFWS, dated 23.09.2021) to conduct a study in the urban areas of Puducherry. This study protocol adhered to SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines and will be conducted from January 2023 to December 2024. All trial procedures and outcome assessments will be completed with face-to-face interaction during the home visit and mobile communication.

Screening and Participant Recruitment: The WHO KISH method was applied while screening obesity to select one adult from each household. After obtaining informed consent from the eligible adults) the benefits of the study are explained, along with the possibility of being recruited for the trial using a simple screening tool consisting of demographic details like age, sex, education, address, contact no, occupation, income,

Table 2: Motivational strategies planned during follow-up

Motivational strategies planned during follow-up
The booklet will be given. Provided with self-monitoring devices (Nutritional measuring cup, Fitbit bands, Diary).
BMI, Ideal body weight, and Calorie requirement will be calculated using online health calculators-www.nin.res.in
A model menu plan (individually tailored) will be prepared based on calorie requirement with 200 Kcal of calorie deficit, biochemical parameters, physical activity, and spending ability on food.
Track their activity and calorie intake using fit bit bands and Diet Cal software and participant will be contacted via mobile or by a visit to inform them about their track. Expected to track the steps and other activity levels.
Participants will make and receive phone calls or text/voice messages related to adherence to intervention and clarification of doubts monthly once the direct visit is not made.
Group exercises for peer motivation will be organized within 6 months in all villages
Counseling will be given to the participants tracked with poor adherence to diet and exercise through video consultation or phone calls or text/ voice messages.
One motivational talk by experts will be audiotaped and sent to participants

