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The feasibility of a dietary intervention to reduce salt intake and increase high-nitrate vegetable consumption in middle-aged and older Malaysian adults with elevated blood pressure

Submission date 08/10/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/10/2019	**Overall study status** Completed	
Last Edited 12/02/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Dementia is an incurable progressive syndrome characterized by multiple cognitive deficits and loss of independence and is caused by one or more of several distinct neuropathological processes including Alzheimer's disease and cerebrovascular disease. Malaysia is experiencing rapid social-economic and nutritional transitions. Changes in individual eating and lifestyle patterns under the influence of westernized habits, as well as a rise in food availability and financial prosperity, have resulted in significant increases in the prevalence of cardiometabolic and neurodegenerative diseases. Observational evidence suggests several of the pathological processes underlying dementia might be delayed or prevented by dietary and other behavioural interventions, and in the absence of a cure, this represents the best opportunity for allaying its individual and social impact.

Healthy dietary patterns such as the Mediterranean Diet or Dietary Approach to Stop Hypertension have been linked in research studies, as well as further confirmed by some clinical trial evidence, to an improved cognitive function and reduced dementia risk. Recent analyses have identified the high content of inorganic nitrate as a potential nutrient involved the improvement of vascular and metabolic health associated with increased fruit and vegetable consumption. Similarly, these dietary patterns are characterized by low consumption of salt, which is mostly derived as a result of dietary displacement from the consumption of foods with low salt content as well as fresh, unprocessed food products. Increased nitrate consumption and lower salt intake may, therefore, have additional benefits on health outcomes such as blood pressure and cognition. However, this hypothesis has never been tested in previous interventions conducted in low-middle income countries which represent the main aim of this research.

This research aims to demonstrate the feasibility, acceptability and the potential to deliver a dietary intervention to increase the consumption in high-nitrate green leafy vegetables and reduce salt intake over a 24-week period in Malaysian adults with raised blood pressure. The results of the feasibility study will be used to inform the development of a follow-on efficacy trial

Who can participate?
Patients with hypertension aged 50 to 75 years

What does the study involve?
This dietary and behavioural intervention will focus on key components of local dietary patterns influenced by nutritional transition trends and aims to target two key components with protective (green leafy vegetables) and negative (salt intake) effects on human health.

Participants will be randomised into one of 4 groups:
Group (1) will receive written education materials on how to reduce salt intake
Group (2) will receive written education materials on how to increase intake of dietary nitrate
Group (3) will receive written education materials on how to reduce salt intake and increase intake of dietary nitrate
Group (4) will receive general healthy eating and lifestyle advice

What are the possible benefits and risks of participating?
The study has a potential health benefit for the participant as if they adhere to the recommended dietary changes, they can improve their blood pressure. They will also benefit from increased knowledge and awareness from the dietary education provided as part of the study. This is a low risk study and not anticipated to have any harmful risks as a result of participation. The participants may experience some time burden in relation to the time required for study assessment visits associated with data collection. Biological samples will be collected as part of these assessments and there is the potential risk, as always, of discomfort while providing these. This will be minimised by the use of trained data collectors who will follow protocol and ensure the comfort of participants at all times.

Where is the study run from?
South East Asia Community Observatory (SEACO), Malaysia

When is the study starting and how long is it expected to run for?
October 2019 to January 2021 (updated 19/07/2021, previously: July 2021 (updated 03/09/2020, previously: September 2020))

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
16/137/62

Study information

Scientific Title
A study to investigate the feasibility of a mixed-method intervention to reduce salt intake and increase high-nitrate vegetable consumption in middle-aged and older Malaysian adults with elevated blood pressure

Acronym
DePEC Nutrition RCT

Study objectives
To evaluate the feasibility of a dietary intervention to encourage dietary behavior change involving an increased consumption of nitrate-rich green leafy vegetables and reduction of salt consumption over a 24 weeks period in 120 Malaysian adults with high blood pressure (age 50 to 75 years).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 15/01/2019 MONASH University Human Research Ethics Committee (MUHREC) (Human Ethics Office, Monash University, Room 111, Chancellery Building E, 24 Sports Walk, Clayton Campus, Wellington Rd, Clayton VIC 3800, Australia; +61 3 9905 5490; muhrec@monash.edu), ref: 17864
2. Approved 30/09/2019, Medical Research and Ethics Committee Malaysia (MREC) (NIH

Secretariat and Ministry of Health Malaysia, Institute for Health Management, Kompleks Institut Kesihatan Negara (NIH), Block A,No 1, Jalan Setia Murni U13/52, Seksyen U13, Bandar Setia Alam, 40170 Shah Alam, Selangor, Malaysia; +60 (3)33628407; mrecsec@moh.gov.my), ref: #NMRR-19-617-45916

Study design
Randomised 2*2 factorial intervention trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pre-hypertensive, stage 1 hypertensive or diagnosed hypertensive

Interventions
This dietary and behavioural intervention will focus on key components of local dietary patterns influenced by nutritional transition trends and aims to target two key components with protective (green leafy vegetables) and negative (salt intake) effects on human health.

Participants will be randomised into one of 4 groups:
Group (1) will receive written education materials on how to reduce salt intake
Group (2) will receive written education materials on how to increase intake of dietary nitrate
Group (3) will receive written education materials on how to reduce salt intake and increase intake of dietary nitrate (combined intervention)
Group (4) will receive general healthy eating and lifestyle advice (control)

Participants will be followed up for 6-months.

