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STUDY PROTOCOL

REVISED Effectiveness of multi-component modular intervention among adults with prehypertension in a village of Dakshina Kannada district - a community-based interventional study – protocol [version 2; peer review: 2 approved]

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Abstract

Introduction: The Joint National Committee (JNC 7) report on Prevention, Detection, Evaluation, and Treatment of Hypertension, defined "prehypertension," as individuals with a Systolic Blood Pressure (SBP) in the range of 120–139 mmHg and a (diastolic blood pressure) DBP of 80–89 mmHg. Prehypertension is directly linked with hypertension which is a precursor of CVDs. Owing to its high conversion rate to hypertension, it is important to identify individuals with blood pressures in this category and bring about lifestyle modifications in them that can prevent them from being hypertensive and from developing cardiovascular diseases later in life.

Methods: This randomized controlled trial will be done among the selected pre-hypertensive adults of all genders residing in Kateel Gram panchayat, Dakshina Kannada district, Karnataka. A baseline survey will be done initially to assess the level of prehypertension among the study population. To study the effectiveness of the intervention, 142 individuals will be randomly allocated using block randomization technique to intervention and control groups. A multi-component module (educational intervention) will be developed, validated, and administered to participants in the intervention group, while the control group receives standard care. Each participant will then be followed up once in four months till the end of the study period of one year to assess for changes in SBP, DBP, WHR, BMI, stress levels, and usage of tobacco and alcohol.

Ethics and dissemination: Institutional Ethics Committee approval was obtained from Kasturba Medical College in Mangalore, India. The plans for dissemination of findings include presenting at scientific conferences and publishing in scholarly journals.

Open Peer Review

Approval Status ✓ ✓

	1	2
version 2 (revision) 22 Sep 2023	✓ view	✓ view
version 1 14 Jun 2023	? view	? view

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Any reports and responses or comments on the article can be found at the end of the article.

Keywords

Hypertension, Prehypertension, Randomized controlled trials, Block randomization, Non Communicable diseases, WHO-STEPS.

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REVISED **Amendments from Version 1**

The prevalence of pre-hypertension across the globe has been summarized. The methodology has been written clearly and appropriate references have been provided wherever applicable. The implication of the study has been added in the abstract and end of the paper. All the typographical errors have been rectified.

Any further responses from the reviewers can be found at the end of the article

Introduction

Hypertension is a modifiable risk factor for cardiovascular diseases (CVD) and a major cause of premature death. Early Identification and prevention lower the risk for the same.[1]

In 2003, the Joint National Committee in their 7th report on the Prevention, Detection, Evaluation, and Treatment of Hypertension introduced a new term 'Prehypertension' which included SBP (Systolic blood pressure) ranging from 120 – 139 mmHg and DBP (Diastolic blood pressure) from 80 – 89 mmHg. This was a redefined new criterion to increase the emphasis on the excess risk factors associated with BP in this range and to bring public attention to the importance of the prevention of hypertension among all genders.[2–5]

Globally, the prevalence of prehypertension is 31% with a high conversion rate to hypertension of 30%.[2] It is responsible for almost 62% of cardiovascular and 49% of ischemic heart diseases.[5] Prevalence of pre hypertension in a study done in Korea was reported to be 31.6%.[6]

The prevalence of pre-hypertension in the Indian subcontinent from a study conducted in 2016 was approximately 47% among young urban residents.[7] A prevalence of 31.5% was observed in South India, 30% in West India, 24.6% in North India, and 20.9% in East India.[8]

A prevalence of 40.2% was noted among males and 30.1% among females.[9,10] A prevalence of 42.8% was noted in southern India.[11]

Prehypertension is directly linked with hypertension which is a precursor of CVDs. Owing to its high conversion rate to hypertension, it is important to identify individuals with blood pressures in this category and bring about lifestyle modifications in them that can prevent them from being hypertensive and from developing cardiovascular diseases later in life.

Multiple lifestyle modifications lower blood pressure by modifying the risk factors of prehypertension and hypertension.[12] The nutritional requirements of a pre-hypertensive individual can be addressed by adopting a DASH diet (Dietary Approaches to Stop Hypertension). This diet promotes the reduced intake of salt, incorporating fruits, vegetables, micronutrients, and lean meat instead of full-fat meat, low-fat dairy, nuts, and legumes.[13]

Physical Inactivity and a sedentary lifestyle are major risk factors for hypertension. Exercise training lowers blood pressure (SBP: 11 mmHg and DBP: 8 mmHg) in about 75% of the individuals diagnosed with hypertension.[14] Another risk factor for hypertension is salt consumption. Reducing salt intake has been identified as one of the most cost-effective measure to reduce the risk of cardiovascular diseases, stroke, and coronary artery disease.[15]

Tobacco use is one of the biggest public health threat world has ever faced and is one of the major causes of cardiovascular diseases.[16] There is a causal relationship between the harmful use of alcohol and increased levels of blood pressure which poses it as a risk factor.[17,18]

Many people with hypertension did not adhere to healthy lifestyle.[19] This resulted in poor treatment outcome. This shows that early identification of individuals with prehypertension along with risk behaviours is important to reduce the burden of non-communicable diseases. The burden of hypertension and prehypertension were found to be high in rural setting.[20,21] Effective non-pharmacological interventions, health education, and lifestyle modifications have been used extensively for lowering blood pressure among the pre-hypertensive individuals.

