



UNIVERSITY OF LEEDS

Dementia Carers Instrument Development: DECIDE



INFORMATION FOR CARERS

We are inviting you to take part in a research study that is developing a new questionnaire to measure the quality of life of a person caring for someone with dementia. The questionnaire will be used to raise awareness of carers' needs, to help evaluate supportive services and inform policy development.

This is a three year project. In the first year we interviewed a wide range of carers about their experiences of caring. From these interviews we created a list of questions built upon the reality of being a carer. Now we need to check which questions will be good to keep and which ones don't work so well. We would like your help with this part of the project. This information sheet explains what taking part would involve. Please read it carefully and discuss it with others if you wish. You don't have to make your mind up straight away. If you have any questions please ask the researcher. Thank you for taking the time to read this information sheet.

Why have I been invited?

We are inviting you to take part because you are caring for someone with dementia who lives in the community. By living in the community we mean people living in their own homes or with someone else, not people living in residential or nursing home care. You may be living with the person you care for or living somewhere else.

Can I choose whether or not to take part?

Yes, it is up to you to decide whether or not you want to take part. If, after consenting to take part, you change your mind, you can pull out at any time and you do not have to say why. If you decide not to take part or to pull out part way through this will not affect your rights in any way or the services the person you care for may receive. You do not have to make up your mind straight away. If you want longer to think it over the researcher will call you after a week to ask if you have any other questions and whether or not you want to take part.

What will happen if I decide to take part?

If you decide to take part, the researcher will send or give you a Consent Form to complete and sign, and a Questionnaire Pack to answer. The Questionnaire Pack is made up of four sections: our new questions about what life is like for you as a carer, questions about your overall health, questions about your emotional well-being and lastly questions about you and the person you care for. This will take about 20-30 minutes to complete. The Questionnaire Packs each have a unique carer identification number on them but it contains no information which will identify you. We are asking for your consent to complete and return Questionnaire Pack at the start, at the first follow-up point around two to four weeks later and, for some, at a second follow-up point at six months.

We will ask you to:

1. At the start:
 - a. Read and sign the Consent Form. Return this either to the researcher, if you are together, or send to the researcher in the stamped addressed envelope provided. You will be given a copy to keep.
 - b. Agree that the researcher can give your name and address to the University of Leeds DECIDE research team. This will allow Leeds to contact you directly at the follow-up time-points.
 - c. Agree that the researcher can contact you by telephone if they have not received the Consent Form from you. This is to give you the chance to ask any

- other questions and to send another study pack if you want it. You can let them know if you have decided not to take part.
- d. Complete the Questionnaire Pack and return this either to the researcher, if you are together, or send to the North Wales Organisation for Randomised Trials in Health (NORTH) Clinical Trials unit based at Bangor University in the stamped addressed envelope provided.
2. At the first follow-up point about two to four weeks after consenting (to test how reliable the new questions are), we will ask if you are still caring for someone with dementia who is living in the community. If you are in the same caring situation we will ask you to complete:
 - a. the new questions about what life is like for you as a carer and
 - b. a question asking if anything has changed regarding your caring role since you completed the first Questionnaire Pack.We will ask you to send the completed Questionnaire Pack to the Leeds DECIDE research team in the stamped addressed envelope provided.
 3. At six months after consenting to take part (to check how good the new questions are at picking up change), we will ask if you are still caring for someone with dementia who is living in the community. If you are in the same caring situation we will ask you to complete:
 - a. the new questions about what life is like for you as a carer, the questions about your health and your emotional well-being and a few questions about you and the person you care for.
 - b. two questions asking if anything has changed regarding your caring role since you completed the first Questionnaire Pack.We will ask you to send the completed Questionnaire Pack to the Leeds DECIDE research team in the stamped addressed envelope provided. For this stage of the work we will only contact carers who were invited to take part in the study during the first ten months it was running.

What are the possible disadvantages and risks of taking part?

Completing the Questionnaire Pack will take a bit of time. This is the only disadvantage we anticipate. If you want to discuss any concerns about caring there are specialist advice lines available. We have provided details of these at the end of the Questionnaire Pack and this Information Sheet.

What are the possible benefits of taking part?

There are no direct benefits in taking part in the study. Sometimes people feel pleased to be able to contribute to research which may benefit future carers of people with dementia.

What if something goes wrong?

If you are unhappy or dissatisfied with any aspect of your part in the study we would ask you first to speak to the Leeds DECIDE research team, so that we can try to address your concerns and find a solution. You can contact the researcher:

[contact details removed when archiving]

or the Principal Investigator:

[contact details removed when archiving]

If you are not satisfied with our response you can make a complaint to an independent professional, [contact details removed when archiving]

What will happen if I change my mind about taking part?

