Participating in research

Alzheimer Society

Research

This information sheet is to help you, a person with dementia, decide if participating in a research study is right for you. If you are someone who supports a person with dementia, you will also find this information helpful.

Research can positively impact the lives of people with dementia, their families and caregivers. Research studies are undertaken to help researchers investigate several things, including:

- If treatments or care practices are safe
- If treatments have any side effects
- If new treatments are better than available treatments
- How best to provide care and support
- How the disease affects different areas of the brain
- How people can control their symptoms and improve their quality of life

The knowledge we gain through research studies helps improve the ways we can prevent, diagnose and treat dementia. Because of this, many people with dementia and their caregivers are interested in participating in research projects.

Is participating in research right for you? Things to consider:

Have you received all the information and the time you need to help you make an informed decision?	• Before accepting or declining an opportunity to participate in a research study it is important that you get as much information about the study as possible, and that you are given time to ask questions and to review the information provided. • The Alzheimer Society has developed a "Checklist for participating in research studies: what should I ask?" to help people with dementia and their caregivers make an informed decision about participating in a research study. You will find this checklist at the end of this information sheet.
Are you able to make informed decisions?	An informed decision is made when you: • have all the information available • can understand the information provided • can communicate your wishes • understand the consequences of your decisions Make your wishes known: • As the dementia progresses, it will be harder for you to make informed decisions, which can put you at a risk for getting involved in procedures that you normally would turn down. • Write down information on procedures that you would not like to be involved in, such as having a lung puncture or other invasive procedures. • Writing down your wishes can help your substitute decision-maker speak on your behalf when you are no longer able to make an informed decision.

Role of the substitute decision-maker	• A substitute-decision maker is a person chosen by you to make personal care decisions, including medical decisions, when you are no longer able to provide informed consent. • If the research team requires your consent for a procedure they want to try, but you are no longer able to provide an informed consent, consent will be requested from your substitute decision-maker. • Your wishes must guide any decisions made by the substitute decision-maker. • If your wishes are not known, the decision should be made with your best interests in mind and should not be guided by what the substitute decision-maker wants.
Using placebos	• A placebo refers to a pill, substance or treatment that may look like the intervention being tested, but is not expected to have any medical effect. • Placebos are used to assess the effect of an intervention without any biases. • To determine if a new intervention (such as a new medication) is safe and effective, research studies will compare a group of people taking the intervention (such as taking a new medication) with a group taking a placebo. • When placebos are used in a study, participants may or may not get a chance to try the new intervention. Because of this, it is important that you understand the procedures of any research study you may be interested in.

Frequently Asked Questions

1. What is the difference between a clinical trial and an observational study?

- **Clinical trials** are studies that examine the **effects of an intervention**, such as the effects of a new exercise program. Interventions can include testing new drugs, assistive devices or ways to receive healthcare, as well as changes in lifestyle, such as diet and exercise.
- In **observational studies** participants **do not receive an intervention**. Participants may be observed for a period of time and/or they may be asked to complete tests and questionnaires related to what the research team is trying to investigate. For example, the Canadian Longitudinal Study on Aging is an observational study which is following 50,000 Canadians aged 45 to 85 years for 20 years. During this time, participants are asked to complete a number of biological, medical, psychological, social, lifestyle and economic questionnaires, but do not participate in any interventions.

2. What are the risks for participating in research studies and how can they be reduced?

- Risks will vary from study to study.
- The decision to participate in a study must be based on your knowledge of potential risks. This is why it is important that the research team provides you with information about the possible risks of participating in their study, and that you are given the time that you need to properly understand the study and the risks involved.
- Information about potential risks will help you decide if the risk is too great for you. In some situations, this will be the decision of your substitute-decision maker.

- It is important to know that participation in a research study might result in some inconveniences, such as lengthy travel to the site of the research study. Researchers may try to make it easier for you to participate by including flexible scheduling of visits and financial compensation for time, travel or home visits. Ultimately, you must weigh the personal risks and benefits and decide for yourself if participating in the research study is right for you.

3. How are the ethics of research studies evaluated?

To protect your dignity, rights, safety and well-being, it is important that researchers adhere to ethical principles. Research ethics boards are set up to ensure that studies conducted in Canada follow appropriate ethical standards.

The research ethics board requires the researcher to complete a detailed, multi-page form, regarding all aspects of the proposed study so that the ethics of the study can be assessed. For example, the researcher must answer questions about:

- the purpose of the study
- who will lead it
- how it will be conducted
- where and when the study will be implemented

To help ensure the safety of participants, a research study cannot begin until the research ethics board has approved the project.