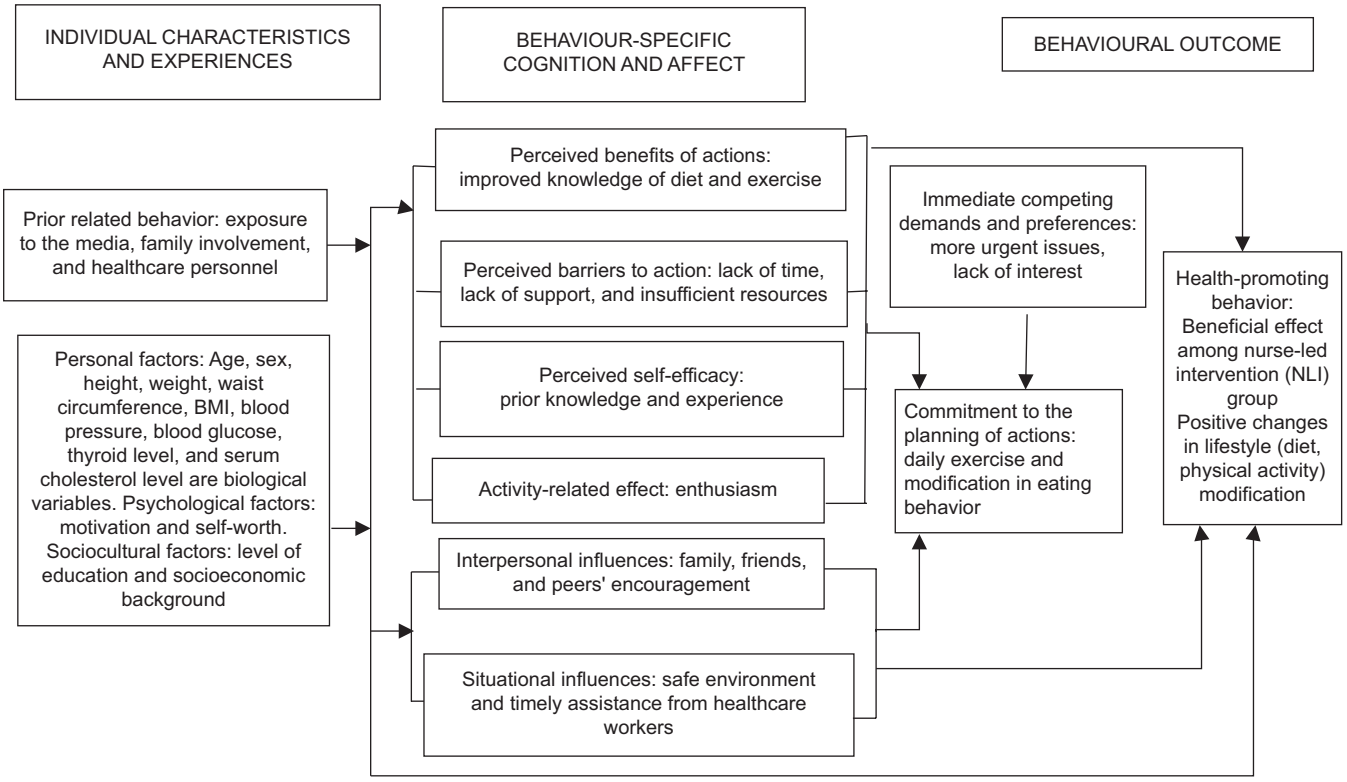

Figure 1: Health promotion model application

present health problems, family history of any diseases, any limitations for physical activities**,** any medications history, treatment or weight loss program, and availability of smartphone along with physical parameters of height and weight. Overall 982 adults were screened for obesity and 622 were found to be obese as per the Asian BMI classification. Multistage random sampling will be employed to recruit 438 samples for this trial [Figure 2].

Phase 1—Baseline assessment: After obtaining informed consent from the eligible adults in all six clusters (areas), 44 adults will be randomly selected in each. The benefits of the study will be explained, along with the possibility of being allocated to either the intervention group or the control group. The baseline information will be collected by the investigator for all adults in six clusters using the WHO STEPS (version 3.2) questionnaire for chronic disease risk factor surveillance to measure individuals' risk factors in three steps. Each interview will last for 20-30 minutes.

Behavioral risk factors (Step 1). Interviews will be conducted on demographic characteristics such as age, gender, residence, education, and occupation income including contact details. The use of tobacco, alcohol, diet, and physical activity will be assessed. Show cards will be used to describe the physical activity (type and intensity), standard drink (alcohol), and a serving of fruits and vegetables.

Physical measurements (WHO Step 2). Height, weight, waist circumference (WC), and blood pressure (BP) will be measured by following standard guidelines. Participants' height will be measured using a portable stadiometer in bare feet ensuring standing straight with calves, upper back, and head against the wall with a head level with a horizontal Frankfurt plane at the nearest 0.1 cm. Weight will be measured in a standing position wearing lightweight clothing barefoot using a digital weighing scale set at the nearest 100 gm. Waist circumference is taken midway between the lower margin of the least palpable rib and the top of the iliac crest right after exhalation using a stretch-resistant measuring tape. Blood pressure will be checked using a digital BP monitor by positioning the client to sit straight with back support and keeping the feet flat on the floor with legs uncrossed. Placing the arm on a table at the level of the chest with the palm face upwards place the bottom of the cuff above the bend of the elbow and tighten the cuff comfortably 2 fingers fit snugly. Explain to a participant that he/she might feel slight pressure while inflating the cuff by pressing the start button. Three BP readings, every three minutes apart will be captured using an automatic blood pressure monitor, and the last two readings will be averaged to determine the BP status.

