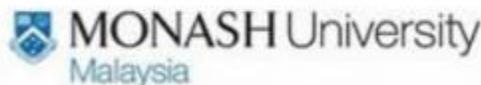


# DEPEC Nutrition – WS 3

Prof Dame Louise Robinson  
Prof Daniel Reidpath  
Dr Mario Siervo  
Dr Devi Mohan  
Dr Andrea McGrattan  
Dr Azizah Hussin



## DePEC nutritional intervention

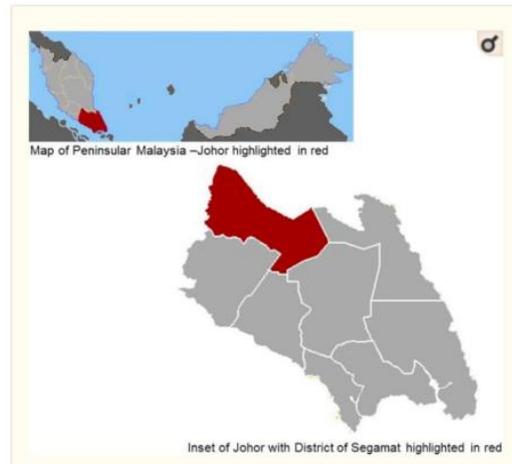
**A study to investigate the feasibility of a mixed-method intervention to reduce salt intake and increase high-nitrate vegetable consumption in middle-aged and older Malaysian adults with elevated blood pressure.**

Technology Research Platforms | South East Asia Community Observatory (SEACO)

## South East Asia Community Observatory (SEACO)

The South East Asia Community Observatory (SEACO) is a research platform in population health and well being in regional Malaysia – a high middle-income country. It was launched on 20 November 2011. The primary purpose in Segamat is to collect salient and high-quality data to gain insights into the factors that affect health in a whole of life context.

Segamat district Malaysia



# Intervention

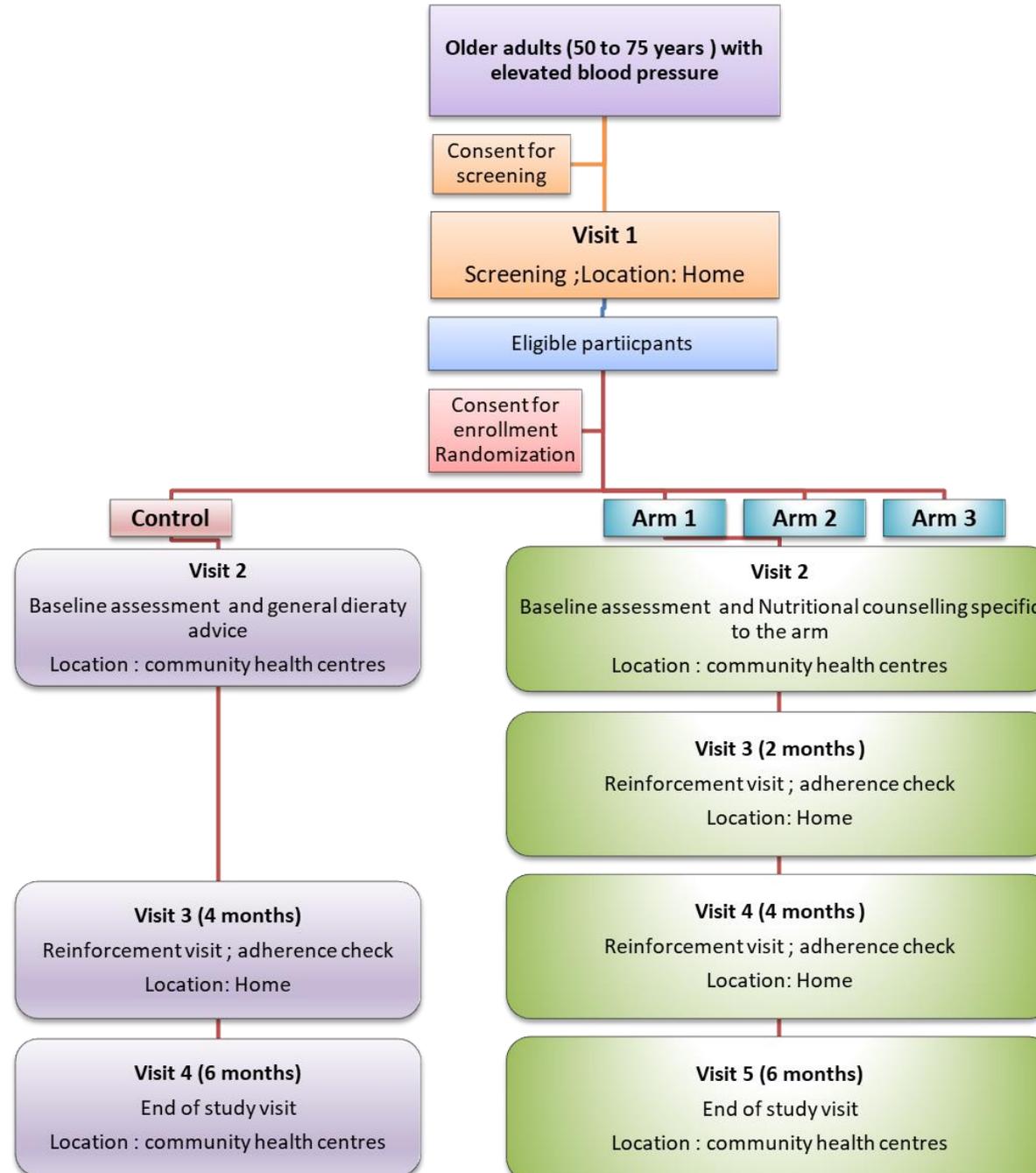
- 24 weeks intervention
- Counselling for modification of diet
  - Reduction in salt intake
  - Increase in nitrate intake – green leafy vegetables
- Control – general health promotion message based on MOH dietary guideline

