Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Lifestyle Modification Intervention to reduce blood pressure among Pre-Hypertensive patients in Maran, Pahang

Protocol summary

Study aim

The general objective of this study is to develop and implement the intervention and determine the effects of lifestyle modification intervention on blood pressure among the pre-hypertensive adults at primary care in Maran district, Pahang. The specific objectives are: a) To compare the socio-demographic characteristics of the respondents between intervention and control group at baseline. b) To identify the SBP, DBP, level of physical activity, dietary intake (total calorie intake, vegetable intake, fruit intake, plain water consumption, fat intake and salt intake), smoking status, alcohol consumption, nutritional status level, information, motivation and behavioural skills score on lifestyle modification at baseline in intervention and control group. c) To investigate the effect of intervention on the change of SBP, DBP, level of physical activity, dietary intake (total calorie intake, vegetable intake, fruit intake, plain water consumption percentage fat intake and salt intake), smoking, alcohol consumption and information-motivation-behavioural skills score in intervention group at baseline and three months after intervention, d) The change in SBP, DBP, level of physical activity, dietary intake (total calorie intake, vegetable intake, fruit intake, plain water consumption percentage fat intake and salt intake), smoking, alcohol consumption and information-motivation-behavioural skills score in control group at baseline and three months after intervention. e) To investigate the effect of intervention on the change in SBP, DBP, level of physical activity, dietary intake (total calorie intake, vegetable intake, fruit intake, plain water consumption percentage fat intake and salt intake), smoking, alcohol consumption and information-motivation-behavioural skills score in intervention group as compared to control group three months after intervention. f) To investigate the effect of intervention on the change in SBP, DBP, level of physical activity, dietary intake (total calorie intake, vegetable intake, fruit intake, plain water consumption percentage fat intake and salt intake), smoking, alcohol consumption and information-motivation-behavioural skills score between intervention and control group at baseline and three months after intervention. g) To investigate the effect of intervention on the change in SBP, DBP, level of physical activity, dietary intake (total calorie intake, vegetable intake, fruit intake, plain water consumption percentage fat intake and salt intake), smoking, alcohol consumption and information-motivation-behavioural skills score between intervention and control group at baseline and three months after intervention after adjusted for other factors.

Design

The study is a cluster-randomized controlled trial intervention study. This will be a two arm intervention study that is randomized into intervention and control group. Study will be an unblended or open label study in which all parties are aware of which group which participants received as this is a population trial.

Settings and conduct

a) Study Location This study will be conducted at health clinics under the operational management of the Maran District Health Office. There are a total of ten health clinics in Maran district, which are Jengka 2 Health Clinic, Jengka 22 Health Clinic, Jengka 7 Health Clinic,Chenor Health Clinic, Bandar Jengka Health Clinic, Maran Health Clinic, Pekan Awah Health Clinic, Pekan Tajau Health Clinic, 1Malaysia clinic Jengka and 1Malaysia Clinic Maran Impian Town. Most of these clinics provide several services like medical outpatient services, emergency medical services, maternal and child care for residents around Maran district. b) Study Population The population of study include adults attending public health facilities for hypertensive screening with systolic blood pressure of 120-139 mmHg and/or diastolic blood pressure of 80-89 mmHg at Maran district under Maran District Health Office. c) Sampling Population The sampling consist of patients diagnosed with pre-hypertension and are not on anti-hypertensive medication and under follow up at public health facilities in Maran districts during data collection period from 15th

February 2018 to 15th December 2018. d)Sampling Frame The sampling frame will be the list of public health facilities in Maran district. e)Sampling Unit The sampling unit is the individual patient who fulfills the inclusion criteria in each selected public health facilities. f) Randomization Technique and concealment The method of randomization will be the randomized block design using computer randomization plan generator. Block will be created to assign numbers equally to each group assign the block. The block size will be 2 in which we can make 2 possible sequences of AB and BA. Allocation sequence and concealment will be conducted by the representative from Maran District Health Office who is not involved in the research. Allocation concealment will be by using a sealed envelopes into which is is the treatment group A with lifestyle modification intervention and treatment group B without lifestyle modification intervention. A representative from Maran District Health Office who is not involved in the research will distribute and open the envelope.

Participants/Inclusion and exclusion criteria

Inclusion criteria The inclusion criteria include: i. Residence of Maran district ii. Age group 18 to 59 years old iii. Owns a working smartphone. Exclusion criteria The exclusion criteria are: i. foreigner ii. pregnant women iii. patients with physical deformities like amputation at upper or lower limbs which makes it difficult for blood pressure measurement by using a sphygmomanometer

Intervention groups

a) Intervention group An intervention group will receive the Lifestyle Modification Intervention developed based on Information-Motivation-Behavioural Skills (IMB) model on blood pressure, which will be conducted after period of baseline data collection and randomization. Intervention will include video presentation to explain the Information component of IMB. Lecture and “focus” will explain the Motivation and Behavioural Skills component of IMB. b) Control group A single control group will receive the usual care of treatment which includes health education material given by the treating medical officer, assistant medical officer and nurse.