Block randomisation will be carried out to assign the eligible participants into one of the four arms. Block sizes of 4 will be used in randomisation. The interviewers will be blinded to the participant assignment to intervention arms

Intervention Type
Behavioural

Primary outcome(s)
Feasibility of the intervention evaluated by:
1. Participant recruitment and retention on the trial
2. Appropriateness and validity of data collection processes and secondary outcome measures
3. Acceptability of intervention by different ethnic group and during different cultural and religious observances
4. Adherence to the intervention evaluated with self-reported (dietary questionnaires) and objective biomarkers (urinary nitrate and salt excretion)
5. Resource capacity for the management of the intervention – identify the direction and magnitude of mismatch in resource expectation and resource capacity

These feasibility considerations will be assessed by questionnaire and review of field notes at baseline, 2 months, 4 months, 6 months, and by focus group discussion post intervention.

Key secondary outcome(s))
1. Cognitive test performance - A validated version of Montreal Cognitive Assessment test (MoCA), auditory verbal learning test, categorical verbal fluency and trail making test (TMT) part B will be conducted at baseline and end of study visits
2. Resting blood pressure - Three consecutive measurements of resting blood pressure readings will be recorded in sitting position using a calibrated OMRON monitor. The median measure will be used to estimate the blood pressure. Blood pressure will be measured at all outcome assessment visits (baseline, 2 months, 4 months and 6 months)
3. Body composition: height (by stadiometer), weight (by weighing scales), waist circumference (by tape measure), body fat (by Tanita body composition monitor). Body composition will be measured at baseline and end of study visits
4. Physical performance: hand-grip strength (by a hand grip-strength dynamometer), gait speed (4 meter walk test) and mobility (Timed Up and Go (TUG) test). Physical assessments will be conducted at baseline and end of study visits
5. Behaviour change - adherence to nutritional interventions measured by dietary methods (multiple-pass 24-hr recall; FFQ) and urinary biomarkers (24-hr sodium and nitrate excretion). These assessments will be conducted at baseline and 6 months (interim adherence check at 2 and 4 months by spot urine). Saliva samples and salivary strips will be also collected to measure changes in nitrite concentrations during the intervention at baseline and 6 months (interim adherence check at 2 and 4 months by saliva strips)
6. Plasma biochemical outcomes monitored including routine biomarkers of cardio-vascular risk (C-reactive protein, glycated haemoglobin, nitro-tyrosine) and more direct brain measures such as plasma brain-derived neurotrophic factor and plasma amyloid β42 and amyloid β40. All blood sampling assessment methods will be conducted at baseline and end of study visits

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Male and female participants with an age between 50 and 75 years from the participants of SEACO
2. Pre-hypertensive, stage 1 hypertensive or diagnosed hypertensive: Any person who has a self-reported history of hypertension (on or not on medication) or those who had a blood pressure recording of systolic blood pressure 120-159 mmHg or diastolic blood pressure 80-99 mmHg
3. Participants will have a body mass index greater than 18.5 kg/m2
4. Not severely cognitively impaired (defined as a Mini Mental Examination Status [MMSE] score of 19 or over)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
73

Key exclusion criteria
1. Are participating in other research clinical studies
2. Are unable to provide consent
3. Adhere to any therapeutic diet such as weight loss treatments or a gluten-free diet
4. Have systolic blood pressure more than or equal to 160 mmHg and /or diastolic blood pressure more than or equal to 100 mmHg
5. Are strictly vegan (likely to have a high intake of vegetables). Since Chinese and Indian participants are more likely to follow a vegetarian or semi-vegetarian diet, in order to maintain representativeness across ethnic groups included in the study, only participants on strictly vegetarian diet (i.e., vegans) will be excluded from the study
6. Have a history of active cancer and any diagnosis of malignant cancer in the last 5 years
7. Have a history of excessive alcohol intake (>21 units of alcohol per week)
8. Have a history of brain damage, significant head trauma (including loss of consciousness as a result)
9. Have a diagnosis of acute and chronic medical conditions interfering with the study outcomes such as systemic infections (tuberculosis, hepatitis B, HIV/AIDS), severe liver and kidney diseases, inflammatory bowel diseases, coronary heart diseases, cerebrovascular diseases or diabetes on insulin therapy
10. Have had any major surgical operations (in the past six weeks or planned in next one year) that could interfere with the study outcomes
11. Have current diagnosis of moderate or severe depression, or other serious mental or brain disorder and currently treated with psychiatric drugs (antidepressants, sedatives, antipsychotics)
12. Have systemic use of sodium-altering drugs (angiotensin-converting-enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), corticosteroids, diuretics, hormonal therapies (oestrogens, thyroxin, and progesterone), non-steroidal anti-inflammatory drugs (NSAIDs), proton-pump inhibitors), organic nitrates
13. Have a change in anti-hypertensive medication regimen for the previous 3 months (to make sure these disorders are under strict control to avoid interference with the study outcomes)
14. Have limited mobility due to any reason
15. Are planning to move house in next one year

Date of first enrolment
28/10/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Malaysia

Study participating centre
South East Asia Community Observatory (SEACO)
6th Floor, Wisma Centrepoint
Jalan Sia Her Yam
Johor
Malaysia
85000 Segamat

Sponsor information

Organisation
Monash University, Malaysia

ROR
https://ror.org/00yncr324

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Sodium intake	19/01/2022	20/01/2022	Yes	No
Results article		13/05/2024	12/02/2025	Yes	No
Protocol article		27/08/2020	19/07/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes