Participant Information Sheet

The effect of family whanau intervention in the Memory Service for the prevention of dementia: A pilot randomized controlled trial.

		Ethics ref:
Lead Investigators:	**Dr Bronwyn Copeland**	07 579 8335
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	Dr Gary Cheung	09 923 9491

We are conducting a study to investigate the usefulness of information about preventable risk factors for the family members of a parent diagnosed with mild cognitive impairment or dementia.

You are invited to take part in this study because you have a parent diagnosed with mild cognitive impairment or dementia. Whether or not you take part is your choice. If you do not want to take part, you do not have to give a reason, and it would not affect the care you or your parent receives. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

The Memory Service, Mental Health Services for Older People Bay of Plenty District Health Board has organized this study. Ethical approval is obtained.

This *Participant Information Sheet* will help you decide if you would like to take part. We will go through it with you and answer any questions you may have. This should take about 20 minutes.

If you agree to take part in this study, you will be asked to sign the *Consent Form* on the last page of this document. You will be given a copy of both the *Participant Information Sheet* and the *Consent Form* to keep.

Please make sure you have read and understood all the pages.

Why are we conducting the study?

Dementia is a growing health concern that is increasing due to an ageing population. At present there is no cure for dementia. Some research suggests changing risky lifestyle practices may aid in the prevention of dementia. Our focus is on testing a brochure (called the intervention) about modifiable prevention measures for family members of a parent diagnosed with dementia or mild cognitive impairment. This brochure was prompted by attending family members supporting their parent at this Memory Clinic questioning their likelihood of developing dementia.

We want to recruit family members of a parent with a diagnosis of mild cognitive impairment or dementia. To take part in this study you will have either attended the consultation clinic with a parent or seen the consultation video about maintaining a healthy brain.

Participants will be randomly allocated to one of two groups; either the intervention or control group. An intervention group member will meet three times, 1-1 over a six month period. A control group member will meet four times, 1-1 over a twelve month period. Meetings will take 45 minutes. Except the final meeting; this will take 60 minutes. All participants will receive the intervention during the study.

What would your participation involve?

If you agree to take part in the study a registered health professional from the Memory Service will meet with you three times to complete a survey form about your general health and wellbeing. You will be given written information about preventable factors known to help reduce the risk of developing dementia. At the last meeting there is an opportunity to share your experience and receive feedback about your information gathered.

We will collect information on your demographics, medical conditions, medications and the questions that measure your well-being, exercise and diet. Some questions may be personal and you do not need to answer all questions. You also have the right to access and request changes to data collected. All the information that is collected will be kept confidential. The test results will only be seen by the researchers. The data will be stored securely for ten years (which is standard research practice).

The usual care you receive will not be affected by taking part in this study.

What are the possible benefits and risks to you of participating?

The booklet offers information known to reduce the risk factors for developing dementia. You may find this a starting point to make some changes.

Foreseeable risks are minimal; if we find when gathering your information the need for further medical evaluation; we may advise you to see your General Practitioner.

As health professionals, we believe the potential benefits would outweigh the potential risks.

No payments will be provided in recognition of participation.

We will also ask your consent to inform the treating health practitioner of your involvement in this study.

What compensation is available for injuries incurred?

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

What are the rights of participants in the study?

Participation is entirely voluntary and you are free to decline to participate or to withdraw from the program at any time, without experiencing any disadvantage.

You have the right to access information about you collected as part of the study.

All lengths will be taken to ensure your details remain confidential throughout the course of the study.

What will happen after the study ends?

The lead investigators will be responsible for the study data. The data will not be used for purposes other than this study. The data is stored securely for 10 years before destruction.

The study findings will be reported at scientific meetings and in publications and all potentially identifiable personal information will be removed. A summary of the findings can be provided to participants on request.

Where can you go for more information about the study, or to raise concerns or complaints?

If you have any questions, concerns or complaints about the study at any stage, you can contact one of the lead investigators of this study:

Dr Bronwyn Copeland	*07 579 8335*
Dr Fiona Miller	*07 579 8335*
Cheryl Collier	*07 579 8335*
Dr Gary Cheung	*09 923 9491*

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@hdc.org.nz

If you wish to talk to the Mental and Addictions Family/ Whānau Advisor you can contact Hori Ahomiro:

Phone	(07) 579 8216
Cellphone:	027 456 1501
Email	hori.ahomiro@bopdhb.govt.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone:	0800 4 ETHICS
Email:	hdecs@moh.govt.nz