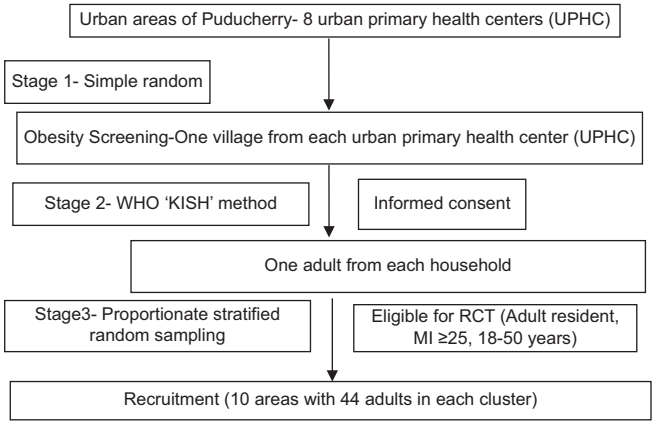

Figure 2: Recruitment of study participants

Biochemical measurements (WHO Step 3). Each participant will be explained the need and purpose for overnight fasting (10–12 hours). A blood sample will be collected in a seated position in their living room on the next day morning and will be transported to the institute's biochemistry laboratory for estimation by maintaining an appropriate cold chain. Fasting blood glucose and total cholesterol will be estimated in a clinical biochemistry lab, tertiary referral hospital, Puducherry using commercially available kits without sample pretreatment on fully automatic random access biochemistry analyzer AU5811 adapted to clinical chemistry auto analyzer based on spectrophotometry (Beckman Coulter Inc, Brea, California, USA). Glucose oxidase peroxide and cholesterol oxidase peroxide will be used for the estimation at 520 nm and for the estimating thyroid profile indirect method immunoassay without deproteinization will be used on DXI 600 (immune—analyzer-Beckman Coulter Inc, Brea, California, USA)

Phase 2—Randomization, allocation, and blinding

Following completion of baseline questionnaires (time point 1), participants are randomized between the intervention (NLI group) and general care control condition (GC group). The randomization is done among eight areas, with four areas in the intervention group and four areas in the control group, which will be done using simple random allocation. The study participants will be assigned to the NLI group and GC group area-wise (to prevent intervention contamination) just before intervention through a simple random technique. Once allocated to a study arm, both participants and research personnel will not be blinded to group allocation. Participants in both study arms will be able to access general care during the 12 months of the trial period. Participants are encouraged to tell their general practitioner (Family Doctor) that they are participating in this research trial as part of the intervention or control study arm. Blinding the researcher and the participants is not possible because the interventions involved health education booklets, personal house visits, and mobile communications.

Phase 3—Intervention

Intervention (NLI group)

Participants allocated to the intervention study arm will be provided with group-wise educational intervention on healthy eating patterns and physical activity—exercise to reduce weight for 2 weeks at the Anganwadi center located in each interventional area. The educational methods used for the

healthy eating pattern sessions are lectures cum discussions, Posters, and healthy food exhibitions.

The educational methods used for the healthy eating pattern sessions are lecture cum discussion, Posters and demonstration, and return demonstration of suriya namaskaram. BMI, Ideal body weight, and Calorie requirement will be calculated using online health calculators-www.nin.res.in). A model menu plan (individually tailored) will be prepared based on calorie requirement with 200 Kcal of calorie deficit, biochemical parameters, physical activity, and spending ability on food. Investigator will track their calorie intake using Diet Cal software. The initial phase of the intervention will involve a one-day recall using measuring spoons and cups, and the same will be evaluated after six and twelve months. The DietCal software accepts food values in the form of portions that can be eaten, and the data will be analyzed to determine the number of nutrients and food groups consumed. Investigator will track their activity regularly through fit bit bands. The amount of physical activity will be calculated by the MET minutes per week in step 1 of the WHO questionnaire on behavior (the time spent being physically active in the last 7 days). The number of steps (data from the fit band) and the reps and sets of the Surya Namaskar will be counted under the same questionnaire. This will be assessed at three points of time at baseline and 6 months and 12 months.

One motivational talk by experts will be audiotaped and sent to participants. Study participants will be provided with a booklet and self-monitoring devices (nutritional measuring cups, and fit-bit bands). Participants will be encouraged to use mobile communication, group exercises, and counseling The educational sessions will be repeated during the follow-up period at the end of the sixth month after the midline assessment (time point 2)

Control (GC group)

Participants allocated to the control study arm will be informed through phone calls and messages that they have completed the first stage of the research study (time point 1; baseline assessment), with two further stages to be completed in 6 months (time point and 12 months (time point 3). Once, all three assessment time points have been completed, participants in the control arm will have completed their participation in this trial and will be provided with educational booklets.

Safety monitoring

Two primary strategies are in place to monitor participants and ensure their safety throughout the trial. Participant progress will be monitored by the investigator to identify the risk of injury. The trial investigators are registered nurses and midwives with additional qualifications in the field of community health nursing in India. The participant will be contacted regularly through phone calls, WhatsApp messages along with direct home visits. This will encourage participants to seek support from their support network (e.g. partner, family member) and health professional (e.g. GP/Family Doctor), and if feeling unsafe, to contact emergency services, JIPMER Hospital. Participants will be contacted by the trial investigator within 72 hours via telephone to conduct a risk assessment and determine whether they participant is still eligible to continue in the study and will be provided assistance to find appropriate support and hospital care if required.