For more information about ethics and other aspects of clinical trials please visit www.ClinicalTrials.gov

4. How are studies funded?

Research studies are typically funded by government agencies and non-government organizations such as charities and research foundations. Drug companies also fund clinical trials.

5. How are the results of research studies shared?

- Results are typically shared through scientific, peer reviewed journals and discussed at academic conferences through presentations, debates or posters.
- Research may also be shared via webinars, information sheets or products that provide summaries for the general public.
- If you decide to participate in a research study, you can request the research team to provide you with a report of the research results at the end of the study.
- It is important to note that the results of the study can never include your identification information, unless you have given permission to include it. Therefore, you will always remain anonymous.

6. Why are some people paid to participate in research studies and others are not?

Typically, participants are not paid to participate in a study. They are, however, compensated for their expenses, such as travel, parking, and lunch. A small honorarium may also be paid if the research study requires a long-term commitment from the participants.

7. Why are some people accepted into studies and others are not?

The research team may only be interested in investigating people with specific characteristics. For example, researchers may want to study women between 60 and 70 years old with mild cognitive impairment. In this example, only individuals with these characteristics will be accepted into the study. These specific characteristics are often referred to as "inclusion criteria", and only individuals who meet all the inclusion criteria for the study are accepted as participants.

8. Where can I go to join a dementia research study?

Sometimes, your family physician will have information on how to become involved in a research study.

You can also find information about researchers looking for participants for their study at www.alzheimer.ca/researchportal

Checklist for participating in research studies: what should I ask?

How do I find out about research studies happening in my community?

Please visit **www.alzheimer.ca/researchportal for information about research studies taking place in Canada.**

We suggest that you use this check sheet to take note of the details of each research study that interests you. ***Make a copy for each study you are considering and leave one blank to use as a master copy.***

Name of research study: _____

Contact information/website: _____

Date: _____

1. Details of the research study

What is the purpose of the study? _____

_____

Why is this study important? _____

_____

Has this study been approved by a Research Ethics Board? ☐ Yes ☐ No

What type of study is it?

☐ Clinical trial (I might receive a new drug device, diet or exercise program)

☐ Observational study (I might undergo extra interviews and/or tests, but I will not be given a new drug, device, diet or exercise program)

Who can participate? _____

_____

Who cannot participate? ***(for example: can I still take my medications?)**** _____

_____

****Note: If you are told that you need to stop taking your medications, you should first discuss this with your family caregivers and health-care providers.***

Who will be responsible for my care during the study? _____

Can I leave after it is started? ☐ Yes ☐ No

Are there any negative consequences for leaving early? _____

_____

What kind of tests and experimental treatments are involved? _____

_____

How long will the study last? _____

What is the time commitment? _____

What else is required of participants? _____

Is hospitalization required at any time? ☐ Yes ☐ No

What happens if my memory or overall health gets worse while I am in the study? _____

_____

Do I need to have an available friend or family member to accompany me to the study? ☐ Yes ☐ No

If "yes," what are their responsibilities and time commitment? _____

_____

_____

_____

What type of long term follow up, if any, is part of this study? _____

_____

_____

Will results of the study be shared with me? ☐ Yes ☐ No

If I have abnormal results, will they be shared with me? ☐ Yes ☐ No

Who funds the study? _____

Where are the study sites in

☐ my country ☐ my province

☐ my community ☐ neighbouring States, provinces, communities?

2. Risks and benefits:

What are the possible side effects and adverse reactions? _____

_____

_____

How will my safety be protected? _____

_____

_____

How will my privacy be protected? _____

How will the study impact my current treatment and care? _____

3. Costs:

Are there any costs associated with the study that I need to pay for? ☐ Yes ☐ No

If "yes," what are the details? _____

Will I be reimbursed for other expenses? ☐ Yes ☐ No

Notes _____

The contents of this document are provided for information purposes only and do not represent advice, an endorsement or recommendation, with respect to any product, service or enterprise, and/or the claims and properties thereof, by the Alzheimer Society of Canada. This information sheet is not intended to replace clinical diagnosis by a health professional.

Alzheimer Society

Alzheimer Society of Canada
20 Eglinton Avenue West, 16th Floor, Toronto, Ontario, M4R 1K8
Tel: 416-488-8772 • 1-800-616-8816 • Fax: 416-322-6656
E-mail: info@alzheimer.ca • Website: www.alzheimer.ca
Facebook : www.facebook.com/AlzheimerCanada • Twitter : www.twitter.com/AlzCanada