EXPLANATORY STATEMENT
Consumers

Project ID: 28273
Project title: Holistic Approach in Primary care for PreventIng Memory Impairment aNd Dementia (HAPPI MIND)

Chief Investigator:
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Monash University
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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone number or email address listed above.

What does the research involve?
In 2020, there was an estimated 459,000 Australians living with dementia and this number is expected to increase to more than one million Australians by 2058. While there is currently no cure for dementia, there is evidence that some health conditions and lifestyles may increase the risk of developing dementia. Some of these risk factors for dementia can exist in mid-life, well before a person may start to show signs or symptoms of dementia. The aim of this research project is to evaluate a new approach for assessing dementia risk and reducing dementia risk factors in middle-aged adults in the primary care (e.g. general practice) setting.

The project requires four main sets of assessments (at the beginning of the study, and then yearly at 12 months, 24 months and 36 months after commencing the study). A brief questionnaire will also be conducted at 6 months. Measures will include questionnaires, interviews and clinical measurements (e.g. blood tests, weight measurement, blood pressure measurement). Each assessment will take approximately one hour, and can be broken into smaller time periods if desired. Questionnaires will be available online and can be completed either at home or at your General Practitioner's clinic. Interviews will be organized in a private area at your General Practitioner's clinic or a mutually convenient place. Clinical measurements will be conducted by a health professional at your General Practitioner's clinic and/or pathology collection service. The intervention nurse may access your health records and laboratory data in order to complete the assessment and/or to assist in the delivery of the intervention. During each assessment you will be asked to;

- Answer questions about you, your health, your lifestyle choices and your well-being
- Measure health parameters (e.g. height, weight, waist circumference, blood pressure)
- Do a fasting blood test (10mLs or less of blood will be taken by a trained health professional, to check blood cholesterol levels, blood glucose levels and glycated haemoglobin [HbA1c])

Your clinic has been allocated to one of two groups in the HAPPI MIND clinical trial, each delivering a different intervention.

Based on the clinic you attend, you have been allocated to intervention B led by a trained nurse. The intervention will include;

- Receiving an individualised report outlining your risk factors known to be linked with increased risk of developing dementia in later-life.
- Receiving Dementia Australia's *Healthy brain, health life* educational booklet on dementia risk reduction.
- Participating in six individualised dementia risk reduction motivational interview sessions with a trained nurse. These sessions will occur face-to-face or via telephone or video telehealth. They will occur every 3 months for the first year then annually for 2 years. The first session will take 30-60minutes, with follow-up sessions likely being shorter (15-30minutes).
- Access to the purpose-built HAPPI MIND app to support self-management of dementia risk factors at home and to track progress against your risk reduction goals.

The nurse may make suggestions regarding your health to your general practitioner, but your general practitioner will continue to be responsible for coordinating your care.

The below table outlines the approximate time commitments of being involved in this study.

Time-point	**Description of commitment**	**Approximate time**
Baseline	*Data collection*: Questionnaires, health parameters, blood test	60 minutes
Baseline	*Intervention*: Receive dementia risk report, education booklet, individualised dementia risk reduction session with nurse and access to HAPPI MIND app.	60 minutes
3 months	*Intervention*: Follow-up individualised dementia risk reduction session with nurse and ongoing use of HAPPI MIND app	60 minutes
6 month	*Data collection*: Brief questionnaire	10 minutes
6 months	*Intervention*: Follow-up individualised dementia risk reduction session with nurse and ongoing use of HAPPI MIND app	60 minutes
9 months	*Intervention*: Follow-up individualised dementia risk reduction session with nurse and ongoing use of HAPPI MIND app	60 minutes
12 month	*Data collection*: Questionnaires, health parameters, blood test	60 minutes
12 months	*Intervention*: Follow-up individualised dementia risk reduction session with nurse and ongoing use of HAPPI MIND app	60 minutes
24 month	*Data collection*: Questionnaires, health parameters, blood test	30 minutes
24 months	*Intervention*: Follow-up individualised dementia risk reduction session with nurse and ongoing use of HAPPI MIND app	60 minutes
36 months	*Data collection*: Questionnaires, health parameters, blood test	60 minutes
	Approximate total time commitment	610 minutes (~10 hours)

You may be invited to participate in two additional data collections used to evaluate the acceptability and delivery of the intervention. These will be optional and you can choose whether or not you participate at the time when they are offered.

1. Audio recording one or more of your individualised dementia risk reduction motivational interview sessions with the trained nurse. These recordings will be used to evaluate the delivery of the intervention.
2. Audio recording one-on-one interview and/or focus group (of 5-10 people) at 12 months and/or 36 months regarding your experiences and perspectives of the intervention. The interview and/or focus group will take approximately 60 minutes and will be conducted face-to-face or using telehealth (e.g. phone call or Zoom platform).