# Four arms

Older adults aged 50-75 years  
Prehypertensive or hypertensive

30 \* 4 = 120 participants

Interventions arms	Decrease in dietary salt consumption	Increase in dietary nitrate consumption (green leafy vegetables)
Arm1 (salt reduction)	✓	×
Arm2 (increase nitrate)	×	✓
Arm3 (salt reduction & increase nitrate)	✓	✓
Control	×	×



# Outcome of the study

## Primary outcome

- **Feasibility of the intervention:**
  - Participant recruitment and retention
  - Appropriateness and validity of data collection processes outcome measures
  - Acceptability of intervention by different ethnic group and during different cultural and religious observances
  - Adherence to the intervention - self-reported and objective biomarkers (urinary nitrate and salt excretion).
  - Resource capacity for the management of the intervention

## Secondary outcomes

- Cognitive test performance – MMSE, MoCA (timed trail And B ), – Montreal Cognitive Assessment (MoCA), Animal Naming , Auditory Verbal Learning Test
- Resting blood pressure
- Body composition: height, weight, waist circumference, body fat
- Physical performance: hand-grip strength, gait speed and timed up and go
- Behaviour change -Adherence to nutritional interventions measured by dietary methods
- Plasma biochemical outcomes monitored including routine biomarkers of cardio-vascular risk

Screening	Baseline(0/12) Community health center <b>One to one education</b>	2 months Home visit <b>Reinforcement message</b>	4 months Home visit <b>Reinforcement message</b>	End of study (6/12) Community health center
<ul style="list-style-type: none"> <li>•Screening questionnaire(including medication history )</li> <li>•Blood pressure</li> <li>•Height, weight</li> <li>•MMSE</li> <li>•Activities of daily living(KATZ)</li> <li>•Self reported Comorbidity</li> </ul>	<ul style="list-style-type: none"> <li>•24 hour diet recall</li> <li>•Food frequency questionnaire</li> <li>•Blood pressure</li> <li>•Body composition- Height, Weight, BMI, Body fat</li> <li>•Frailty – hand grip, gait speed. Time up and go</li> <li>•Depression – Geriatric depression scale (GDS)</li> <li>•Physical activity – Physical activity Scale for Elderly (PASE)</li> <li>•Cognition – Montreal Cognitive Assessment (MoCA), Animal Naming , Auditory Verbal Learning Test</li> <li>•Urine- Spot urine , and 24 hour urine for urinary sodium and nitrate</li> <li>•Blood- venipuncture cardiometabloc markers, Random blood glucose, Dried blood spot</li> <li>•Saliva- nitrate</li> </ul>	<ul style="list-style-type: none"> <li>•Adherence questionnaire</li> <li>•Blood pressure</li> <li>•Weight</li> <li>•Spot urine for sodium</li> <li>•Salivary strip for nitrate</li> </ul>	<ul style="list-style-type: none"> <li>•Adherence questionnaire</li> <li>•Blood pressure</li> <li>•Weight</li> <li>•Spot urine for sodium</li> <li>•Salivary strip for nitrate</li> </ul>	<ul style="list-style-type: none"> <li>•24 hour diet recall</li> <li>•Food frequency questionnaire</li> <li>•Self reported Comorbidity</li> <li>•Blood pressure</li> <li>•Body composition- Height, Weight, BMI, Body fat</li> <li>•Frailty – hand grip, gait speed. Time up and go</li> <li>•Depression – Geriatric depression scale (GDS)</li> <li>•Physical activity – Physical activity Scale for Elderly (PASE)</li> <li>•Cognition – Montreal Cognitive Assessment (MoCA), Animal Naming , Auditory Verbal Learning Test</li> <li>•Urine- Spot urine , and 24 hour urine for urinary sodium and nitrate</li> <li>•Blood- venipuncture cardiometabloc markers, Random blood glucose, Dried blood spot</li> <li>•Saliva- nitrate</li> <li>•Focus group discussion among participants</li> </ul>

## Screening

- Screening questionnaire (including medication history)
- Blood pressure
- Height, weight
- MMSE
- Activities of daily living (KATZ)