You can withdraw from the study at any time without giving a reason. If you withdraw it will not affect any services or rights you or the person with dementia that you care for receive in any way.

We will use the information collected from you up to the time of your withdrawal unless you state otherwise. If you do not want us to use your information we can remove it for up to two weeks following the completion of the first Questionnaire Pack. This has to be time limited to two weeks as some of the analysis planned includes very recently collected data.

Will my taking part in the study be kept confidential?

Yes, your taking part will be kept confidential.

- All Consent Forms will be held securely by the research team from the Trust to whom you gave consent.
- Each site research co-ordinator will transfer a list of the contact details of all carers who consented to the study to the Leeds DECIDE research team using a University of Leeds secure electronic transfer system. The Leeds DECIDE research team will store this information on a secure password protected file that only they have access to.
- Your Questionnaire Packs will be sent to NWORDH. The NWORDH team will not have any information about who you are or where you live. They will only have your study identification number. They will enter your questionnaire responses on to a secure computer system. These responses will be sent to the Leeds DECIDE research team for analysis.
- The Leeds DECIDE research team will contact you about completing the follow-up questionnaires. The questionnaires will not include any identifiable information about you. You will be asked to send these back to the team in Leeds. The paper questionnaires returned will be stored securely in a locked filing cabinet which is only accessible by the Leeds DECIDE research team.
- The DECIDE research team in Leeds will enter your follow-up questionnaire responses on to a secure computer system. The responses will be marked with your study identification number only.
- Questionnaire data will be kept separately and securely from your contact details.
- No-one will ever be able to identify you personally from anything that we present or publish about the research.
- The only situation in which we might need to share information about you with others would be if the researchers see or hear anything that causes very serious concern about the health, safety or well-being of you or the person you care for. If this happens the researchers have a duty to inform an appropriate professional, such as your GP or social worker. We would make every effort to explain why we need to share this information before doing so.

What happens to the information I have provided?

The paper Questionnaire Packs held at NWORDH and by the Leeds DECIDE research team will be kept for five years after the study has closed. The Leeds DECIDE research team will keep your name and address for up to 6 months after the study has closed, at which point it will be destroyed. This is in case you get in touch with us about any queries regarding the study. Your details will be kept in a secure electronic file within a restricted part of the University of Leeds computing system. Only the Leeds DECIDE research team will have access to this. They will then be destroyed.

The information collected will be available to other researchers to use for research and educational purposes. This will be completely anonymous and you will not be able to be identified. Researchers wanting to use the questionnaire data will have to make a formal application to the research team.

What will happen to the results of the research study?

When the study is complete, we will publish the new questionnaire and make it freely available to health, social care staff, and researchers. We will present the results at scientific conferences, publish them in journals, and present them to carers. Please inform us if you would like to know the results of this work and we will be very happy to provide them. Up to date information about the study can be found on our website www.decideproject.co.uk. We expect the results to be available by July 2018.

Who is organising and funding the research?

This research project is led by Dr Penny Wright from the University of Leeds. The research is funded by the Medical Research Council. This funding covers the running costs of the research project.

Who has reviewed the study?

The quality of our proposed research has been reviewed and approved by the Medical Research Council. Also, our research is connected with the NHS, as we are contacting some carers to take part through NHS services. All research connected with the NHS is reviewed by a Research Ethics Committee, to protect the safety, rights, well-being and dignity of those taking part. This study has been reviewed and approved by the South West - Exeter Research Ethics Committee. Research Ethics Committee.

Who can I contact for further information?

[contact details removed when archiving]

Thank you for reading this information sheet and for considering taking part in this research study.

If you would like to know more about this study then please visit our website: www.decideproject.co.uk



If reflecting on your situation has caused anxiety or uncertainty in any way, please contact your GP.

Below are two organizations which provide confidential telephone advice.

Alzheimer's Society has trained helpline advisors available on the telephone on 0300 222 1122 and online via https://www.alzheimers.org.uk/site/scripts/home_info.php?homepageID=428

The Helpline is usually open from:
9am - 8pm Monday to Wednesday
9am - 5pm on Thursday and Friday
10am - 4pm on Saturday and Sunday

Carers UK Advice line 0808 808 7777

The Helpline is usually open from:
10am - 4pm, Monday to Friday

(Listening service available Mondays and Tuesdays, from 9am to 7pm).

<http://www.carersuk.org/help-and-advice>