CARER INFORMATION LEAFLET

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Study Title: **Language Sensing Study: Dementia Diagnosis and Monitoring**

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Introduction

You are invited to take part in a study for automatically identifying changes in language usage by people living with dementia in order to develop new methods for diagnosis and monitoring of dementia. Before you decide whether you would like to participate, you need to understand why the research is being done and what is being asked from participants. Please take the time to read the following information carefully.

This study consists of two types of participants: (1) people with dementia or people from the same age group who are not suspected of having dementia (controls) and (2) carers or family members who are paired with people with dementia or controls and assist them in this study.
From this point onwards we will refer to the first group as **participants** and their carers or family members as **carers**.

Part 1 discusses the purpose of the study and what taking part involves.
Part 2 gives more detailed information about the study itself.

Please ask us if there is anything that is not clear or if you would like more information. You have up to a week to decide if you wish to take part in this study.

PART 1

Goal: We aim to use automated computational methods for analysing language to create a cost effective, non-invasive method for tracking changes in language use over time that can be used for diagnosing dementia and monitoring its progress.

Background to the study

Dementia affects over 850,000 people in the UK and costs UK society £23 billion a year. Early diagnosis can dramatically improve quality of life. However, only 59% of people with dementia are currently being diagnosed (ARUK figures, March 2016) and accuracy of diagnosis varies greatly. Current methods for diagnosis are expensive and intrusive, including brain scans and expensive spinal fluid tests.

What will this study do?

This study will: (a) Create a platform for collecting conversation data between people with dementia and their carers over time, as well as written thoughts, triggered by images from the past. (b) Use the data collected to develop computational methods for studying patterns of language change in people with dementia.

We will provide our study participants with a special computer tablet application that will allow them to record daily conversations between themselves and their carers as well as written text by participants with mild to moderate dementia. Our pilot study will comprise 30 participants, 20 people living with dementia and 10 people of the same age who are not suspected of having dementia. Data will be collected over time, for 54 weeks (just over a year), in three intermittent 4-week periods.

We will ask our participants to record daily 15 minutes of conversation with their carers on the basis of images from the past, provided by the tablet application. We will also ask our participants to write thoughts stemming from the images using the tablet. We would like our participants to alternate between recording conversations and recording thoughts. This is important so that we can study how dementia affects both spoken conversation and the ability to write text.

Once data is collected, we will work on analysing the language using computational and statistical methods. Our computational models will be designed to track use of words, expressions and linguistic structure as well as emotional content, fluency, topic relevance and how these features interact and change over time. This will allow us to build models for predicting whether a participant has dementia and how the disease is progressing.

We anticipate that the results from this study will provide a path to identify change in language use by people living with dementia and finally lead to new methods of diagnosing and monitoring dementia. Because our methods involve using language as a measurable quantity that changes over time we call this a language sensing study.

How long will the study last?

There will be three periods of data collection per participant, each 4 weeks long and 14 weeks apart. At the start and end of each period we will provide participants with a tablet and administer a standard memory test (MMSE test), as well as an Addenbrooke's Cognitive Examination-III (ACE-III test) only at the start of each study period. During each of the three 4-week periods participants will be asked daily to alternate between recording a 15 minute conversation with their carer or writing their thoughts using the tablet. The study will last 54 weeks, just over a year, in three 4-week periods, so that each participant will spend 12 intermittent weeks on the study. After data collection we will work on computational methods for analyzing the data but this will not require participant involvement.

How will participants be selected?

We are looking for participants meeting the following criteria: 20 participants, raised in Britain, aged 65-80 with early to middle stage dementia and 10 participants, from the same age group and ethnic background, not suspected of having dementia.

Participants living with dementia would need to have received a diagnosis of mild to moderate dementia or mild to moderate cognitive impairment and disclose to us the method of diagnosis.

Participants without dementia will be chosen from the same age group as participants living with dementia.

