COnSiDER Study

Project summary

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COnSiDER
CORE OUTCOME SET

Background

The global ageing population is accompanied by a rise in the number of people with impaired decision-making due to conditions such as dementia and stroke. There is also an increase in the number of patients requiring critical care due to the current COVID-19 pandemic. COVID-19 has also had a devastating impact on people living in care homes, including older people who account for over half of the excess deaths during the pandemic, and people with learning disabilities who have also experienced an increase in excess deaths. This has shone a spotlight on the need for more research to improve the care for these populations who are often unable to provide their own consent to take part in research and are often under-represented in research as a result.

In circumstances where an adult lacks capacity to consent to research, a substitute or proxy decision-maker is involved in making a decision about participation on their behalf. This is usually a family member or close friend who is asked to make a decision based on what they think that person's preferences would be about taking part. One of the challenges of involving these populations in research is that 'proxy' decision-makers often find it hard to make decisions, partly due to the challenges of establishing what the person's wishes and preferences would be about participation.

Our previous research found that family members find it difficult to make decisions about research on behalf of someone they care for. This has led to the development of interventions to help family members making decisions about research on behalf of someone with impaired capacity. However, before we can test whether new tools like this are effective or not, we first need to establish which outcomes should be measured and reported. Currently there is no agreed set of outcomes for testing interventions to improve decisions made about research on someone else's behalf, which makes it hard to compare different interventions.

In the COnSiDER Study we aimed to establish which outcomes are important when testing interventions to improve decisions about research made on behalf of someone who lacks capacity to consent and should be included in a core outcome set (or 'COS').

> "A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care"

We adapted methods which have previously been used in projects developing core outcome sets for assessment of clinical treatments, and registered the study on the COMET (Core Outcome Measures in Effectiveness Trials) database. The first part of the study was a literature review to identify which outcomes might be relevant. We then carried out Delphi study with a range of stakeholders using an online survey over two rounds to rank the outcome items and then through a meeting to reach consensus as a group on the final COS. This report summarises the initial findings of the project.

Findings

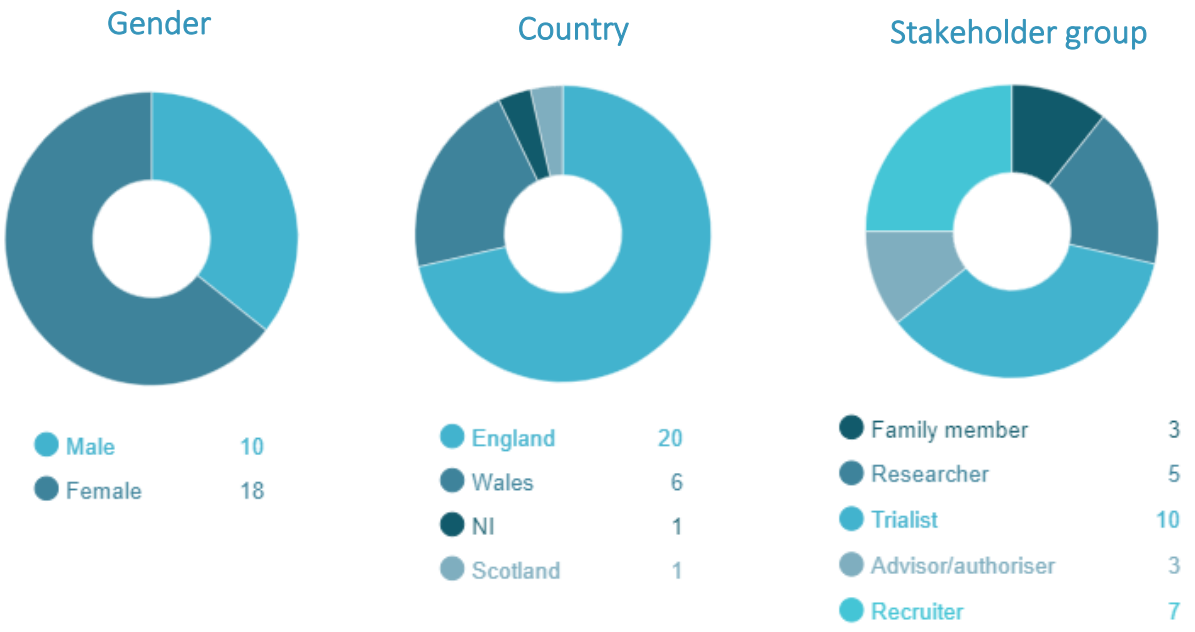
Scoping review

As this is a new area for research, we conducted a scoping review of relevant literature, including interventions to improve 'own consent' decisions in trials and decision support interventions to improve proxy decision-making for care and medical treatment. As a good quality decision is one that is based on both an effective **decision-making process** and the quality of the choice (**decision quality**) that is made, we included outcome items (and related outcome measures) relevant to either element. The candidate outcome items we identified were broadly categorized into three areas: how family members make decisions (e.g deliberation processes), their experiences of making decisions (e.g feeling satisfied), and the personal aspects that influence the decision (e.g being informed). The list of candidate items was then taken forward to the next phase of the study for consultation with stakeholders and the outcome measures were held separately for future work to establish which measures capture the outcome items included in the final COS.

Online survey

The Delphi was conducted online in two rounds between March and July 2020. A total of 28 participants from across the UK completed the online survey (see Figure 1.). They included family members of people with impairing conditions such as dementia, researchers in a range of relevant areas, trial designers and clinicians leading trials in areas such as emergency care, trial authorisers or advisors (e.g members of PPI groups and Research Ethics Committees), and trial recruiters (e.g research nurses).