Phase 4—Outcomes assessment

Primary and secondary outcomes will be assessed through a face-to-face interview using the WHO STEPS questionnaire and blood sampling at the 6-month and 12-month follow-ups, respectively [Table 3].

Data analyses

All analyses will be undertaken in SPSS software version 22.0. The intention to Treat Approach will be followed with a loss to follow-up or missing data imputed by the latest observations carried forward. Analyses will be carried out within and between clusters. Unadjusted relative risk with a 95% confidence interval will be calculated as a measure of the strength of the association. A *P* value of less than 0.05 will be considered statistically significant. A consort flow diagram is showing the progress through phases [Figure 3].

Discussion

The worldwide prevalence of obesity nearly tripled between 1975 and 2016. Overweight and obese are linked to more deaths worldwide than underweight. In comparison with NFHS-4, most States/UTs in NFHS-5 have higher prevalence rates of overweight or obesity. From 21 to 24 percent for women and 19 to 23 percent for males, respectively, are the national increases. More than a third of women (34–46%) are overweight or obese in the following states: Kerala, A and N Islands, Andhra Pradesh, Goa, Sikkim, Manipur, Delhi, Tamil Nadu, Puducherry, Punjab, Chandigarh, and Lakshadweep.[13] A large percentage of NCDs are preventable through the reduction of behavioral risk factors such as tobacco use, harmful use of alcohol, physical inactivity, and unhealthy diet are largely modifiable.

Table 3: Outcomes schedule with time points

	Pretest T_1	Intervention 0	6-month follow-up T_2	12-month follow-up T_3
Primary outcome				
Weight	X	-	X	X
Secondary outcome	X	-	X	X
Tobacco	X	-	X	X
Alcohol	X	-	X	X
Diet	X	-	X	X
Physical activity	X	-	X	X
Waist circumference	X	-	X	X
Blood pressure	X	-	X	X
Blood glucose	X	-	X	X
Lipid profile	X	-	X	X
Thyroid profile	X	-	X	X