Both sets of participants should:

- Be resident in their own home or with family.
- Be in daily contact with a carer or family member.
- Have access to a broadband connection at home.
- Be able and willing to record conversations with their carer in English.
- Be able and willing to write text in English.
- Be able and willing to engage with the study on a daily basis for 15 minutes.
- Be available for a 12-week intermittent period over a year.

There are no particular requirements regarding carers, as long as they are willing to record daily conversations with participants in English and are available throughout the participant's time on the study.

Why do participants need to have been raised in Britain?

The conversations and written thoughts we plan to record on the tablet as part of this study will be triggered by images from the past. These images are taken from everyday life in Britain in the 1950s so it is important that our participants have memories from living in the UK during this period. **There is no such restriction with respect to carers other than being able to communicate in English.**

What would I need to do as a carer in this study?

- As a carer, you would need to be paired with one of our participants and help them with daily tasks on the study. This would be required during four intermittent 12-week periods, spanning 54 weeks (just over a year).
- At the start of each 4 week long study period participants will be asked to complete a memory test (MMSE test) and a cognitive examination test (ACE-III), and will be provided with a tablet. **No action is required from you as a carer, other than supporting the participant in taking part.**
- Each participant, using the tablet application and with the help of their carer (yourself), will be asked to record daily 15 minutes of conversation with their carer based on images from the past available on the tablet and the memories they evoke.
- Also, the participants will be asked to write thoughts triggered by the images using the stylus pen or the keyboard provided by the tablet. **For this task no action is required from you as a carer other than helping the participant use the tablet.**
- We would like participants to alternate between recording conversations and writing their thoughts evoked by the images from the past. **For this task no action is required from you as a carer other than supporting the participant and providing your encouragement.**
- At the end of each 4-week long study period participants will be asked to take another MMSE test and return the tablet to us. **No action is required from you as a carer, other than supporting the participant in taking part.**

What is an MMSE test?

An MMSE test (**mini–mental status examination**) is a standard memory test used extensively in clinical and research settings to measure cognitive impairment. It is commonly used to screen for dementia. It is also used to estimate the severity and progression of cognitive impairment and to follow the course of cognitive changes in an individual over time. Administration of the test takes between 5–10 minutes.

What is an ACE-III test?

An ACE-III test (**Addenbrooke's Cognitive Examination-III**) is a screening test used to assess cognitive performance. It is often used in conjunction with the Standardised Mini Mental State Examination (SMMSE) to provide more detailed screening of cognitive abilities on later life and is helpful in the diagnosis of dementia. The assessment focusses on five cognitive domains: attention, memory, verbal fluency, language and visuospatial abilities.

A patient's scores are then calculated for each domain to provide a cognitive profile, which are added together to provide a total score out of 100 with higher scores indicating better cognitive functioning. A patient's performance can be compared to those for people of various ages and disabilities.

Administration of the ACE-III takes, on average, 15 to 20 minutes.

Can I take part in the study if I don't have dementia?

Yes, you can take part in the study even if you are not suspected of having dementia. If you are 65-80 years old and have been raised in Britain you can be one of the members of our control group. We need data from a control group so that we can differentiate between changes in language use that are affected by dementia and various other factors. **You can either be a carer or a member of the control group, but not both.**

What is the role of the carer?

You can also take part in our study as a carer if you are in daily contact with one of our participants living with dementia or a member of our control group and you are willing to help them with the daily requirements of the study. As a carer you will:

- Help the participant use the tablet and record daily 15 minutes of conversation together based on the images provided by the tablet application.
- Be offered some training on how to facilitate conversation using the image material.
- Assist the participant in using the tablet to write their thoughts and help them look after the tablet.
- Either the carer or the participant may contact us if there are any difficulties or questions regarding the study.

Do I have to take part?