Main outcome variables

The primary outcomes of this study: a) Systolic Blood Pressure (mmHg) three months post intervention as compared to baseline. b) Diastolic Blood Pressure (mmHg) three months post intervention as compared to baseline. The secondary Outcome of this study: Information, motivation and behavioural skills score on lifestyle modification (physical activity, healthy diet, smoking and alcohol).

General information

Reason for update

Acronym

LMIPHPT

IRCT registration information

IRCT registration number: **IRCT20180124038497N1**
Registration date: **2018-03-15, 1396/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-15, 1396/12/24**
Update count: **0**

Registration date

2018-03-15, 1396/12/24

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-01, 1396/12/10

Expected recruitment end date

2018-12-01, 1397/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Lifestyle Modification Intervention to reduce blood pressure among Pre-Hypertensive patients in Maran, Pahang

Public title

Lifestyle Modification Intervention to reduce blood pressure among Pre-Hypertensive patients in Maran, Pahang

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Blood pressure range between 120-139 mmHg Systolic and/or 80-89 mmHg diastolic Resident of Maran district, Pahang Own a working smartphone with installed Whatsapp application

Exclusion criteria:

Not taking any anti-hypertensives Pregnant women Not physically impaired like amputated limbs

Age

From **18 years** old to **59 years** old

Gender

Male

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **408**

Randomization (investigator's opinion)

Randomized

Randomization description
The method of randomization will be the randomized block design using computer randomization plan generator. Block will be created to assign numbers equally to each group assign the block. The block size will be 2 in which we can make 2 possible sequences of AB and BA. Allocation sequence and concealment will be conducted by the representative from Maran District Health Office who is not involved in the research. Allocation concealment will be by using a sealed envelopes into which is is the treatment group A with lifestyle modification intervention and treatment group B without lifestyle modification intervention. A representative from Maran District Health Offie who is not involved in the research will distribute and open the envelope.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Research and Ethics Committee

Street address
Jalan rumah sakit, Bangsar

City
Kuala Lumpur

Postal code
59000

Approval date
2017-06-08, 1396/03/18

Ethics committee reference number
11KKM/NIHSEC/P17-775

Health conditions studied

1

Description of health condition studied
Pre-hypertension

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
a)Systolic Blood Pressure (mmHg) three months post intervention as compared to baseline. b) Diastolic Blood Pressure (mmHg) three months post intervention as compared to baseline.

Timepoint
Before intervention and 3 months post intervention

Method of measurement
Blood pressure will be measured using a sphygmomanometer.

Secondary outcomes

1

Description
Information, motivation and behavioural skills score on lifestyle modification (physical activity, healthy diet, smoking and alcohol).

Timepoint
Before intervention and 3 months post intervention

Method of measurement
Questionnaire consisted of questions related to the Information and motivation to follow a healthy lifestyle to reduce pre-hypertension. For this include several sub-sections that include: a. Information on pre-hypertension b) Individual and social motivation related to pre-hypertension c. Behavioural skills on reducing pre-hypertension.

Intervention groups

1

Description
The intervention will be a Lifestyle modification intervention on blood pressure among pre-hypertensive patients module that will assert the information on risk factors of pre-hypertension and effects of unhealthy diet, smoking, physical inactivity and benefits of healthy diet. It will also include motivation to follow a healthy lifestyle to prevent hypertension. There will also be behavioural skills on following a healthy lifestyle to prevent hypertension. The IMB Model asserts that health-related information, motivation and behavioural skills are fundamental determinants of performance of health behaviours. To the extent that individuals are well informed, motivated to act and possess the requisite behavioural skills for effective actions, they will likely to initiate and maintain health-promoting behaviours and to experience positive health outcomes. The IMB approach to understanding and promoting health behaviour specifies a set of generalizable operations for constructing, implementing, and evaluating health promotion interventions for specific populations and health promotion behaviours of interest.Intervention will be delivered over a period of 2 months that will include two parts which are the half day health intervention session and the whatsapp session. There will be two half day health intervention session in which the second half day health intervention session will be conducted 2 weeks after conclusion of the 1st half day health intervention session and that both session will be in the same month. The second month will be second part of