Research gaps identified

Even though a high prevalence of pre-hypertension is observed in India, there is a paucity of literature on its prevalence in rural areas of South India. Many hypertensive patients do not adhere or practice life-style modifications to control blood pressure. Also, adequate emphasis is not given to the importance of halting progression of pre-hypertension blood pressure levels to hypertensive levels in preventive programs. The present study is undertaken to fill the gap in existing information on the effectiveness of multi-component intervention in preventing the progression of pre-hypertension to hypertension among adults in a rural area of South India.

Review of literature

The term "pre-hypertension" was used by the Joint National Committee's Seventh Report to describe a group of people who have elevated blood pressure and a greater burden of other risk factors, like obesity, diabetes, dyslipidemia, and coronary artery disease.[2–5]

In the Cross-sectional study conducted by McNiece KL et al, the prevalence of prehypertension and hypertension was 15.7% and 3.2% respectively. The factors like risk for overweight or overweight along with the racial trait and gender were associated with pre-hypertension independently.[18]

In a cross-sectional study done by Parek A *et al.* in Vadodara, the prevalence of prehypertension was found to be 24.2%. The mean systolic and diastolic blood pressures were directly proportional to age. The study concludes that periodic screening of people, especially high-risk people regularly, can help in the early detection of hypertension and thus prevent cardiovascular diseases.[22]

In the study conducted by Parthaje PM on the prevalence of prehypertension in adults in urban South India, blood pressure levels in the prehypertensive range were found in 343 (55%) of the total 643 adults and 185 (29.6%) had previously undiagnosed hypertension. Among the study subjects, a higher proportion were females (69.1) and people in the age group 20 to 39 years (40.5%). A high prevalence of prehypertension was found among the study population.[4]

A study, done by Pimenta E. *et al* which evaluated the effects of pre-hypertension concluded that all prehypertensive patients should get non-pharmacological treatment with lifestyle changes such as weight loss, dietary changes, and an increase in daily physical activity because these measures significantly lower the risk of cardiovascular events.[23]

In an interventional trial conducted by Darviri C. *et al.* to examine the effectiveness of an 8-week health promotion program consisting of multiple lifestyle modifications intended to lower blood pressure (BP) in pre-hypertensive and patients with hypertension, a significant decline in the blood pressures and anthropometry measurements in the intervention arm was observed when compared to the control arm.[24]

In a randomized controlled trial studying the importance of multiple lifestyle modifications for patients with prehypertension and hypertension, the intervention tool included health education modules regarding various food pattern changes and increased physical activity. The lifestyle modification and follow-up lasted for two months. The study concluded that combination of various lifestyle interventions, physical activity, and dietary interventions diminished blood pressure and reduced CVD events.[25]

A study conducted by Rubinstein A in Latin American countries, showed that after 12 months of mHealth (mobile Health) interventions consisting of diet and physical activity among prehypertensives, there was an increase in daily intake of fruits and vegetables and a decrease in daily dietary fat, refined sugar, and high sodium post intervention. A reduction in body weight was also observed at the end of the study period.[26]

Aim

To study the effectiveness of the multi-component modular intervention on pre-hypertension among adults in a rural area of Dakshina Kannada District in Karnataka.

Objectives

The objectives are:

- To develop a comprehensive multi-component module for people with pre-hypertension.

- To assess the effectiveness of modular interventions among prehypertensive individuals.

Methods

Background information on the study area

The study will be conducted in the three selected villages of Kateel, a temple town in the Moodubidri taluk[27] of Dakshina Kannada District of coastal Karnataka in south India. The population of all the selected villages within Kateel Gram panchayat, according to the census India 2011 is 4470 with 2378 in Kondemula (literacy rate of 87.87%), 1454 in Nadugodu (literacy rate: 85.82%) and 658 in Kilinjur (89.84%).[28]

Study design

The initial baseline survey estimated 32% prevalence of prehypertension. One forty-two hypertensive individuals, as per the sample size calculation will be included in the trial.

This will be an open-label study RCT with the parallel group. The trial will be reported along with the Consolidated Standards of Reporting Trials (CONSORT).[29]

The protocol for this study is reported along with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Guidelines. The Reporting guideline criteria include a completed SPIRIT checklist.[30]

Study participants

The study population will be selected from the prehypertensive individuals identified during the baseline by simple random sampling.

Duration of the study

The study will be conducted for one year from June 2021 to Dec 2022.