- Home visit – consent for screening
  - Sociodemographic
  - Comorbidities
  - **Drug history**
  - Blood pressure-
  - Height, weight
  - Mini mental State examination
  - KATZ

**Map of 5KM From KK Sg. Segamat**

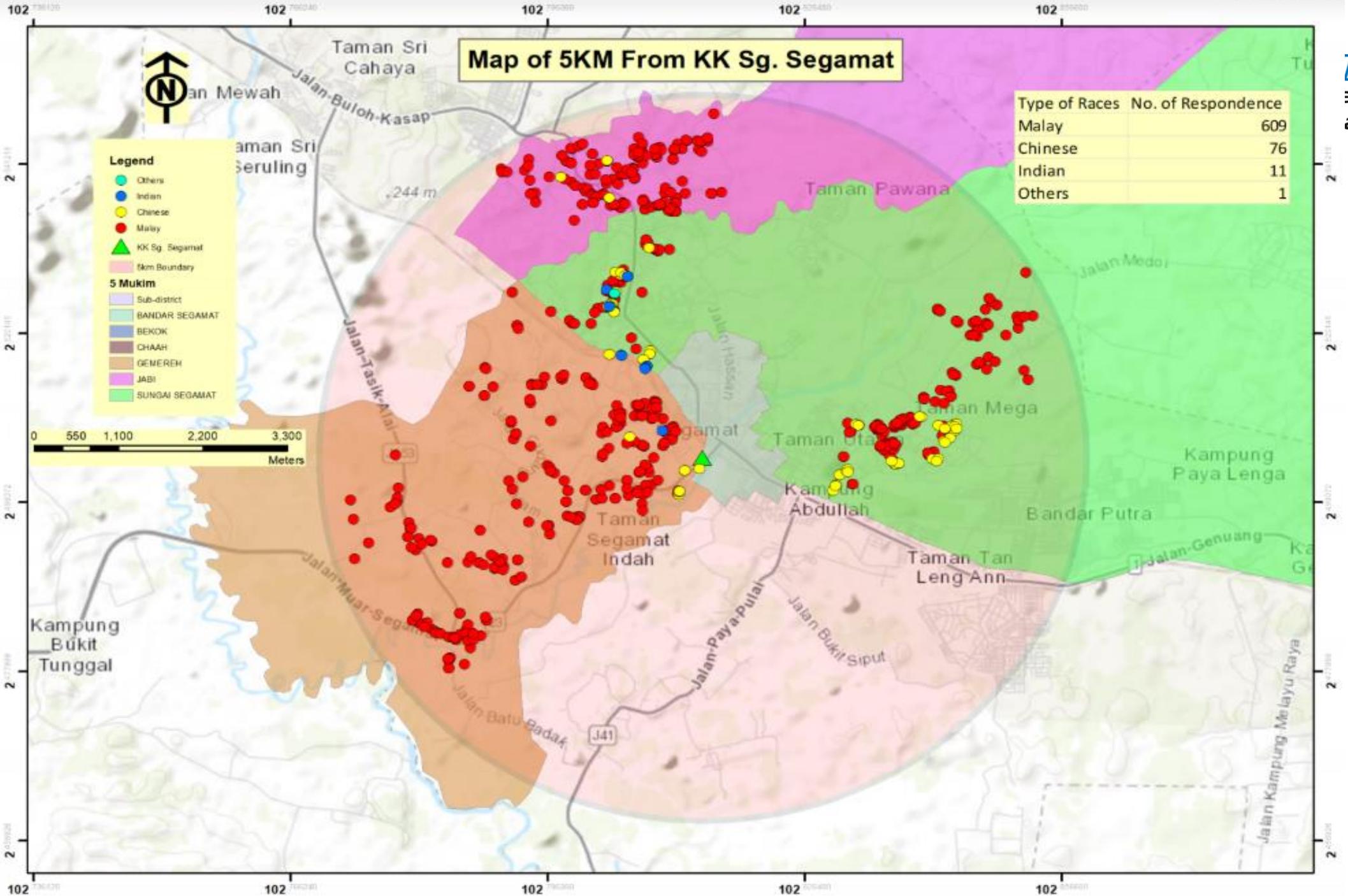
Type of Races	No. of Respondece
Malay	609
Chinese	76
Indian	11
Others	1