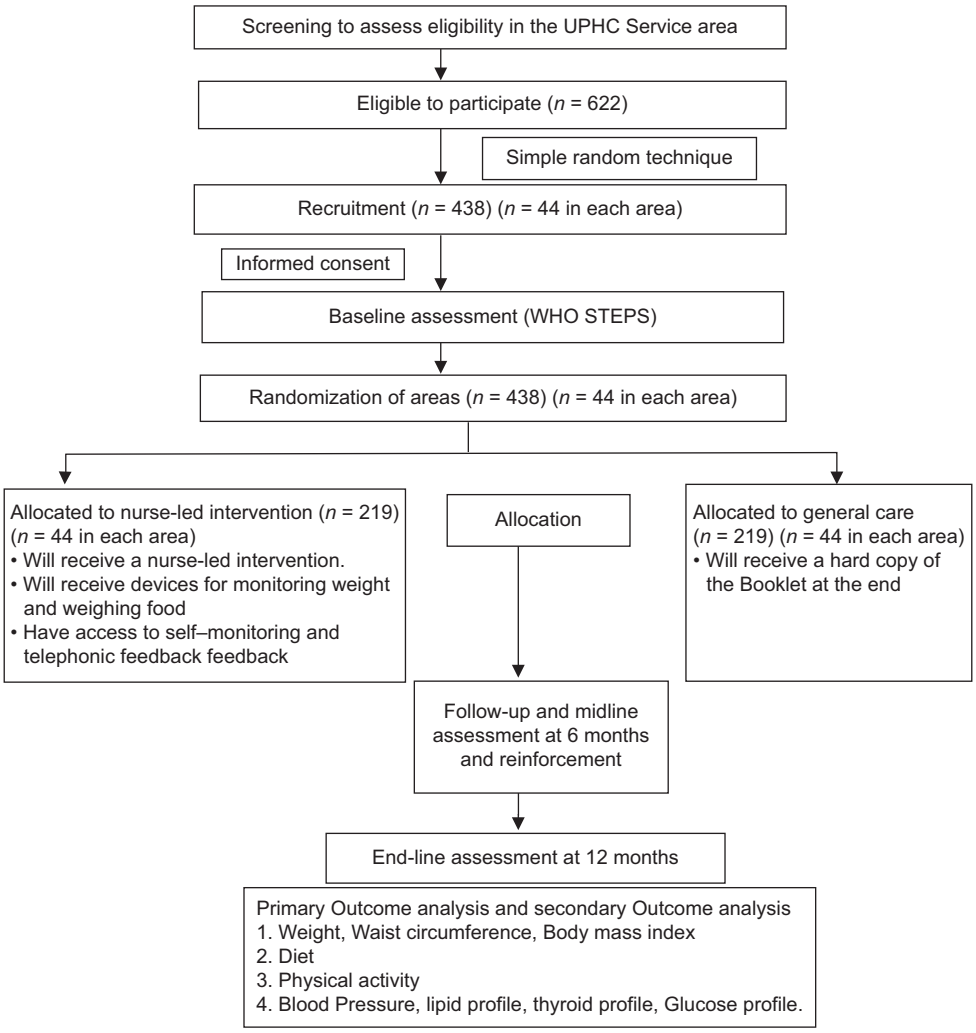

Figure 3: Consort Diagram

The majority of behavioral weight loss strategies have not shown to be sustainable in terms of weight management or long-term success. Since this unrealistic focus on weight loss by providers was a critical takeaway from our intervention, it may be crucial to urge more emphasis on other non-weight-related outcomes of obesity treatment interventions.[14] The consensus of the National Dietary Guidelines calls for reducing carbohydrate intake, favoring complex carbohydrates and low glycemic index foods, increasing fiber intake, decreasing saturated fat intake, finding the right balance of essential fatty acids, reducing trans fatty acids, slightly increasing protein intake, reducing salt intake, and limiting sugar intake. These recommendations apply to Asian Indians in any location, although they are especially relevant to those who live in metropolitan and semi-urban settings. Applying these recommendations correctly will aid Asian Indians' rising "epidemics" of obesity, metabolic syndrome, hypertension, T2DM, and CVD.[15] Because of their limited time, many doctors can only offer basic nutritional recommendations. Lack of information about a balanced diet, frequent festivals and socializing, and lack of access to professional nutrition guidance are obstacles to Asian Indians sticking to their diets successfully. To improve weight reduction, patients should be checked for dietary compliance and encouraged to increase their physical activity time and intensity after having their activity levels evaluated. Patients who reduce or discontinue their physical activity should receive advice on starting it up again.[16] Also studies support and proved the importance of follow-up to adhere to diet and exercises for a better outcome.

Strengths and Limitations

For the first time, a community-based weight loss program utilizing mobile technology will be studied within Puducherry urban areas with long-term follow-up. Additionally, the intervention was planned with the same population's facilitators and challenges in mind. Every step of the intervention and follow-up care is entirely focused on an individual's needs. Additionally, follow-up at various intervals will be assessed over a full year. The outcomes are thus representative of this group. We anticipated a diverse demographic in the control and NLI group as well. It is impossible to include men and women equally because we screened more women than men due to the nature of their jobs, males were not available at home during

the day. It is important to address the "digital divide," unequal access to digital technologies, and differences in participants' technological literacy.

Overcoming barriers like the stigma of obesity, self-interest, and family support will make it easier to implement the intervention of health care practitioners. Also, the cost of interventions must be considered before implementing these interventions into the program.

Conclusion

Along with addressing obesity, this intervention will provide the participants with the tools they need to transition easily and get past any challenges. These studies will benefit not only the study population but also other parts of India and undoubtedly pave the way for upcoming public health investigations into NCDs. Adults will learn healthy life skills, have better health, and be able to take responsibility for their health, which will ultimately prevent or delay non-communicable diseases.

Trial status

This trial will recruit and conduct a baseline assessment of the participants between November 2022 and January 2023 from the screening conducted between February and May 2022.

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Conflicts of interest

There are no conflicts of interest.

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