Sample size calculation

A sample size of 142 prehypertensive individuals (71 in each group with 1:1 allocation) was calculated using the formula mentioned below and considering a difference in change score of 0.37 (standard deviation- 0.88)[26] in SBP between the intervention and control groups, assuming a clinically acceptable difference of 0.5 irrespective of gender, 95 % confidence interval, 90% power, and along with 10 % non-response error

$$N = 2 \times \left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 X S^2 / (\delta - \delta_0)^2$$

Where Z 1-α =1.96 for a 95% confidence interval, Z1-β = 1.281 for 90% power. δ - δ0 = 0.5 (clinically acceptable difference). S is the combined standard deviation.

Eligibility criteria

Adults of all genders above the age of 18 who are diagnosed with prehypertension will be eligible to participate. Pregnant women, individuals diagnosed with hypertension, genetic disorders/disabilities, and those who are bedridden will be excluded. Those who do not give consent will also be excluded from the study.

Sampling method and randomization technique

Simple random sampling will be used to select the study participants from the prehypertensive individuals identified at the baseline assessment. In this randomized controlled Trial (RCT), 142 individuals irrespective of gender, who are pre-hypertensives will undergo random allocation to the intervention and control group. i.e. intervention (A) and control group (B).

Applying the block randomization technique, for allocating the 142 participants into two groups 36 blocks are needed, with 4 participants in each block (36 blocks x 4 participants =144 participants). The allocation of the participants will be done by one of the investigator (NK). The collected data will be recorded by another investigator (PM).

Intervention procedure

A health education module will be developed based on the inputs from the subject experts, an extensive literature review, and in-depth interviews with the local stakeholders. This will be a multi-component audio-visual module with relevant textual information.

The creation and curation of the educational module will be done in the vernacular language and local context. Before the modules are used in the study environment, their content validity will be assessed. The module will contain four parts.

Part I will include general knowledge about hypertension, its causes, and risk factors. It will emphasize the importance of treating it on a prehypertensive level and preventing the conversion to hypertension.

Part II will include pictorial demonstrations of various dietary modifications, the food that they should avoid to prevent the progression of prehypertension to hypertension, and the food that they should eat more to improve their health.

Part III will be about the importance of physical activities, their benefits, different types of exercises, and the guidelines to follow them.

Part IV will consist of different kinds of stress and anxiety relieving techniques and the guidelines to follow them.

The expected group size per session will be 10. The interventional session will be administered by the investigator.

Three sessions of multi component modular intervention with a duration of 20 minutes each will be administered to the pre-hypertensive individuals in the intervention group at an interval of three months.

Sessions will be conducted in groups at the Rural Health Training Centre of Kasturba Medical College at Kateel. The participants missing one intervention session will be contacted and will be rescheduled with a different group. Participants in the study who miss two or more sessions will be deemed to have dropped out.

Instruments used for data collection

A Pretested, content validated and semi-structured questionnaire will be used. The instrument will include the following sections: A) General participant information B) Knowledge about high blood pressure, C) WHO STEPS Questionnaire,[31] D) Perceived Stress Scale,[32] E) Socio-economic scale.[33]

Data collection methodology

The study area will be visited on a pre-informed date. All the selected individuals (n=142) with prehypertension from the three villages of Kateel will be included. Participants will be then approached in their houses. They will be explained in their vernacular language regarding the objectives of the study and a participant information sheet will be provided to each one of them which consists of details regarding any queries on dropping out. Written informed consent will be obtained from the participants who are willing to take part. Each eligible participant will be interviewed, and their anthropometric measurements and blood pressure will be measured using standard methods.[31] Stress levels will be assessed. It will be in the form of a 5-point Likert scale will be used. The responses ranging from strongly agree (5) to strongly disagree (1) will be recorded. The control group will receive standard patient care.

The intervention and control groups will be followed up every four months. On each visit, the blood pressure and anthropometry of the intervention group will be recorded at Rural Health Training Centre (RHTC), Kateel. The study participants allocated to the control group will be followed up in their houses.

A daily track record of diet, physical activity, and stress reduction activities will be maintained by the participants. This will be verified by the investigator during each intervention session. At the end of the fourth follow-up session, an assessment will be done concerning their perception of hypertension, perceived stress, usage of tobacco and alcohol, and anthropometric measurements.

The data will be collected by the Investigator.