the intervention which is the serial whatsapp delivery of health messages for a total duration of one month (15 messages every 2 days).During the first half day session, group of 30 to 40 will watch a video presentation on pre-hypertension, risk factors, complication and prevention of pre-hypertension. This video presentation address the information component of the Information Motivation and Behavioural Skills module. The video presentation will be in a DVD format and will be 10 minutes in duration. The video preparation will be prepared by the researcher and the health education committee of Maran district Health Office. The group of 30 to 40 participants will later be given a lecture to address the aspect of personal motivation to follow a healthy lifestyle. This lecture will address the motivation component of the Information, Motivation and Behavioural Skills module. The lecture will be prepared by the researcher and be delivered by the researcher himself. Duration of the lecture will be around 30 minutes. The group of 30 to 40 will later be broken up into smaller group of 8 to 10 (4 groups). The 4 groups will move around four booths with each session at each booth lasting 30 minutes. The 4 booths include a) understanding healthy diet, food calorie and reading food label b) recording height, weight and body mass index c) importance of physical activity d) Importance of drinking water and recording of drinking water. During the second half day session, group of 30 to 40 will again watch the video presentation addressing the information component of the IMB module. The group of 30 to 40 participants will be given a lecture addressing the motivation component of the IMB module and the group of 30 to 40 will be broken up into smaller groups of 8 to 10 (4 groups). The 4 groups will move around four booths with each session at each booth lasting 20 minutes. The 4 booths include a) importance of healthy diet, food calorie, understanding food label, importance of drinking water b) sharing session of Quit Smoking clinic, and teaching skills on how to stop smoking and which include making plan to stop, picking a start date c) telling the family and friends for social support to stop smoking and alcohol d) identify your triggers, learn to de-stress, using an alternative and replacement to smoking and alcohol. The next part of the Intervention module is the Whatsapp messaging from educator to participant. The Whatsapp educator to participant ratio is one educator to 200 participants. The indication for the Whatsapp messaging is for the continuous motivation component of the research.The relevant qualification for educator or educationist are health care staff in the clinic employed by the Ministry of Health Malaysia , who is well trained in the non-communicable diseases prevention and have participated in previous health events that include health campaigns and KOSPEN events.On a summary, the frequency of number of information lectures is two and is given on two separate days. The mode of delivery of lectures are given on a group of 30 lecture. The frequency of motivation lectures will be two given on separate days. The group size of group discussions in the behavioural arm of the study is of ‘group of 6 to 10’ and that the discussions are guided by the educators. The frequency and number of behavioural group discussions is eight with four lectures on each separate days. The arm of study (Information, Motivation and Behavioural) occur simultaneously together. Strategy to monitor adherence to intervention include face to face adherence reminder session that will take place after patient had agreed to join the intervention during the recruitment phase. This session include importance of following study guidelines for adherence to following intervention module. Subsequent session will occur at the follow up visits during the intervention day. Participants will be asked about any problems of following the intervention at home, and that participants will have an opportunity to ask questions and key messages from the initial session will be reviewed as needed.

Category

Prevention

2

Description

Control group will not receive the lifestyle modification intervention to reduce blood pressure among the pre-hypertensive patients. Control group will not be receiving any form of treatment for pre-hypertension. The control group will receive nothing in form of treatment or intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Jengka 2 Health Clinic

Full name of responsible person

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Web page address

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center

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4

Recruitment center

Name of recruitment center

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Full name of responsible person

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Recruitment center

Name of recruitment center

Pekan Tajau Health Clinic

Full name of responsible person

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6

Recruitment center

Name of recruitment center

Jengka 22 Health Clinic

Full name of responsible person

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7

Recruitment center

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Recruitment center

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Recruitment center

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10

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Universiti Putra Malaysia
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Subject's name will be kept on a password protected database and will be linked only with a study identification number for this research. The research identification number instead of patient's name will be used on subject data sheets. All data that will be entered into the computer will be password protected. On completion of study data in the computer will be copied to a USB and the data in the computer erased. USB and the hardcopy data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of study. The USB and data will be destroyed after period of storage. Study information will not be informed to the subjects. Subjects will not be allowed to view personal study data, as the data will be consolidated into a database. No personal information will also be disclosed and subjects will not be indetified when findings of surveys are published. In the event that new new information relevant to consent become available, subjects will informed.

When the data will become available and for how long
Privacy and confidentiality of personal information will be protected. Duration of storage and archieved of medical records will be kept until completion of data analysis which is from September 2017 to September 2020.

To whom data/document is available
Data/document will only be available for researchers.

Under which criteria data/document could be used
There is no further information

From where data/document is obtainable
There is no further information

What processes are involved for a request to access data/document
There is no further information

Comments