

## Development of a combined scale for measuring the quality of proxy informed consent decisions: cognitive testing of the CONCORD scale

- Some people with conditions such as dementia may not be able to make a decision about whether to take part in a research project.
- In these situations, family members are usually asked to help make a decision on their behalf.
- Our previous research showed that some family members found it hard to make these decisions and families thought that more support would be helpful.
- We are developing ways to help support families through the decision-making process but need to have a way of measuring if these are effective forms of support or not.
- We developed a new questionnaire to capture the experience of making a decision about research on behalf of someone else.
- In this study we wanted to see if family members are able to complete the questionnaire, if the questions can be understood, and if the questionnaire is acceptable to family members.

### THANK YOU

We would like to thank all those who have kindly given their valuable time to take part in the CONCORD Study. Your help is much appreciated.

### FUNDING

This study was funded by the Welsh Government through Health and Care Research Wales.

### Why did we do this study?

Involving people with conditions such as dementia in research may require asking a family member to decide on their behalf whether they should take part or not. However, some family members find it difficult to decide. Families have suggested that providing support for family members when making such decisions may be helpful. We are developing new tools to help family members make a decision about participation in a study that best reflects the values of the person they represent and reduce the burden families may feel when they are involved in decisions. However, we need to find a way of measuring whether these tools are effective or not.

The aim of the CONCORD Study was to explore family members' views about a new questionnaire we have developed that measures the 'quality' of a decision about research made on behalf of someone else. This will help us to refine the questionnaire prior to using in a future study where we are testing the effectiveness of a new support tool for families.

### What did we do?

We asked family members of people with dementia or other conditions which can affect memory and understanding to take part in an interview via Zoom. During the interview we asked them to complete the questionnaire and asked them how they understood each question, if any of the questions were not clear, and what further changes could make it better.

#### SUMMARY QUOTE:

*“I think it’s good that the questions raise those issues, because it does prompt you to feel that you are weighing up the issues.”*

Daughter of someone living with dementia

#### MORE INFORMATION

Please contact:

Dr Victoria Shepherd  
Centre for Trials Research,  
Cardiff University  
ShepherdVL1@cardiff.ac.uk

### What did we find?

We interviewed 11 family members (3 men, 8 women) from England and Wales who were a range of different ages and had either a parent, grandparent or sibling living with dementia. The interviews lasted an average of 43 minutes, and the questionnaire took between 1 ½ and 5 minutes to complete. After the first set of the interviews, the questionnaire was revised to change some of the wording and ordering of the questions.

Participants generally understood the purpose of the questionnaire, found the questionnaire to be a reasonable length, and all viewed the content as being acceptable. The format was considered to be acceptable, although one participant commented that the font size may be a little too small, for example for people with visual impairments. After changing the order of some questions, the questionnaire was generally considered to flow in a logical order.

The instructions for completing the questionnaire were generally understood (although not everyone read them!). After feedback from the first set of interviews, we added a brief heading to each of the three parts. This helped participants to understand better which bit of decision-making each part referred to.

As it was a hypothetical exercise, it was sometimes difficult for participants to answer some of the questions. Participants often distinguished between questions that related to their own feelings and knowledge, and those that required thinking about the person they were representing and their wishes which therefore required more time and consideration. Whilst some participants viewed individual items as being either a duplication or unnecessary to include, others thought that it was important to include each one as they covered different aspects of the decision-making process and experience.

### What are the next steps?

Thanks to those who kindly gave their time to take part, this study has given us important information that will help us to find effective ways to support family members making decisions about research for people with conditions such as dementia. This will hopefully help families in the future.

Following on from these interviews, the next step is to make final changes to the questionnaire where needed. We will then use it with family members who are making real-life decisions about research studies. We will provide family members with a new tool we have developed (a decision support booklet) and compare their experiences with family members who have not been given the new tool. The questionnaire will help us to measure whether the tool makes any difference to how supported and informed families feel during the decision-making process.