CONSORT diagram[29]
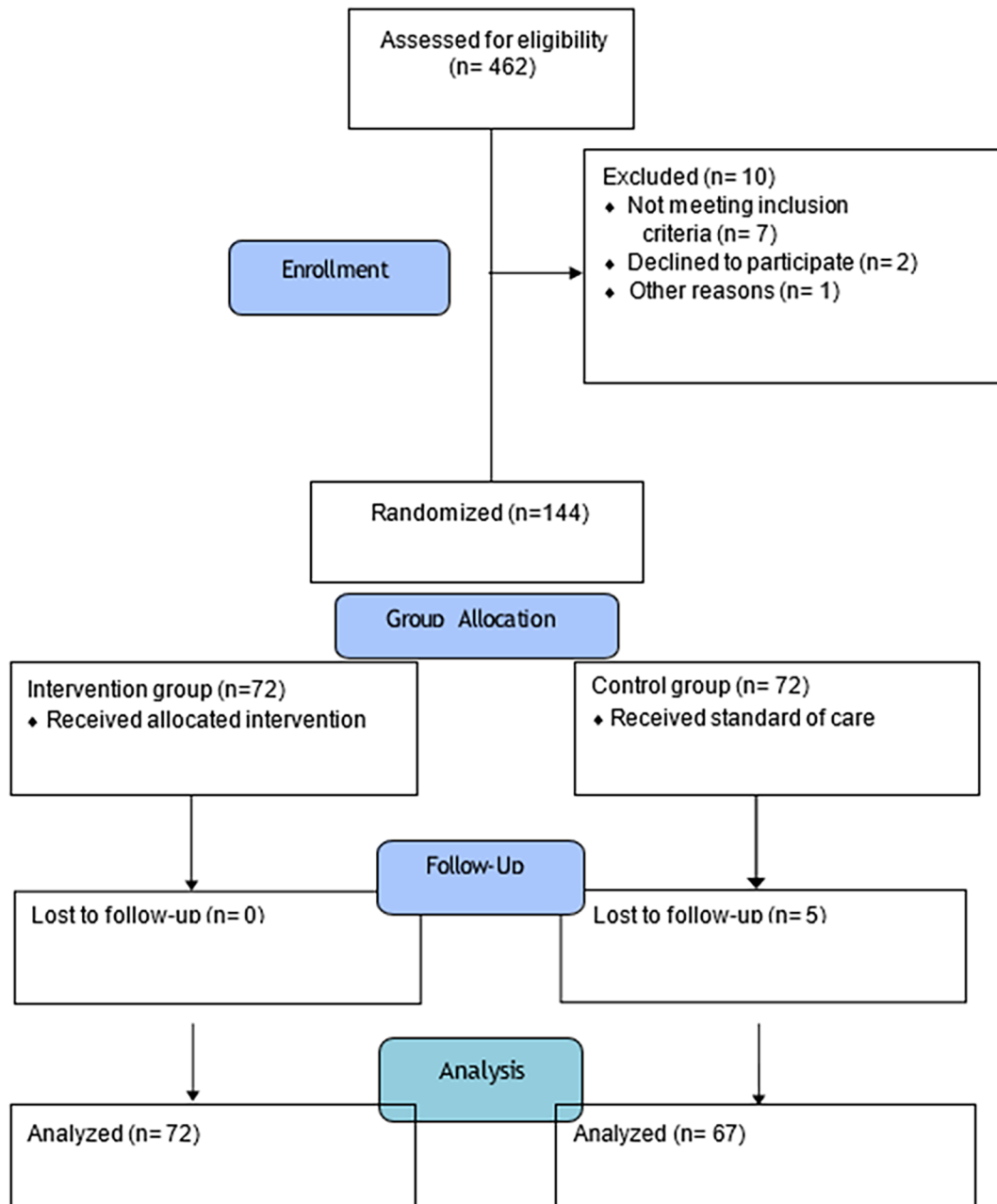
Test procedures
Measurement of weight[31]

A portable digital weighing scale will be used to measure weight. The person will be requested to take off their shoes, slippers, sandals, and socks before being instructed to step one foot onto either side of the scale. The instructions will be given to the participant to stand still with their arms at their sides and to face forward. On the instrument, the weight will be measured in kilos to the nearest 0.1 cm. After each use, the scale will be reset to zero.

Measurement of height[31]

A portable length measuring board will be used to measure height. The participant will be required to take off their shoes, slippers, sandals, and/or headgear which includes a hat, cap, hair bows, comb, etc It will be measured over a thin fabric. The participant will be instructed to face the investigator while standing on the board. The contestant must stand with their feet together, their heels pressed up against the backboard, and their knees straight. The subject is instructed to maintain a straight-ahead gaze with eyes level with ears. By lowering the measuring arm to the patient's head, the reading will be measured to the nearest 0.1 cm.[31]

Body mass index[31]

The formula to calculate BMI will be

$$BMI = Weight\,(in\,kg) / \left\{ height\,(in\,meters)^2 \right\}$$

Asian BMI Classification:

< 18.5 kg/m^2 = underweight

>18.5-22.9 kg/m^2 = ideal

>23-24.9 kg/m^2 = overweight

> 25 kg/m^2 = obese

Measurement of waist-circumference[31]

A tape with consistent tension will be used to measure waist circumference. It will be measured at the midpoint between the bottom of the last rib and the top of the iliac crest at the end of regular respiration while the arms are relaxed at the sides. The participant will be instructed to wrap the tape over themselves, and the investigator will assist them in positioning it properly. The subject will be instructed to stand with their feet together, their weight spread evenly over both feet, and

their arms relaxed by their sides. Only one reading of the measurement will be made at the level of the tape, to the closest 0.1 cm.