It is entirely up to you to decide. We will describe the study and go through this information sheet, which we will give you to keep. If you choose to participate, we will ask you to sign a consent form to confirm that you have agreed to take part. We would like you to confirm your intention to take part in this study within a week of receiving this information. We will arrange for a member of our team to take consent as soon as possible once you have confirmed your wish to participate and we can confirm you meet the criteria in the above section. During consent taking we will ask you to disclose the type of dementia and method of diagnosis and give us the contact details of your GP so we can notify them (not applicable for carers). You will be free to withdraw at any time from the study by notifying us, without giving a reason and this will not affect you or your circumstances in any way. We will use any data collected during your time on the study.

What will happen if I decide to take part?

If you agree to take part in this study you will be asked to do the following:

1) Notify us of your intention within a week of receiving this document.
2) We will arrange for a member of our team to take consent as soon as possible once you have confirmed your wish to participate. You will need to sign the "CONSENT FORM" for carers. Participants have a different consent form. Carers will need to sign a consent form to tell us they agree to participate in the study by supporting the participant they are paired with and allow us to use their conversation data for research purposes. You will need to be available for an intermittent data collection period of 12 weeks (split into three 4-week periods) within a year (54 weeks actually) in total.
3) At the start of each data collection period we will provide you and the participant with a tablet, which runs a purpose-built application. You will need to use the tablet device daily, to help the participant record 15 minutes of conversation with you or help them write their thoughts based on images from the past provided by the tablet.
4) We will ask you to support the participant in taking part in this study and help them look after the tablet. Participants take an MMSE test at the start and end of each data collection period, as well as an ACE-III test at the start of each data collection period.
5) Before the study commences we will provide you with training on how to use the tablet and how to engage in conversation based on images from the past.
6) The tablet will need to be connected to the internet during the data collection period. At the end of each data collection period we will be collecting the tablet which will be given to another participant. We expect you to look after the tablet and deliver it in the same condition as presented to you. The tablet is programmed to be used only for the purpose of this study.

How will my data be used?

During the data collection period your conversation and written text data will be collected securely on servers (large computers connected to the internet) managed by Clinvivo (our industrial collaborator). The data will be subsequently stored on a secure server located at the University of Warwick. Once the data collection part of the study is over, we will work on analysing the language using computational and statistical methods. Our computational models will be designed to track use of words, expressions and linguistic structure as well as emotional content, fluency, topic relevance and how these features interact and change over time. This will allow us to build models for predicting whether a participant has dementia and how the disease is progressing.

What are the possible benefits of taking part in this study?

All participants will be obtaining a copy of any publication resulting from the study. The investigators can also give participants their own personalized results, regarding their own patterns of language usage. Furthermore, we anticipate that the daily exercise involving conversation based on images from the past and helping the participant write their thoughts may have a positive effect on both the carer's and participant's psychology. We want everyone taking part in the study to have fun and find it a rewarding experience.

What are the possible disadvantages, side effects, risks, and/or discomforts of taking part in this study?

There are no risks associated with participating in this research. We want everyone to enjoy their time on the study. All the data gathered will be treated as strictly confidential and will be used and analysed anonymously. The data will be collected from the tablet automatically when you are online. Note that the tablet is programmed to work exclusively for the purpose of this study and should be handled with care.

Expenses and payments

Any expenses incurred within the context of this study (training for carers and travel expenses) will be reimbursed. We will be providing the tablets and MMSE and ACE-III test administration will be covered by the study. We expect that our participants will be paying for their own broadband connection. There will be no payment for participating in the study.

What will happen when the study ends?

As per the University of Warwick's Research Code of Conduct, data will be retained in a secure place intact in electronic format, normally for a period of at least 10 years from the date of any publication based upon it.

Will my taking part be kept confidential?

Yes. We will follow strict ethical and legal practice and all information about you will be handled in confidence. Further details are included in Part 2.

