SWAT 159: Feasibility and effectiveness of a decision aid for family members considering trial participation on behalf of an adult who lacks capacity to consent

Objective of this SWAT
To assess the feasibility and effectiveness of a decision aid for family members acting as a consultee or legal representative, including its effectiveness on decision quality

Study area: Recruitment
Sample type: Carer/Parent
Estimated funding level needed: Unknown

Background
Adults with significantly impaired decision-making through dementia, learning disabilities, or critical illness are often excluded from research because of the ethical and methodological challenges of conducting research with people who lack capacity to consent [1]. Concerns are often raised about who can act as a consultee or legal representative (usually a family member), and how they make a decision about research participation [2]. Family members can find making proxy decisions about participation challenging and some experience decisional and emotional burden as a result [3]. Some studies have reported that nearly all proxies experience some degree of burden when making decisions about research [4]. This leads to a high proportion of families declining participation [5]. Despite numerous innovations to improve informed consent processes for research, there are no interventions for proxies who are making decisions on behalf of someone who lacks capacity.

Decision aids (DAs) support healthcare decision-making processes by providing information about available options and their associated outcomes, alongside information that enables patients to consider what value they place on particular outcomes and provide structured guidance on steps of decision making. DAs have recently been developed for people considering participating in clinical trials in order to better engage potential participants in the decision-making process about clinical trials and allow them to make more personally relevant decisions about their participation [6]. These DAs have shown some potential promise in improving key decision outcomes such as knowledge, values clarification, and decision conflict, whilst not negatively impacting recruitment or intention to participate [7]. A novel DA for proxy decision-making about research has now been developed [8], which requires evaluating to determine if it is an effective form of support, and if so, in which contexts.

This SWAT will assess the feasibility and the effectiveness of the DA (a colour A5 booklet) in a range of host trials, which aim to recruit adults who lack capacity. Trial recruiters will be randomised to either deliver the intervention to family members approached as consultee/legal representative alongside standard study information, or to provide standard study information alone. A novel scale is being developed, ‘Combined scale for proxy informed consent decisions (CONCORD)’, which builds on the outcomes identified in a core outcome set (COnSiDER) [9] and existing scales such as the Decisional Conflict Scale.

Interventions and comparators
Intervention 1: Decision aid alongside standard study information documentation
Intervention 2: Standard study information documentation alone

Index Type: Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Combined scale for proxy informed consent decisions (CONCORD). CONCORD scores will be recorded both for consultees and legal representatives who provide agreement to participation on the person’s behalf and those who decline participation. Outcome measure

completion will be aligned with the host trial processes but is expected to be completed in a relatively short timeframe following the decision.
Secondary: Secondary outcomes include selected CONCORD subscales of values clarity and preparedness, and the proportion of consultees and legal representatives who provide agreement to participate on the person's behalf and the proportion who decline participation.

Analysis plans
The primary analysis is the comparison of the CONCORD scale between each randomised group. Subgroup analysis will be considered for age, education level, relationship to the person being represented and delivery mode of the intervention.

Possible problems in implementing this SWAT
This is the first intervention (and SWAT) involving consultees and legal representatives making decisions about participation on behalf of someone who lacks capacity to consent, rather than prospective participants themselves. The DA has undergone acceptability testing and cognitive testing as part of the development process. As it is a novel intervention, further work is underway to qualitatively explore the barriers and facilitators to using the decision aid. We will then conduct a feasibility study to explore implementing the intervention and conducting the SWAT before commencing this SWAT across a range of trial types and settings. Randomisation to intervention or control will preferably be at an individual level, but will be dependent on the host trial design (e.g whether cluster or individually randomised, number of sites and recruiters).

The feasibility study will enable us to explore randomisation, recruitment and data collection processes. Following this, we will finalise the primary and secondary outcomes. Ethical approval will be required for parent trials hosting the SWAT. Embedded process and economic evaluations will be conducted alongside the SWAT to enable greater understanding about the contexts within which it may or may not be effective, and the resource implications of its use.

References
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8. Shepherd V, Wood F, Griffith R, et al. Development of a decision support intervention for family members of adults who lack capacity to consent to trials. BMC Medical Informatics and Decision Making 2021;21:30 doi: 10.1186/s12911-021-01390-4
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Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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