Measurement of hip-circumference[31]

Hip circumference will be measured using a constant tension tape. The measurement will be taken with the subject minimally clothed. The individual is instructed to stand with their feet together, their weight evenly spread over both feet, and their arms at their sides. The tape would be positioned horizontally over the maximum circumference of the buttocks. Measurement will be read at the level of the tape to the nearest 0.1 cm. It will be measured only once.[31]

Waist - hip ratio (WHR)[31]

WHR will be calculated using the formula

$$Waist\,Hip\,Ratio = waist\,circumference / hip\,circumference.$$

As recommended by the WHO,

$$< 0.9 - Normal > 0.9 - High\,(Men)$$

$$< 0.85 - Normal > 0.85 - high\,(Women)$$

Physical activity[31]

The subjects were questioned regarding their physical activities during work and leisure time using WHO STEPS questionnaire.

1) **Sedentary:** Any daytime behaviour that involves spending less than 1.5 metabolic equivalents (METs) of energy when sitting, reclining, or lying down is considered sedentary behaviour.

2) **Moderate:** physical activities that required moderate effort and increases the pulse rate, eg: brisk walking, dancing, painting houses, roofing, thatching, household chores, moving loads less than 20 kg.

3) **Rigorous:** Highly strenuous activity resulting in fast breathing and a significant rise in heart rate. such as jogging, swimming quickly, digging trenches, volleyball, and lifting loads weighing more than 20 kg.

WHO recommendations for physical activity:

150 minutes of moderate-intensity exercise each week, 75 minutes of vigorous-intensity exercise, or an equivalent amount of both moderate- and vigorous-intensity exercise that results in at least 600 MET-minutes.

Blood pressure measurement[31]

Using a digital automatic blood pressure monitor, blood pressure will be measured. Participants will be requested to sit on a chair with their feet flat on the floor, their legs uncrossed, and their backs supported. At the level of the heart, the cuff will be placed on the patient's uncovered upper arm. It will be placed over the brachial artery. A maximum of two fingers should fit between the distal portion of the cuff and the skin when it is properly positioned. A few centimeters (one-two) above the antecubital fossa will be where the distal portion of the cuff is placed. After detecting a pulse, the monitor will begin taking measurements. Three measurements will be done and the average of the second and third reading will be taken.

Outcome measures

- Mean change in blood pressure measurements (SBP, DBP)

- Change in mean BMI, waist circumference and hip circumference, WHR

- Difference in the usage of tobacco and alcohol

- Change in mean stress levels.

Data management

The collected data will be entered into an excel sheet. After the entry, the data will be cleaned and the missing information will be obtained by reaching out to the study participant. Validation of the proforma will be checked with 10% of the data obtained. A committee for data management will not be formed. The data will be kept confidential with password protection. It will be coded and analyzed using the software 'IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.[34]

Data analysis

Results will be expressed as proportions and summary measures (Mean±SD). Appropriate tables and figures will be used. Intention to treat analysis (ITT) will be followed.

The variables will be compared across the prehypertensive and the normotensive groups using the chi-square test. The factors associated with prehypertension will be studied using Binary logistic regression and multivariate logistic regression. The 'Hosmer and Lemeshow goodness-of-fit test will be used to assess the fit of the logistic model. A P value < 0.05 will be considered a significant association between predictive and outcome variables (Prehypertension). The confidence intervals (95%) for both the unadjusted and adjusted odds ratios will be reported.

The baseline and post-intervention values across the intervention and control groups will compare using the Mann-Whitney U test for the data that are non-normally distributed and an independent t-test will be used for the normally

distributed data (SBP, DBP, BMI, WHR, and stress levels) and chi-square test (Usage of Alcohol and Tobacco). The change score within the group will be compared using repeated measures of ANOVA (WHR) and Friedman's test (SBP, DBP, BMI, and Stress). A 'p-value less than < 0.05 will signify statistical significance.

Implications

The findings of this study may help in prioritizing the resources towards the reduction of NCD risk factor. The urban areas have better access to healthcare facilities, including hospitals, clinics, and specialists which allows for more frequent check-ups, early diagnosis, and timely treatment. In Rural areas there is limited access to healthcare services, with fewer healthcare facilities and specialists available. As a result, individuals in rural areas may face challenges in getting regular check-ups and accessing specialized care. The multi-component module developed can be used for conducting health education sessions among pre-hypertensive adults in rural areas.

Such modular educational interventions will encourage individuals to adapt healthy lifestyle and self-care practices which can promote healthy living.

Study status

Currently, the participants have been recruited and two sessions of multi-modular comprehensive intervention have been conducted for the participants in the intervention group.

Ethical consideration

IEC (Institutional Ethics Committee) of Kasturba Medical College, Mangalore has approved the study (IECKMCMLR-12/2020/399).

Any changes in the protocol during the course of the study will be submitted to the IEC and approval will be obtained.

This trial is registered prospectively in CTRI India (CTRI/2021/11/037852). Necessary permissions will be obtained from the district health authorities.