Figure 1. Participant characteristics (n=28)



Participants were asked to consider how important they thought each item would be in judging how well the decision-making process had been conducted, and score each one from 1-9 (divided into categories of 1-3 = not important, 4-6 = important not critical, and 7-9 = critical to include). For each outcome, the proportion of respondents scoring 1-3, 4-6 and 7-9 was calculated for each item. Using pre-defined thresholds, each outcome was classified as either 'consensus in', 'consensus out', or 'no consensus' for items that were equivocal (i.e no consensus reached) and required further discussion. Participants in Round 1 could also propose additional outcomes they felt were important to include but were not currently in the candidate list.

In Round 2, participants were asked to rescore all outcome items (including one proposed additional item) and consider whether they should be included in a core outcome set, with a text box provided for an explanatory comment. In total, 27 outcome items reached consensus for inclusion and there was no consensus reached for 10 items.

Consensus meeting

Of the stakeholders who participated in the online survey, 20 registered to take part in the online consensus meeting held via Zoom in October 2020. However, as this coincided with a 'second wave' of COVID-19 some participants who provide clinical services were unable to attend on the day. As members of the public (including patients and families) were under-represented in the original stakeholder group, additional public contributors were invited from a PPI group who support the wider programme of research. Sixteen participants attended the consensus meeting, including representation from England and Wales and across the five stakeholder groups.

Each of the 10 items was presented and discussed by the group in turn, followed by on screen polling. Participants were asked to vote on whether the item should be included or not in the final COS, with 70% of those voting needing to agree to its inclusion.

A range of views were expressed about the importance of each item which echoed the lack of consensus reached during the online survey rounds. Discussions centred around the complexity of decision-making and proxy consent decisions made on behalf of others, and the overlapping relationships between many of the outcomes (e.g the role of regret about decision-making vs regret about the decision made vs role regret) and related outcome domains. There were particular discussions around the process of decision-making and the outcomes of decision-making, and how much these could be considered features of decision-making rather than problematic areas that should be targeted for reduction, and how (and particularly when) the outcomes should be measured.

The results of the polls similarly quantified the polarized views of the meeting participants for some items. Some items were closely matched in terms of the number of participants who voted for its inclusion or exclusion, a small number received almost unanimous votes for exclusion, others achieved a clear majority for inclusion but did not reach the pre-defined threshold. Of the 10 items needing consensus and discussed at the final meeting, one was included and nine did not reach the threshold for inclusion.

Core outcomes

A total of 28 outcome items were included in the final COS, divided across the three broad areas of how family members make decisions, their experiences of making decisions, and the personal aspects that influence the decision. The included COS items are shown in Figure 2.

Figure 2. Items included in the COnSiDER core outcome set

How family members make decisions

Whether the family member:

- Makes a decision that fits with the person's own values, wishes, and preferences (values congruence)
- Is able to determine the person's own values, wishes and preferences about the choices
- Is clear about which risks and side-effects would matter most to the person
- Is clear about which benefits would matter most to the person
- Is clear about which would be more important to the person (balancing benefits or risks and side-effects)
- Uses consideration and thought when making the decision or making a choice (deliberation)

Their experiences of making decisions

Whether the family member:

- Feels it was the right decision
- Feels satisfied with the decision
- Feels that they had enough time to make a decision
- Feels that the decision made was a good quality decision (regardless of the outcome)
- Is comfortable (feels happy and relaxed) with the decision
- Feels that the decision was a wise one

Personal aspects that influence the decision

Whether the family member:

- Recognises that a decision needs to be made (choice awareness)
- Has been informed about the purpose of the study, procedures, risks and benefits
- Has been informed about their role in making the decision
- Understands that the person's own values, wishes, and preferences affect the decision
- Understands the information needed to make the decision (objective understanding)
- Feels that they understand the information well enough to make the decision (subjective understanding)
- Recognises they do not have enough information about the views of the individual to represent their views^
- Feels confident in their knowledge to make a decision
- Feels confident to make a decision
- Feels able and has the opportunity to ask questions
- Feels able to express their opinion about each choice
- Feels as involved in the decision as they want to be
- Feels prepared to make the decision
- Is ready to make a decision
- Feels that they can delay their decision if they feel that they need more time

^ Additional outcome proposed by participant in Round 1

Conclusions

This project summary reports the initial findings of the COnSiDER study which aimed to establish which outcomes are important when testing such interventions. Informed by a scoping review, a set of 28 core outcome items has been agreed through stakeholder consensus.

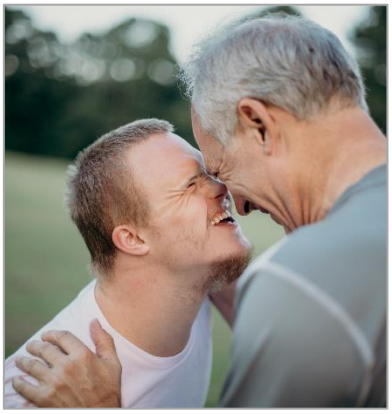
Thank you to all those who have kindly given their time and contributed to this work.

The aim is to share the findings of this project with the research and practitioner communities, and the wider public, including publishing the findings and updating the COMET database of core outcome sets. As this is the first work to explore outcomes in this novel area of research, the outcome items included in the COS may need to be revisited as our understanding in this area evolves and interventions are developed and tested.

Next steps

Having now established **what** outcome items should be measured, in future work we will look at **how** we can measure these outcomes and **when** they are most appropriately measured.

We hope that the stakeholders who kindly participated in this project, and others who may be interested, will help ensure this future work is relevant to the experiences of patients, families, researchers and practitioners who remain at the centre of this work.



If you have any questions or comments, please contact:

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