Information about the tablet

At the start of each 4-week data collection period we will give you a tablet. A tablet is a portable device that looks like a small computer or a large mobile phone. The tablet will run a special application that makes it possible to record conversations with your carer and write thoughts triggered by images from the past also provided on the tablet. The tablet is especially programmed to work only for the purpose of this study and you should not try to use it in any other way. It has been fitted with a special programme that allows us to track it if it goes missing. We ask you to look after the tablet during your time on the study.

What if there is a problem?

If there is a problem with any aspect of the study you can contact the principal investigator. Detailed information is given in Part 2.

This concludes Part 1.

If the information in Part 1 is of interest to you and you are considering participating, please read the additional information in Part 2 before making any decision.

PART 2

Who is organising and funding the study?

The study is organised by Dr Maria Liakata at the University of Warwick, Department of Computer Science, together with Dr Matthew Purver, Queen Mary University of London, School of Electronic Engineering & Computer Science, Prof Martin Underwood, University of Warwick, Warwick Medical School, Dr Maria Wolters, Edinburgh University, School of Informatics, Drs Sarah MacPherson and Dr Tom Russ, Edinburgh University, Department of Psychology. It is currently funded by the Engineering and Physical Sciences (EPSRC) Impact Acceleration Account allocated to the University of Warwick.

What is the role of the investigators?

Dr Maria Liakata is leading and coordinating the study and is advising on matters pertaining to the analysis of human language using computational methods. Dr Matthew Purver will also offer expertise on computational methods for analysing human language with emphasis on analysis of dialogue. Prof Martin Underwood from the Warwick Medical School will advise on matters pertaining to medical trials and working with the elderly. Dr Maria Wolters will be joining as co-I from Edinburgh providing expertise in health Information Technology for people with dementia. Her colleagues Drs Sarah McPherson and Tom Russ will also be co-Is from Edinburgh, providing expertise on old age psychiatry.

What will happen if I don't want to carry on being part of the study?

Participation in this study is entirely voluntary. If you decide to take part, you will need to sign the carer consent form, which states that you agree to participate in the study tasks and allows us to analyse your conversation data.

If you agree to participate, you and your participant may nevertheless withdraw from the study at any time by notifying us. If the participant you are looking after is willing to participate and you no longer wish to take part we would appreciate it if you could recommend another carer as the participant cannot otherwise continue participating in the study. If both you and the participant decide to withdraw from the study, you will need to return the tablet. The tablet also needs to be returned to the principal investigator at the end of each data collection period. In case you choose to withdraw, any data collected so far will be used for analysis in the study unless you object to this by writing to the PI. The data will already have been anonymised and linked to a numeric ID.

You have the right to withdraw from the study completely and decline any further contact by study staff after you withdraw.

What are my rights as a subject?

For questions about your rights as a research participant, you may contact the University's Research and Impact services Department.
This study is covered by the University of Warwick's insurance and indemnity cover. Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Tel: 024 76 522746
Email: Jane.Prewett@warwick.ac.uk

Will my taking part be kept confidential?

Yes, your records used in the study (consent forms and administrative records) as well as the data recorded (conversations and written text) will be kept in strict confidentiality by the study investigators. The data will be used and analysed anonymously. The investigators will not normally access your name and identity, and are primarily interested in analysing the language data recorded using the tablet application.

What will happen to the results of the study?

The findings of this study will be published in conferences and journal papers. All data will be used anonymously. It is also possible that the conversation data and written text will be used in future studies by other researchers studying dementia. The data will always be used anonymously.

Who has reviewed the study?

The project was reviewed by an internal review panel, on behalf of the Warwick Impact Fund. The project has also received HRA Approval (Number XXXXX), which is the assessment process of governance and legal compliance for the NHS in the UK.

What if I want more information about the study?

If there is anything about the study or your participation that is unclear or that you would like to receive more information on you may contact the Principal Investigator:

Dr Maria Liakata,
M.Liakata@warwick.ac.uk,
Associate Professor, Department of Computer Science, University of Warwick,
Tel: +44 (0) 24 7652 3681

Thank you for taking the time to read this participant information leaflet!