Why were you chosen for this research?
You are being invited to take part in this research because your health records indicate that you may be at increased risk of developing dementia and your health professionals thought that you may match the entry criteria for this study.

Source of funding
This project is funded by the National Health and Medical Research Council (NHMRC) through the Boosting Dementia Research Grants Scheme – Priority Round Five: Implementing Dementia Risk Reduction and Prevention Research (APP1171851).

Consenting to participate in the project and withdrawing from the research
Consenting to participate in this project involves signing and returning the attached consent form. Participation in any research project is voluntary and you may withdraw from further participation without being disadvantaged. Your decision to participate or participate and then withdraw will not have any implications on your relationship with your practice, health professionals, the investigators, Monash University or the partner organisations.

In case you withdraw from further participation in the project, we would like to use data already collected from you. However, you may request that all data collected up to the point of withdrawal be removed from the study data set.

Possible benefits and risks to participants
We cannot guarantee any benefits to you from participating in this project. Evidence indicates that there a number of risk factors that can contribute to increased dementia risk. Participation in this project may help identify and manage health conditions and behaviours that may act as risk factors for dementia, and encourage uptake of health behaviours which act as protective factors for dementia.
We do not foresee any risks to you from participating in this project. Inconvenience and/or discomfort from participation in this project will be minimal. Participation may make you think about your health and lifestyle habits and prompt you to make changes. Screening of your health and risk factors for dementia may identify issues, which may require medications and/or non-drug treatments. The nurse/researcher will require access to your medical records to work with your General Practitioner and other members of your healthcare team to provide dementia risk reduction recommendations. The nurse/researcher will explain potential risks of the medications and/or non-drug treatments and you can decide whether or not to use those medications or non-drug treatments. If you become upset or distressed as a result of your participation, the researcher will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team. You may contact the following organisations, to directly organise counselling or support:

http://www.salvationarmy.org.au/melbourne-counselling-service	Tel: 03 9653 3250
http://www.lifesupportscounselling.com.au/melbourne-counselling/	Tel: 1300 735 030

Payment
You will receive $20 reimbursement for completion of each main data collection assessment. There will be four main data collection assessments: at baseline, 12 months, 24 months and 36 months. There will be no reimbursement for the brief questionnaire conducted at 6 months.

You will receive $20 reimbursement for participation in each of the risk reduction motivational interview sessions with the trained nurse. There will be six sessions: at baseline, 3 months, 6 months, 9 months, 12 months and 24 months.

You will receive $50 reimbursement if you choose to participate in the one-on-one interview and/or focus-group that may occur at 12 and/or 36 months.

Confidentiality
You will not be named or identified in any report or publications resulting from the study. No potentially identifiable information will be included in any publications or presentations. Only group results will be published.

Storage of data
According to the University regulations, the data will be stored for 5 years and kept in a locked cupboard or filing cabinet. An electronic copy of the data will also be stored in a password protected computer. Only the investigators involved in the study will have access to the data.

To dispose of the information at the end of this period, all electronic copies of files will be permanently deleted; the hardcopies documents will be shredded and placed in a confidential bin for destruction. Any identifiable information about the participants will be removed from the documents prior to disposal.

Use of data for other purposes
Aggregated de-identified data may be used by the investigators for future research projects where ethics approval has been granted. De-identified data may also be deposited into a secure data repository and made available to other researchers after verification and journal reviewers upon request, as this is an expectation of peer-reviewed journals for publication of results.

We may contact you for further follow-ups in the future. Separate consent will be sought for this purpose from you at the time of enrolment and will be subject to ethics approval being granted.

Results
You may obtain a copy of the summary of the study findings when the research is completed, by contacting Dr George in approximately 4 years.

Complaints
Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D,
26 Sports Walk, Clayton Campus
Research Office
Monash University VIC 3800
Tel : +61 3 9905 2052 Email : muhrec@monash.edu Fax : +61 3 9905 3831

Thank you,

Dr Johnson George

CONSENT FORM – Consumers

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I have been asked to take part in the Monash University research project specified above. I have read and understood the Explanatory Statement and I hereby consent to participate in this project.

I consent to the following:	Yes	No
The investigators accessing my health records including laboratory data		
The investigators discussing my health and management with my health professionals		
The investigators offering me support for dementia risk reduction		
The investigators accessing health information entered into the HAPPI MIND smart phone application		
Be available for follow-up interviews after 12, 24 and 36 months		
Taking part in an audio and/or video recorded interview/focus group		
The data that I provide during this research may be used by the investigators in future research projects		
Being contacted for further follow-ups over the next 10 years should funding become available and ethics approval be granted.		

Name of Participant (please print):_____

Participant Signature:_____ Date :_____