**Legend**

- Others
- Indian
- Chinese
- Malay
- ▲ KK Sg. Segamat
- Km Boundary

**5 Mukim**

- Sub-district
- BANDAR SEGAMAT
- BEKOK
- CHAAH
- GEMEREH
- JABI
- SUNGAI SEGAMAT



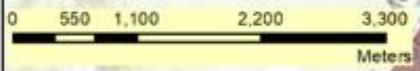
Map of 5KM From KK Chaah

**Legend**

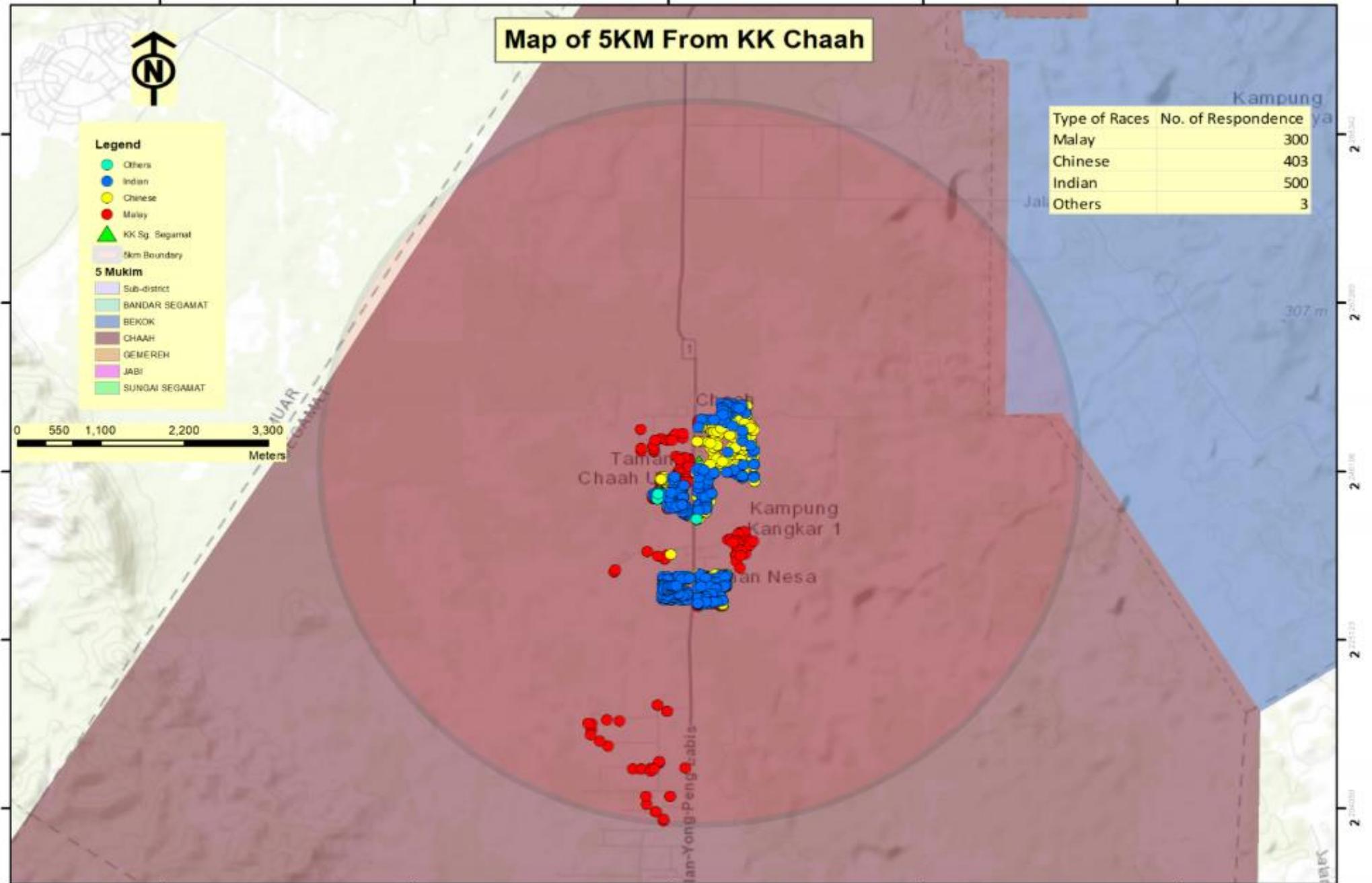
- Others
- Indian
- Chinese
- Malay
- ▲ KK Sg. Segamat
- 5km Boundary

**5 Mukim**

- Sub-district
- BANDAR SEGAMAT
- BEKOK
- CHAAH
- GEMEREH
- JABI
- SUNGAI SEGAMAT



Type of Races	No. of Responde
Malay	300
Chinese	403
Indian	500
Others	3



# Screening for drugs

## Two step screening

1. Data collector in field – checklist
2. Pharmacist based on the drug history and photographs - <https://pillbox.nlm.nih.gov/>



### DePEC Study Medication History Interview Guide (English)

DC: Data collector from SEACO P: Participant FM: Family member C: Carer

Interview Scripts	Activity
<b>1. Opening</b> <ul style="list-style-type: none"> <li>• Introduce yourself</li> <li>• Explain the reason for the interview/ interaction</li> <li>• Inform the participant about approximate amount of time that the interview will take</li> </ul>	
DC Hi. Mr/ Mrs (name of participant), I'm (name of data collector), the SEACO staff. I want to talk to you about your medication. It should only take about 15 minutes. P Okay	Record date of interview
<b>2. Obtain comorbidity of participant</b>	
DC Besides high blood pressure, have you had any other medical history? P No	Record medical history
<b>3. Obtain medication history of participant</b>	
DC Do you take any medication on a regular basis currently? P Yes	Record regular medications (Y/N)
DC Do you take your own medications OR your family member gives you the medications? P I take it on my own. *If participant's family member(FM)/ carer(C) serves the medication, continue the interview with FM or C.	Record the person has been interviewed for detailed medication history
DC What prescription medications (medicines prescribed by doctor) do you take on a regular basis? P/FM/C High blood pressure medicines	Document ALL medications a participant is currently taking. For each medicine, document: Medication (generic/trade