A participant information sheet will be administered to all participants. Participants who agree to take part in the study will be asked for a written statement of informed consent. The participant information data will be kept in confidence.

Data Monitoring

Interim analysis will be conducted at 6 months after the initiation of the study. Trial conduct audit will be carried out by the investigators at regular interval of 3 months. No known adverse effect is associated with this study. A separate Data Monitoring Committee (DMC) will not be constituted. The modular intervention will be administered among the participants in the control group at the end of the study.

Author contributions

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Roles: Conceptualization, Validation, Writing – Original Draft Preparation, Writing – Review & Editing

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Data availability

Underlying data

No underlying data is associated with this article.

Extended data

Open Source Framework: Effectiveness of multi-component modular intervention among adults with prehypertension in a village of Dakshina Kannada district - a community-based interventional study – protocol, https://doi.org/10.17605/OSF.IO/X7N2C.[35]

The supplementary materials available are:

- Informed consent form and participant information sheet

- Questionnaire

- SPIRIT checklist

- Consort diagram

Reporting guidelines

SPIRIT checklist. Open Science Framework. EFFECTIVENESS OF MULTI-COMPONENT MODULAR INTERVENTION AMONG ADULTS WITH PREHYPERTENSION IN A VILLAGE OF DAKSHINA KANNADA DISTRICT - A COMMUNITY-BASED INTERVENTIONAL STUDY – PROTOCOL. DOI: https://doi.org/10.17605/OSF.IO/YWSJ4

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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Open Peer Review

Current Peer Review Status: ✓ ✓

Version 2

Reviewer Report 03 October 2023

https://doi.org/10.5256/f1000research.155720.r208639

✓ **Hon Lon Tam** 🆔
The Nethersole School of Nursing, The Chinese University of Hong Kong, Hong Kong, Hong Kong

No new concern is raised in the revised version.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cardiometabolic diseases, controlled trial, systematic review, meta-analysis, gerontological nursing

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 25 September 2023

https://doi.org/10.5256/f1000research.155720.r208638

✓ **Karani Magutah** 🆔
Moi University, Eldoret, Uasin Gishu County, Kenya

I have no further comments

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Medical physiology and epidemiology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

- -

Version 1

Reviewer Report 06 July 2023

https://doi.org/10.5256/f1000research.141793.r178670

?

Hon Lon Tam (ID)

The Nethersole School of Nursing, The Chinese University of Hong Kong, Hong Kong, Hong Kong

Abstract:
The use of abbreviation in abstract is not a common practice. CVD was not introduced before the first use. Please add a section to describe the significance and contribution of the study to current research and practice.

Introduction
1. The use JCN7 was good, but the it was very old. Also, none of the cited Reference #2-4 was the direct JNC7 document. There are many updated hypertension guidelines you can refer to (1-3).

2. You mentioned lifestyle modifications were important to pre-hypertension people. Please summarize the points as it was too long now.

3. Please summarize the prevalence of pre-hypertension from various studies.

4. You may mention that many people with hypertension did not adhere to healthy lifestyles (4). You can use this point to link with the development of interventions for pre-hypertensive people.

5. You described that several studies had shown the effectiveness of using multi-components to improve blood pressure and lifestyles among pre-hypertensive people, What was the value/significance of current study?

Methods:
1. Where are the villages, South, North, East or West India? Any specific reasons to select these villages?

2. The study had been done in Dec 2022. Why to publish a study protocol, but not the study findings?

3. "For getting a block of four participants with an equal .... The participants will be allocated into either group in a batch of four." Might not be necessary.

4. Please describe the development of the intervention. Any guideline to follow the development of the content?

5. What will be the expected group size? Who delivered the education? What was the interval between each session, daily, weekly?

6. It was unclear that there were 4 modules, but only 3 sessions. Please describe with modules will be delivered in session 1, 2, and 3.

7. How to control subject contamination between intervention and control groups?

8. Please update blood pressure measurement. It has been suggested to measure at least twice in one measurement (1-3).

9. Who collect the data from the participants? Who assign the participants to groups?

10. The use of ITT is good, but how to treat missing data?

11. The change score within the group will be compared using repeated measures of ANOVA and Friedman's test. Any test to examine the change between groups (intervention vs control)?

Implications:

Please use paragraph format. Urban-rural disparities in hypertension management has been shown globally for years (4, 5, 6). The authors need to make further discussion.

Figure:
There was only 71 participants assigned to intervention group, but 72 will receive the modules?

Suggested references:
1. Unger T, Borghi C, Charchar F, et al. 2020 International Society of Hypertension Global Hypertension Practice Guidelines. Hypertension. 2020;75(6):1334-1357.

2. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology. 2018;71(19):e127-e248.

