

Study Information Sheet

DemPower: Living Life and Doing Things Together couple-management guide for couples living at home in which one partner has dementia

You and your partner are being invited to take part in a research project. Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please feel free to ask us if there is anything that is not clear or if you would like more information.

If you decide you would like to take part, we will ask you to read and sign a consent form. We will then give you a copy to keep. If you decide that you do not wish to take part, it will not affect the standard of care that you or your spouse/partner receives in any way.

What is the purpose of the study?

The study will help to find out, how much support you need to engage with this app and whether you find this helpful and make use of it in your day-to-day lives. It will also help future research explore how app compares to the usual care. The aim of the DemPower app is to foster your couple relationship and suggest ways for staying active, engaged and managing everyday tasks.

Why am I being asked to take part?

You have been invited to take part in this study because you are a couple, where one of you might be supporting your partner who has a diagnosis of dementia and who may be receiving dementia care. We invite you both to take part in the study together.

Do I/we have to take part?

- No. You are completely free to choose whether to take part.
- If you do decide that you would like to take part you will be asked to sign a consent form.
- If you decide to participate, you can change your mind and withdraw from the study at any time. You are not required to give any reasons for your decision.
- If you decide to withdraw your participation anytime, we would like to continue to use your data. However you may decide that none of the information provided until the point of withdrawal be used and we will withdraw all your data from the study.

- If you decide to participate and your partner decides not to participate then we will not be able to include you in the study. We would require both of you to be willing to participate in the study together.
- If you decide not to participate, your spouse/partner's current or future clinical care will not be affected in any way.
- If you or your partner, lack or fluctuate in your capacity to consent during the course of the study, you will be requested to withdraw from the study.

What will the project involve?

- We will give you a Samsung tablet with DemPower app saved on it.
- You will be trained and provided ongoing support on how to use the tablet and the app.
- You are required to use the app on a weekly basis and are encouraged to complete two sections of the app per week. On an average each section takes between 20-30 minutes.
- You may choose to navigate through the sections in any order. If you choose to engage with only a part of the guide, you will be asked to explain your decision.
- You will be asked to complete a set of questionnaires before you start working with the app and also after you have completed the app. A researcher will support the person with dementia to complete these questionnaires and also offer support to the caring partner if required.
- The app has four themes and several sections under each of these themes. On completing each theme you will be asked to answer a theme specific questionnaire together.
- We will collect usage data such as – number of times each screen has been viewed, initial screen opened and how you navigate the app from the tablet by physically downloading the data to an encrypted laptop.

What are the possible benefits of taking part?

- You will have access to an extensively compiled resource in the form of a guide and some useful tips on managing everyday life.
- You will receive dedicated support to learn how to use the tablet and the app.
- The app involves videos, suggestion for games, music, outdoor activities and preloaded games on the tablet. It will provide you both the opportunity to try and engage with games, watch videos and actively engage in activities together.
- You can keep the tablet for your use after the end of the study and all that you have uploaded onto the tablet during your participation.

Are there any possible risks involved when taking part?

The app and the questionnaires are not expected to cause any direct harm. If at any point you experience psychological or emotional discomfort whilst using the app or answering questions then the researcher will allow time to rest or stop the study altogether.

You might find using the tablet or the app difficult, to deal with this concern you will be offered a lot of support and training.

You might find answering questionnaires burdensome, if this happens you will be encouraged to talk to the researcher and researcher will offer support either in person or over the telephone.

Will my information stay confidential?

Yes. All information collected about both of you during the course of the research will be kept strictly confidential and stored on a password protected laptop/computer at the University of Manchester. All identifiable information will be stored safely on an encrypted storage device and the hard copies will be stored in a locked cabinet away from any code sheets at the university of Manchester. The identifiable information will be disposed after the study has ended.

As this study is being conducted in Manchester and Sweden, we recruit couples from both countries. Individual researchers from both the countries ensure that all the data are anonymised prior to being shared with the wider research team. None of the identifying information will be shared across countries. Members of the research team in the UK and Sweden will have access to only the anonymous information.

Everything you say / report is confidential unless you tell us something that indicates you or someone else is at risk of harm. We would discuss this with you before telling anyone else. The photographs and recorded reflections that you save on the tablet as a part of the suggested activity in the app will not be forwarded to the research team and will not be used as a part of this research project. However, if you face technical issues or there is a fault with the app/tablet, then the researcher and/or the app developer may have access or might need to access these to address the problem.

Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data but all individuals

involved in auditing and monitoring the study, will have a strict duty of confidentiality to you as a research participant.

What will happen to the results of the research study?

The results from both Manchester and Sweden will be combined and the data will be used to develop the app. It will help us to determine if the app is acceptable, usable and plan a larger study to test the effectiveness of the app. We will also present the results to researchers and health and social care staff, and will be published in scientific journals. If you wish to have feedback from the study, please let the researchers know. All the findings will be anonymised so it will not be possible to identify individual participants. This ensures your confidentiality.

What if there is a problem?

If you have a minor complaint then you need to contact the researcher, **Dr Reena Lasrado** on **0161 306 7884/ reena.lasrado@manchester.ac.uk** in the first instance.

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who has funded and sponsored this research study?

The study is being funded by the Economic and Social Research Council (ESRC) and the National Institute for Health Research (NIHR). It is being organised by the University of Manchester and Linköping University in Sweden.

Who has reviewed the study?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by a NHS Research Ethics Committee before it goes ahead. This study has been reviewed and given favourable opinion by the **[ADD NAME]** NHS Research Ethics Committee. Approval does not guarantee that you will not come to any harm if you take part. However,

approval means that the Committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision about whether to take part or not.

What if I have any comments?

If you have any questions or concerns or complaints please contact the researcher **Dr Reena Lasrado** on **0161 3067884** / **reena.lasrado@manchester.ac.uk** or the Chief Investigator, **Prof John Keady** on **0161 306 7854**.

Thank you for taking the time to read this information sheet.