### Case Report Form: DePEC Study

Subject ID: <input type="text"/> <input type="text"/> <input type="text"/>					
<b>VISIT 1 (SCREENING): Medication History</b>					
Date of Assessment					
Has the participant had any relevant medical history? (besides high blood pressure)				<input type="checkbox"/> No <input type="checkbox"/> Yes If _____ yes, _____ please specify.....	
Is the participant taking any regular medications?				<input type="checkbox"/> No <input type="checkbox"/> Yes (complete below)	
Person has been interviewed for medication history				<input type="checkbox"/> Participant <input type="checkbox"/> Family member <input type="checkbox"/> Carer	
Medication (Generic or Trade Name, Strength, Form)	Reason for use	Dose & Frequency	Start Date (DD/MM/YY)	Stop Date (DD/MM/YY)	OR tick if ongoing at the time of screening visit
E.g. Paracetamol 500mg tablet	Pain	1g as needed	01/04/19	03/04/19	<input type="checkbox"/>
1.			__/__/__	__/__/__	<input type="checkbox"/>
2.			__/__/__	__/__/__	<input type="checkbox"/>
3.			__/__/__	__/__/__	<input type="checkbox"/>

Baseline(0/12)

Community health center

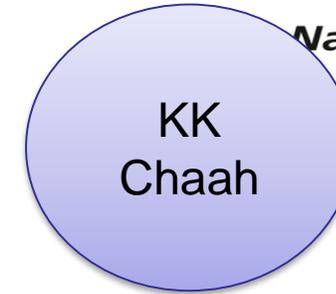
**General health promotion message**

- 24 hour diet recall
- Food frequency questionnaire
- Self reported Comorbidity
- Blood pressure
- Body composition- Height, Weight, BMI, Body fat
- Frailty – hand grip, gait speed. Time up and go
- Depression – Geriatric depression scale (GDS)
- Physical activity – Physical activity Scale for Elderly (PASE)
- Cognition – Montreal Cognitive Assessment (MoCA), Animal Naming , Auditory Verbal Learning Test
- Urine- Spot urine , and 24 hour urine for urinary sodium and nitrate
- Blood- venipuncture cardiometabloc markers, Random blood glucose, Dried blood spot
- Saliva- nitrate

# At Klinik Kesihatans



**National Institute for Health Research**



**DCs**

- Consent Questionnaire
- Anthropometry
- BP
- Frailty
- PASE
- Physical activity

**PhD**

- Depression
- Cognitive
- FFQ
- 24 hr diet recall

**Lab technician /phlebotomist**

- 15 ml whole blood
- Dried blood spot
- GRBS
- Saliva
- Spot urine collection
- Instruction and kit for 24 urine collection

**Counselling**

- Nutritionist/ dietician

# Mini-Mental State Examination (MMSE)

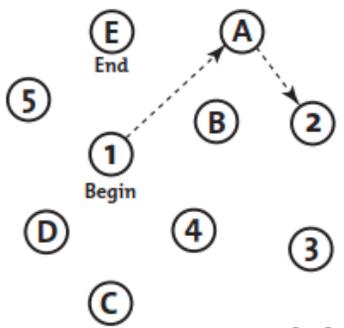
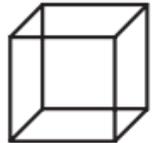
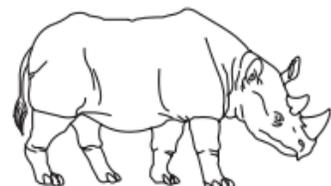
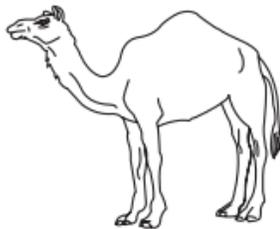
Patient's Name: \_\_\_\_\_ Date: \_\_\_\_\_

**Instructions: Score one point for each correct response within each question or activity.**

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day? Month?"
5		"Where are we now? State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then the instructor asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible.
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 

## MONTREAL COGNITIVE ASSESSMENT (MOCA)

Education : \_\_\_\_\_ Sex : \_\_\_\_\_ Date of birth : \_\_\_\_\_ DATE : \_\_\_\_\_