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4. Tam HL, Chair SY, Leung ISH, Leung LYL, Chan ASW. US Adults Practicing Healthy Lifestyles Before and During COVID-19: Comparative Analysis of National Surveys. JMIR Public Health

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5. Ba HO, Camara Y, Menta I, et al. Hypertension and Associated Factors in Rural and Urban Areas Mali: Data from the STEP 2013 Survey. International Journal of Hypertension. 2018:6959165.

6. Ratovoson R, Rasetarinera OR, Andrianantenaina I, Rogier C, Piola P, Pacaud P. Hypertension, a Neglected Disease in Rural and Urban Areas in Moramanga, Madagascar. PLoS One. 2015;10(9):e0137408.

References

1. Unger T, Borghi C, Charchar F, Khan NA, et al.: 2020 International Society of Hypertension Global Hypertension Practice Guidelines.*Hypertension*. 2020; **75** (6): 1334-1357 PubMed Abstract | Publisher Full Text

2. Whelton PK, Carey RM, Aronow WS, Casey DE, et al.: 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.*Hypertension*. 2018; **71** (6): e13-e115 PubMed Abstract | Publisher Full Text

3. Williams B, Mancia G, Spiering W, Agabiti Rosei E, et al.: 2018 ESC/ESH Guidelines for the management of arterial hypertension.*Eur Heart J*. 2018; **39** (33): 3021-3104 PubMed Abstract | Publisher Full Text

4. Tam HL, Chair SY, Leung ISH, Leung LYL, et al.: US Adults Practicing Healthy Lifestyles Before and During COVID-19: Comparative Analysis of National Surveys.*JMIR Public Health Surveill*. 2023; **9**: e45697 PubMed Abstract | Publisher Full Text

5. Bâ HO, Camara Y, Menta I, Sangaré I, et al.: Hypertension and Associated Factors in Rural and Urban Areas Mali: Data from the STEP 2013 Survey.*Int J Hypertens*. 2018; **2018**: 6959165 PubMed Abstract | Publisher Full Text

6. Ratovoson R, Rasetarinera OR, Andrianantenaina I, Rogier C, et al.: Hypertension, a Neglected Disease in Rural and Urban Areas in Moramanga, Madagascar.*PLoS One*. 2015; **10** (9): e0137408 PubMed Abstract | Publisher Full Text

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cardiometabolic diseases, controlled trial, systematic review, meta-analysis, gerontological nursing

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 06 Sep 2023

Rekha Thapar

1.The use of abbreviation in abstract is not a common practice. CVD was not introduced before the first use. Please add a section to describe the significance and contribution of the study to current research and practice.

Response
Thank you sir for the suggestion. We have included a section on the importance of the study in the abstract. The use of abbreviations before the first use has been rectified in the manuscript.

2.The use JCN7 was good, but the it was very old. Also, none of the cited Reference #2-4 was the direct JNC7 document. There are many updated hypertension guidelines you can refer to (1-3).

Response
Thank you sir for your observation. The term prehypertension was a classification introduced in JNC VII. The main objective of the trial is to study the effect of modular intervention in halting the progress of prehypertensives to overt hypertension. Prehypertension was initially redefined in JNC 7. Our focus is on individuals with prehypertension as they can progress to hypertension. Since the main focus of our study is on pre-hypertensives we have used the JNC-VII report.

3.You mentioned lifestyle modifications were important to pre-hypertension people. Please summarize the points as it was too long now.

Response
Thank you, sir. We have summarized the points as per your suggestion.

4.Please summarize the prevalence of pre-hypertension from various studies.

Response
Thank you. We have incorporated the suggestion in the manuscript.

5.You may mention that many people with hypertension did not adhere to healthy lifestyles (4). You can use this point to link with the development of interventions for pre-hypertensive people.

Response
Thank you sir We have incorporated your suggestion in the manuscript.

6.You described that several studies had shown the effectiveness of using multi-components to improve blood pressure and lifestyles among pre-hypertensive people, What was the value/significance of current study?

Response
Thank you, sir.
Studies using multi-component modular interventions have not been conducted previously in our study setting.
The intervention in our study will be administered using a module that is easy to comprehend and practice with the participants.
Modular interventions break down the process of improving health into manageable steps or modules, making it easier for individuals to implement changes gradually. The active food tracking component will self-motivate the participants to adopt healthy behaviour.

7.Where are the villages, South, North, East or West India? Any specific reasons to select these villages?
Response
The villages selected for the study are located in the southern part of India. These villages are the rural field practice area of the Department of Community Medicine, KMC Mangalore, to which the authors of the study are affiliated to.

8.The study had been done in Dec 2022. Why to publish a study protocol, but not the study findings?
Response
Analysis of the data is still underway.

9."For getting a block of four participants with an equal …. The participants will be allocated into either group in a batch of four." Might not be necessary.
Response
Thank you, sir. We have removed the same from the manuscript.

10.Please describe the development of the intervention. Any guideline to follow the development of the content?
Resposne
The intervention module is prepared based on the recommendations from WHO STEPS and National programme for prevention & control of cancer, diabetes, cardiovascular diseases & stroke (NPCDCS.

