1. Title of study:

Objective evaluation of cognitive impairment and related psychosocial outcomes in populations with Mild-Cognitive Impairment and mild-to-moderate Alzheimer’s disease, by characterizing interpersonal communication between older persons and caregivers.

2. Introduction:

You are being asked to participate in this study as a healthy volunteer. You will be required to complete a series of tests at the Memory Clinic in St James’s Hospital. It should not take more than two hours to complete all tests.

This study is being carried out by Dr. Céline De Looze (postdoctoral researcher at Trinity College), Prof. Brian Lawlor (Consultant psychiatrist at St. James’s Hospital) and Prof. Richard Reilly (Professor of Neural Engineering at Trinity College).

This study is designed to investigate the way people with cognitive impairment and their caregivers communicate with each other. This will help us to

(1) identify the speech markers that can be used to diagnose cognitive decline at an earliest possible stage; and

(2) determine which communication strategies are effective to help a patient complete a task, to improve a patient’s social engagement and well-being, and to decrease a caregiver’s emotional distress.

3. Procedures:

You can take part in this study if:

- you are a man or a woman over 50;
- you are able to attend the Memory Clinic in St James’s Hospital for the assessment session;
- you have NO history of neurological disorders and/or history of major psychiatric disorders or depression;
- you are fluent in English to reliably complete all study assessments and tasks;
- you are literate.

If you agree to participate in this study,

(1) You will be required to complete and sign an informed consent form,
confirming that you agree to take part in this study and that you are aware of any risks it might involve.

(2) You will be required to undergo three neuropsychological tests, which consists of a set of questions. This test will evaluate cognitive functioning. It will last 30 minutes in total.

(3) You will be required to complete two speech tasks. First, you will read a set of sentences. Then you will engage in a game (a collaborative referencing task) with the caregiver of a person with Mild Cognitive Impairment or mild-to-moderate Alzheimer’s disease. For these two tasks, your speech will be recorded. These tasks will last 20 minutes in total.

(4) You will be required to fill in three questionnaires, which consist of a set of questions. These questionnaires will evaluate your perception of the speech tasks, quality-of-life and engagement in social activities. They will last 20 minutes in total.

(5) You will be asked if you are willing to undergo a Functional Magnetic Resonance Imaging (fMRI) examination or scan, which uses a powerful magnet and a computer to produce detailed images of the brain and examine its anatomy. This examination is optional. If you are willing to undergo an fMRI scan, please tick the box below.

By ticking this box, I accept to undergo an fMRI scan.

If you participate in the examination: Before the examination, you will be asked to complete a safety questionnaire to ensure that you are eligible to be scanned. You will then be asked to remove all metallic objects, hearing aids and jewellery that you may have. You may be asked to change into a hospital gown too. Once you are ready for the scan, a radiographer will position you on the scanner table. During the imaging process, you will be asked to remain still. You will also be provided with a buzzer, which you can press if you would like to be removed from the scanner for any reason. When the scan is finished you may go. The examination will last 30 minutes.

4. Benefits:

Taking part in this study will not benefit you directly.

However, this study will provide speech-based tools for the diagnosis of cognitive impairment in Mild Cognitive Impairment and Mild-to-Moderate Alzheimer’s disease.

In addition, this study will provide recommendations for formal and informal caregivers about the way they can communicate with a patient with cognitive impairment. Effective communication can help a patient complete their daily
activities successfully and can augment a patient’s social engagement and well-being. Effective communication can also decrease a caregiver’s emotional distress.

5. Risks:

There are no potential risks or harm (expected or known) associated with the study. Although there are no known side-effects associated with fMRI, people with pacemakers, metal fragments in their eyes, surgical clips and certain other types of implants cannot be scanned for safety reason. This is why, if you participate in this examination, you will be asked to fill in a safety questionnaire before the scan. The knocked sounds of the scanner are loud and can make people feel uncomfortable. The confined space can also be stressful for some people.

6. Confidentiality:

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone.

The data collected (speech recorded) during the two speech tasks will only be available to the present investigators and their research team. Recordings will be stored onto a password protected computer drive in Trinity College Dublin. Your recording will be assigned a study specific confidential code number to kept your identity confidential.

7. Compensation:

Nothing in this document restricts or curtails your rights.

8. Voluntary Participation:

You have volunteered to participate in this study. You may quit at any time. If you decide not to participate, or if you quit, you will not be penalised and will not give up any benefits which you had before entering the study.

9. Stopping the study:

You understand that you may stop your participation in the study at any time.

10. Permission:

The St. James’s Hospital, Ethics and Medical Research Committee have reviewed and approved this study.

11. Further information:
You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Dr. Céline De Looze, who can be telephoned at 01 8964214.