

DECISION 2 Study

Proxy decision-making for research involving adults who lack capacity to consent: cognitive testing of a novel decision support intervention



- 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 developed a decision support booklet to help guide families through the decision-making process.
- In this study we asked families of someone living with dementia for their views about the booklet.

THANK YOU

We would like to thank all those who have kindly given their valuable time to take part in the DECISION 2 Study. Your help is much appreciated.

FUNDING

This study was funded by the Wellcome Trust Institutional Strategic Support Fund (ISSF) through Cardiff University

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 and they worry about whether it was a 'good' decision. Families have suggested that providing support for family members when making such decisions may be helpful. A new tool (a decision support booklet) was developed 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. The aim of the DECISION 2 study was to explore family members' views about the decision support booklet and if any information is unclear or missing. This will help us to refine the booklet prior to testing its effectiveness in a future study.

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 talk through what they thought about the booklet, a technique called 'think aloud', and asked them what might be missing from the booklet, and what further changes could make it better.

SUMMARY QUOTE:

"I think it is a good idea for you to have that bit of support because it makes you think about things, which you didn't before. I think if I'd have had the booklet in the first place, it would have enhanced my knowledge of deciding what's the right thing to do."

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 18 family members (3 men, 15 women) from England and Wales who were a range of different ages and either a partner (or ex-partner), child or grandchild of someone living with dementia. The interviews lasted an average of 42 minutes.

Participants generally liked the appearance of the booklet and thought that the colour palette and design was bright and attractive, although two participants didn't like the 'blank faces' of the figures used in the booklet. Participants described the contents as informative and well balanced and thought that the language was accessible and had a warm and friendly tone, although some changes to the text were suggested. Most expressed a preference for having a paper copy of the booklet rather than in an electronic format. The general preference was for receiving it ahead of a consultation with the clinical or research team in order to have time to go through it, although being able to discuss the study with the clinical or research team and ask them questions was viewed as very important.

Participants thought that the sections on advantages and disadvantages and the six-step decision-making process were very helpful. They appreciated having the space to write down any notes or questions as they went along. They also liked the reminder that they were making a decision based on what the person they represented would want to do, which might be different to what they would do. The message that there was no right or wrong answer was viewed as reassuring, as were reminders that they could take time to make a decision and that the person they represented could be withdrawn from the study at a later stage if they felt that was needed.

There were differing opinions about the 'values clarification' exercise which was designed to help family members consider the different aspects of a study, including any advantages and disadvantages, and reflect on what the person they represented would think about them. A number of participants were unsure how to complete the exercise and felt the layout was confusing. Some participants liked having the five options to choose between, others thought that three would be enough. Some participants thought that the descriptions about what elements of the study they should consider needed to be clearer, and most thought that better instructions on how to complete the exercise were needed.

What are the next steps?

This study has given us important information that will help us to support family members making decisions for people with conditions such as dementia in the future. Following on from these interviews, the next step is to make changes to the booklet where needed. We then need to find out whether it is effective in supporting families making decisions about research in practice. To test this, we will ask family members who are making real-life decisions about research studies to use the booklet and compare their experiences with family members who are not given the booklet. We will also look at when and why it is effective or not.