11. What will be the expected group size? Who delivered the education? What was the interval between each session, daily, weekly?
Response
The expected group size is 10 and the sessions are delivered by the principal investigator once in three months.

12. It was unclear that there were 4 modules, but only 3 sessions. Please describe with modules will be delivered in session 1, 2, and 3.
Response
The intervention tool (module) consists of four components. All the components are delivered during all three sessions.

13. How to control subject contamination between intervention and control groups?
Response
At the designing stage, we thought of assigning one of the selected villages for intervention and another selected village as control. However, this approach might result in an unequal number of prehypertensives in the intervention and control arm.
Only one prehypertensive from every household will be recruited for the study to prevent cross-contamination.

14. Please update blood pressure measurement. It has been suggested to measure at least twice in one measurement (1-3).
Response
Thank you sir. We have updated the measurements.

15. Who collect the data from the participants? Who assigns the participants to groups?
Response
The data is collected by the principal investigator (NF). Randomization and record keeping was done by co-investigators

16. The use of ITT is good, but how to treat missing data?
Response
The imputation technique will be used to treat the missing data. Also, the sample size was calculated considering a 10% loss to follow-up.
The same has been incorporated in the manuscript.

18. The change score within the group will be compared using repeated measures of ANOVA and Friedman's test. Any test to examine the change between groups (intervention vs control)
Response
Thank you, sir. Mann Whitney U tests will be used to examine the change between groups. The same has been included in the manuscript.

19. Please use paragraph format. Urban-rural disparities in hypertension management have been shown globally for years (4, 5, 6). The authors need to make further discussion.
Response
Thank you, sir. We have incorporated the changes as per your suggestion.

20. There was only 71 participants assigned to intervention group, but 72 will receive the modules?
Response
Thank you sir for pointing out the mismatch in the number. The same has been corrected in the manuscript.

Reviewer Report 04 July 2023

https://doi.org/10.5256/f1000research.141793.r178663

? **Karani Magutah** 🆔

Moi University, Eldoret, Uasin Gishu County, Kenya

I have 2 major and 1 minor comments as here below:

1. This is a trial and will have interventions in the one group and not the other (control). Participants are drawn from the same villages/community and this is likely to have contamination where individuals in the control group may see and be influenced by those in the intervention group. There is need for careful quality control considerations to fend off likely cross-over mainly from control to intervention arm when the investigators do not want this. One way to do this is having separate but homogenous villages for intervention and the control group.

2. To avoid a likely recall bias that may be introduced by weekly tracking of diet that participants were on throughout a week that has already passed, this could either be done more regularly (like twice a week) or have participants fill daily record-logs after every meal or at the end of every day. These records can thereafter be collected at the end of the week. This will help reduce recall bias that may compromise quality of the results.

3. Physical activity (PA) should be defined such that the intensity to be considered, the length and the frequency is clear for the reader. Usually, we have mild, moderate and vigorous intensity PA. Because participation in either may yield differing outcomes, the investigators may need to in their intervention have only form form that the participants could adopt. Similarly, the number of minutes in a week that is determined by the frequency and the length for each session could be clarified.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Medical physiology and epidemiology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 06 Sep 2023
Rekha Thapar

1.This is a trial and will have interventions in the one group and not the other (control). Participants are drawn from the same villages/community and this is likely to have contamination where individuals in the control group may see and be influenced by those in the intervention group. There is need for careful quality control considerations to fend off likely cross-over mainly from control to intervention arm when the investigators do not want this. **One way to do this is having separate but homogenous villages for intervention and the control group.**

Response
Thank you sir for your suggestion.
At the designing stage, we thought of assigning one of the selected villages for intervention and another selected village as control. However, this approach might result in an unequal number of prehypertensives in the intervention and control arm.

Only one prehypertensive from every household will be recruited for the study to prevent cross-contamination.

2. To avoid a likely recall bias that may be introduced by weekly tracking of diet that participants were on throughout a week that has already passed, this could either be done more regularly (**like twice a week) or have participants fill daily record-logs after every meal or at the end of every day.** These records can thereafter be collected at the end of the week. This will help reduce recall bias that may compromise the quality of the results.

Response
Thank you sir. We have incorporated your suggestion to record-log every meal of the participant on a daily basis.
The manuscript has been modified accordingly

3. Physical activity (PA) should be defined such that the intensity to be considered, the length and the frequency is clear for the reader. Usually, we have mild, moderate and vigorous intensity PA. Because participation in either may yield differing outcomes, the investigators may need to in their intervention have only form that the participants could adopt. Similarly, the number of minutes in a week that is determined by the frequency and

the length for each session could be clarified.

Response
The definition and recommendations for physical activity have been incorporated from the WHO-STEPS questionnaire.
The STEPS questionnaire includes questions to assess an individual's level of physical activity. It typically covers aspects such as the frequency, duration, and intensity of physical activity, as well as the types of activities individuals engage in (e.g., walking, cycling, sports).

Competing Interests: NIL

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