VISUOSPATIAL / EXECUTIVE		Copy cube	Draw CLOCK (Ten past eleven) (3 points)	POINTS			
			<input type="checkbox"/> Contour <input type="checkbox"/> Numbers <input type="checkbox"/> Hands	___/5			
NAMING							
				___/3			
MEMORY							
Read list of words, subject must repeat them. Do 2 trials. Do a recall after 5 minutes.		FACE	VELVET	CHURCH	DAISY	RED	No points
1st trial							
2nd trial							
ATTENTION							
Read list of digits (1 digit/ sec).		Subject has to repeat them in the forward order [ ] 2 1 8 5 4			___/2		
		Subject has to repeat them in the backward order [ ] 7 4 2					
Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors		[ ] FBACMNAAJKLBAFAKDEAAAJAMOF AAB			___/1		
Serial 7 subtraction starting at 100		[ ] 93	[ ] 86	[ ] 79	[ ] 72	[ ] 65	___/3
		4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt					
LANGUAGE							
Repeat : I only know that John is the one to help today. [ ]		The cat always hid under the couch when dogs were in the room. [ ]			___/2		
Fluency / Name maximum number of words in one minute that begin with the letter F		[ ] _____ (N ≥ 11 words)			___/1		
ABSTRACTION							
Similarity between e.g. banana - orange = fruit		[ ] train - bicycle	[ ] watch - ruler	___/2			
DELAYED RECALL							
Has to recall words WITH NO CUE		FACE	VELVET	CHURCH	DAISY	RED	Points for UNCUE recall only
		[ ]	[ ]	[ ]	[ ]	[ ]	
Optional Category cue							
Multiple choice cue							
ORIENTATION							
[ ] Date		[ ] Month	[ ] Year	[ ] Day	[ ] Place	[ ] City	___/6

# ANIMAL NAMING

**Introduction:** “I’d like to ask a question to check your memory.”

**Instruction:** “Tell me the names of as many animals as you can think of, as quickly as possible.”

**Procedure:** Time for 60 seconds and record all responses.  
 If the person stops before 60 seconds, say “Any more animals?”  
 If the person says nothing for 15 seconds, say “A dog is an animal.  
 “Can you tell me more animals?”

- |          |           |
|----------|-----------|
| 1. _____ | 12. _____ |
| 2. _____ | 13. _____ |
| 3. _____ | 14. _____ |
| 4. _____ | 15. _____ |
| 5. _____ | 16. _____ |
| 6. _____ | 17. _____ |
| 7. _____ | 18. _____ |
| 8. _____ | 19. _____ |

**WHO/UCLA Auditory Verbal Learning Test (WHO UCLA AVLT)**

The subject is verbally presented with the 15-item list of words, which are to be learned over five trials. The sixth trial is an interference list, which the subject is also asked to recall immediately. Following the interference list, the subject is asked to recall the original list which was repeated five times. Delayed recall is obtained, without prior warning, after 30 mm, and a verbally presented recognition trial is administered immediately thereafter. All responses are sequentially marked by the examiner on the test protocol which contains all word lists.

*ASEAN Journal of Psychiatry Vol.10 (1): Jan - June 2009*

**Appendix 1 : WHO / UCLA version of the Auditory Verbal Learning Test.**

<i>List A</i>	<i>List B</i>	<i>Recognition items</i>	
<i>Arm</i>	<i>Boot</i>	<i>Mirror</i>	<i>Lips</i>
<i>Cat</i>	<i>Monkey</i>	<i>HAMMER</i>	<i>Tree</i>
<i>Axe</i>	<i>Bowl</i>	<i>KNIFE</i>	<i>ARM</i>
<i>Bed</i>	<i>Cow</i>	<i>Candle</i>	<i>Nose</i>
<i>Plane</i>	<i>Finger</i>	<i>Motorcycle</i>	<i>Sun</i>
<i>Ear</i>	<i>Dress</i>	<i>AXE</i>	<i>Truck</i>
<i>Dog</i>	<i>Spider</i>	<i>CLOCK</i>	<i>EYE</i>
<i>Hammer</i>	<i>Cup</i>	<i>CHAIR</i>	<i>Fish</i>
<i>Chair</i>	<i>Bee</i>	<i>PLANE</i>	<i>EAR</i>
<i>Car</i>	<i>Foot</i>	<i>Turtle</i>	<i>BIKE</i>
<i>Eye</i>	<i>Hat</i>	<i>HORSE</i>	<i>Snake</i>
<i>Horse</i>	<i>Butterfly</i>	<i>Leg</i>	<i>Stool</i>
<i>Knife</i>	<i>Kettle</i>	<i>DOG</i>	<i>Bus</i>
<i>Clock</i>	<i>Mouse</i>	<i>Table</i>	<i>BED</i>
<i>Bike</i>	<i>Hand</i>	<i>CAT</i>	<i>CAR</i>

## Geriatric Depression Scale (Short Form)

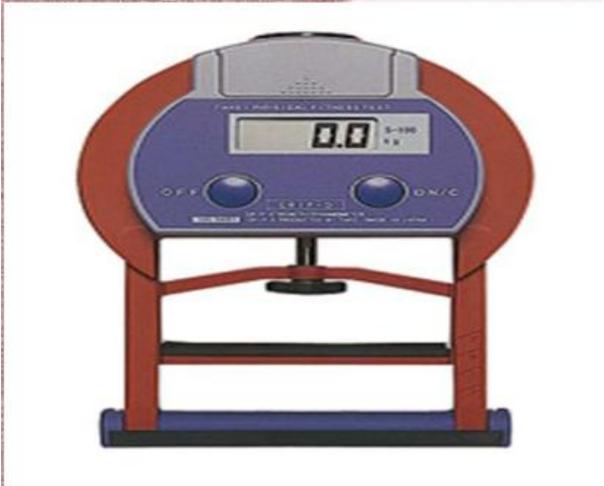
Patient's Name: \_\_\_\_\_ Date: \_\_\_\_\_

**Instructions:** Choose the best answer for how you felt over the past week. Note: when asking the patient to complete the form, provide the self-rated form (included on the following page).

No.	Question	Answer	Score
1.	Are you basically satisfied with your life?	YES / <b>NO</b>	
2.	Have you dropped many of your activities and interests?	<b>YES</b> / NO	
3.	Do you feel that your life is empty?	<b>YES</b> / NO	
4.	Do you often get bored?	<b>YES</b> / NO	
5.	Are you in good spirits most of the time?	YES / <b>NO</b>	
6.	Are you afraid that something bad is going to happen to you?	<b>YES</b> / NO	
7.	Do you feel happy most of the time?	YES / <b>NO</b>	
8.	Do you often feel helpless?	<b>YES</b> / NO	
9.	Do you prefer to stay at home, rather than going out and doing new things?	<b>YES</b> / NO	
10.	Do you feel you have more problems with memory than most people?	<b>YES</b> / NO	
11.	Do you think it is wonderful to be alive?	YES / <b>NO</b>	
12.	Do you feel pretty worthless the way you are now?	<b>YES</b> / NO	
13.	Do you feel full of energy?	YES / <b>NO</b>	
14.	Do you feel that your situation is hopeless?	<b>YES</b> / NO	
15.	Do you think that most people are better off than you are?	<b>YES</b> / NO	
		TOTAL	

# Functional assessment

## Handgrip strength

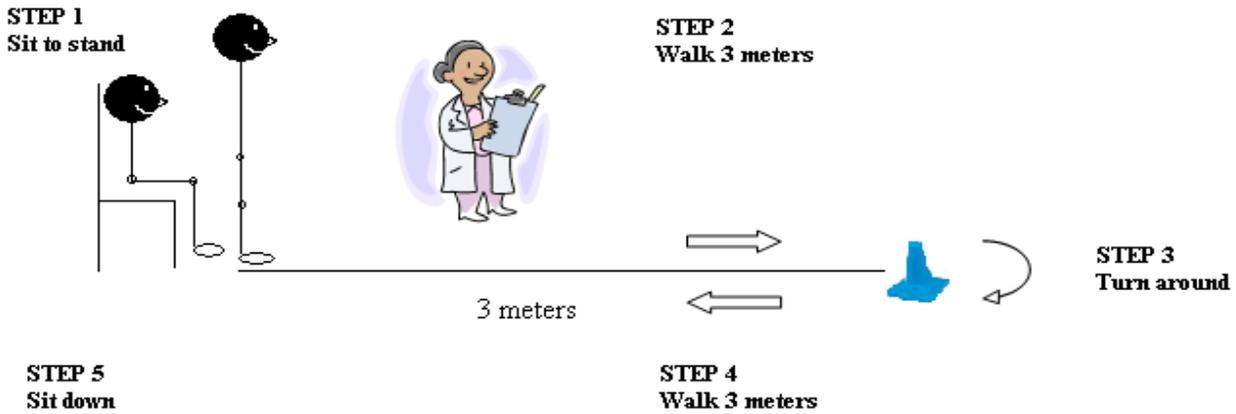


## Gait speed



Ask the patient to walk from A to D. Start the stop watch when patient crosses point B and Stop when he crosses C.

## Timed up and go test



# Capillary blood- finger prick sample

Dried blood spots



Glucometer random blood  
sugar



# Venous blood- 15 ml

Blood samples will be centrifuged within 45 minutes from collection.

Centrifuge conditions are: 3000rpm, 10 minutes, 4°C. samples will be aliquoted and properly labelled using the following scheme:

- Lithium Heparin: 3 aliquots of 1.5mL each
- EDTA: 3 aliquots of 1.5mL each

Samples collected will be stored at -20°C and then moved for long term storage to -80 °C freezers.

# Saliva

## Berkeley Life Nitric Oxide Saliva Test Strips:

- Patented, non-invasive saliva test strips
- See your Nitric Oxide level in seconds
- Track your Nitric Oxide status throughout the day
- Simply place on your tongue and then see where you are on the NO scale



## Collection of saliva sample

### Procedure

- (i) A small piece of cotton wool should be torn from the roll or a cotton wool ball may be used. This is placed in the mouth and chewed for 30-60 seconds until the cotton wool feels saturated.
- (ii) Whilst chewing, remove the syringe from the packet and remove the plunger from the barrel.
- (iii) Place the wet cotton wool into the barrel of the syringe. Replace the plunger.

2 months

Home visit

Reinforcement message

- Adherence questionnaire
- Blood pressure
- Weight
- Spot urine for sodium
- Salivary strip for nitrate

- 2 month and 4 month home visit
- Reinforcement message
- Adherence check list

4 months

Home visit

Reinforcement message

- Adherence questionnaire
- Blood pressure
- Weight
- Spot urine for sodium
- Salivary strip for nitrate

End of study (6/12)

Community health center

- 24 hour diet recall
- Food frequency questionnaire
- Self reported Comorbidity
- Blood pressure
- Body composition- Height, Weight, BMI, Body fat
- Frailty – hand grip, gait speed. Time up and go
- Depression – Geriatric depression scale (GDS)
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- Urine- Spot urine , and 24 hour urine for urinary sodium and nitrate
- Blood- venipuncture cardiometabolic markers, Random blood glucose, Dried blood spot
- Saliva- nitrate
- Focus group discussion

- Same as baseline
- At the end of the study

Focus group discussion in the community (4)- for each arm of the intervention

# Progress

- MUHREC clearance



## Monash University Human Research Ethics Committee

### Approval Certificate

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

**Project ID:** 17864

**Project Title:** Feasibility study of a mixed-method intervention to reduce salt intake & increase high-nitrate vegetable consumption in middle-aged & older Malaysian adults with elevated blood pressure

# Updates

- NMRR and MREC in progress
- Resource mapping , procurement and DC recruitment – Project manager has been recruited
- Screening will start by May
- Mario and Andrea visit mid- late May for training

# Systematic review on salt and cognition

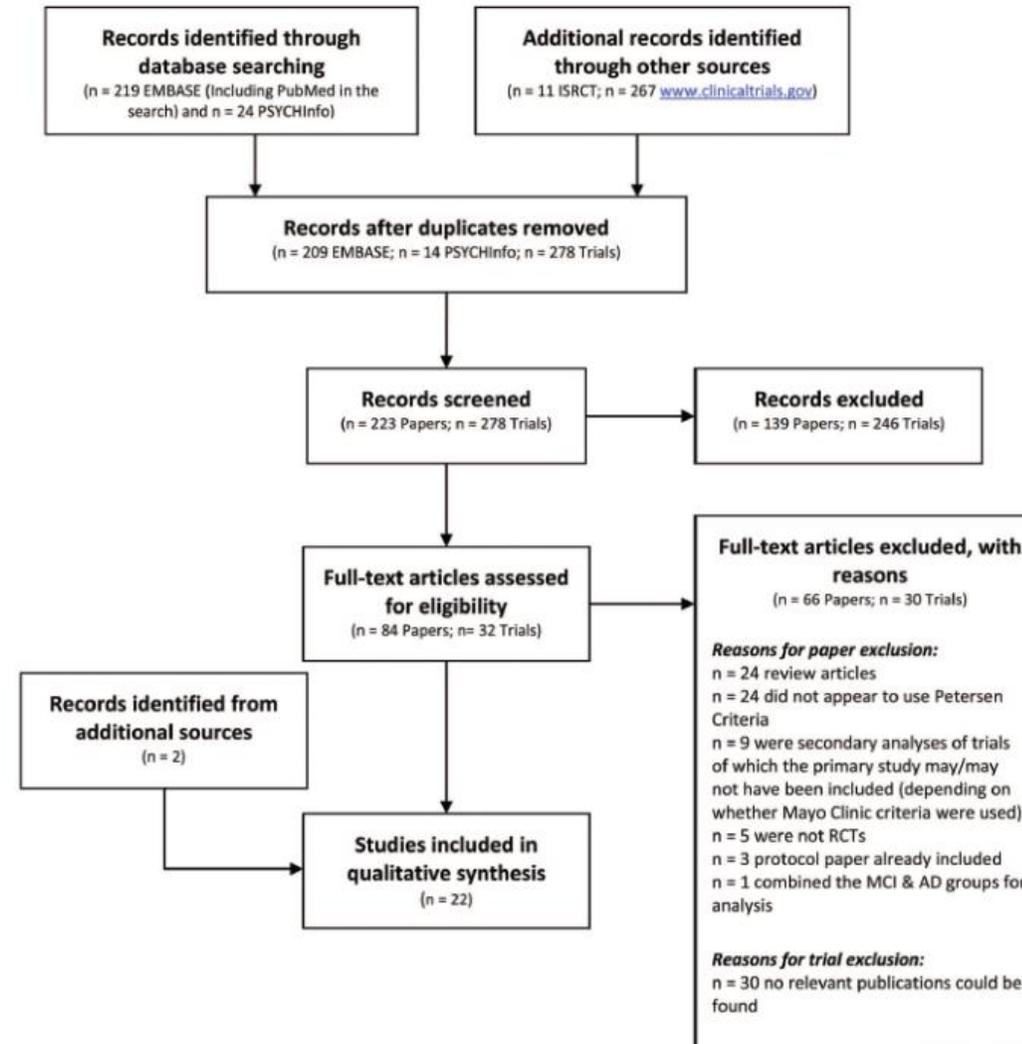


Figure 2 PRISMA (2009) flow diagram of article selection.