ADDRESSING THE BARRIERS TO CONDUCTING TRIALS INVOLVING ADULTS WITH IMPAIRED CAPACITY TO CONSENT

Findings from CONSULT-ENABLE Study

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INTRODUCTION

An estimated two million people in England and Wales have significantly impaired decision-making. This may be due to an acute medical event, long-term conditions such as dementia, or associated with learning disabilities, mental health conditions, or at the end of life. However, adults with impaired decision-making who are unable to provide their own consent, are often excluded from research.

> *1 in 3 patients with a hip fractures also have a cognitive impairment, yet this population is **excluded or ignored** in 8 out of 10 hip fracture trials*
>
> Mundi et al 2014

This is due to the complex ethical, legal and methodological challenges encountered when designing and conducting randomised controlled trials (RCTs) involving adults lacking capacity to consent. Exclusion form research results in a poorer evidence base for their treatment and care compared to other groups, and contributes to the health inequalities many of these groups already experience .

> *90% of RCTs are designed in a way that **excludes** people with a learning disability*
>
> Feldman et al 2014

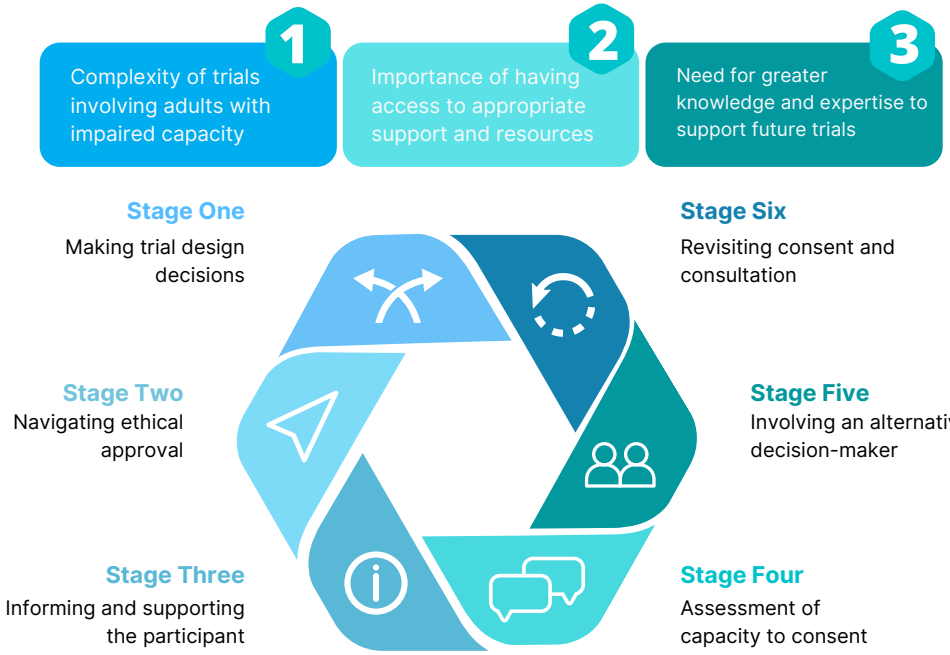
Despite a growing emphasis on making trials more inclusive of under-served populations, such as the National Institute for Health and Care Research (NIHR) INCLUDE initiative, few trials are designed to include participants who lack capacity.

We conducted the CONSULT-ENABLE Study to explore the barriers and facilitators to designing and conducting trials involving adults who lack capacity. We have made a series of recommendations that will ensure that trials are more inclusive of this under-served group.

KEY FINDINGS

Semi-structured interviews were conducted remotely during 2021 with 26 researchers and healthcare professionals with experience in a range of roles, trial populations and settings across the UK. Data were analysed thematically.

A number of barriers and facilitators were identified, grouped into three themes. These were mapped against key trial stages including when making trial design decisions, and navigating ethical approval.



Key themes were identified. Trials involving adults lacking capacity were viewed as challenging, which included the complexity of the legal frameworks, and the role of gatekeepers. A lack of access to expertise and the resource-intensive nature of these trials also created challenges for researchers.

> *"As a researcher it feels like just an insurmountable **black box of horrendousness**. It feels very much that if you get this wrong you will be **illegal** and the **ethics police** will come for you or something. It's scary"*

Trials were facilitated by prior experience, effective communication between research teams, and through public involvement. Participants highlighted the importance of 'designing in' flexibility and identified a need for better training and support.

KEY RECOMMENDATIONS

Researchers conducting trials with adults lacking capacity encounter a range of generic and context-specific barriers, which are exacerbated by resource limitations and knowledge deficits. This impacts on the ability to provide evidence-based care for these populations.

'Designing in' inclusivity, having greater access to information and support when designing and reviewing trials, ensuring trials are adequately resourced, and effectively involving and communicating with others, are all needed to facilitate conducting trials with this under-served group

INCLUSIVE DECISIONS

Decisions during the design and approvals process should take account of impact on inclusivity

INFORMATION & SUPPORT

Knowledge, training and support is needed to overcome the legal, ethical and practical challenges

APPROPRIATE RESOURCES

Trials involving adults with impaired capacity may be more resource-intensive and must be adequately resourced

COMMUNICATING WITH OTHERS

Involvement and participation requires effective communication with people with impairing conditions and those who care for them

RECOMMENDATIONS FOR FUNDERS

Funders such as the NIHR, have made a clear commitment to addressing inclusivity in research. However, researchers described the need for funders to consider the 'missing costs' that are required to fully resource inclusivity in this context. The need to appropriately resource inclusivity is summarised in the quote "*you can't ask for the world and not fund it*". This includes resources required for meaningful and accessible public involvement with people with cognitive impairment, where default approaches (e.g group meetings, email discussions) are less appropriate for people with additional communication and support needs

Recommendation	Category
Funders should signpost applicants to information and guidance on the design and conduct of trials involving adults with impaired capacity to consent	
Funding committees should consider whether issues around capacity and consent have been appropriately considered by applicants proposing research involving populations where these issues may be encountered. This may include requesting justification for their exclusion if appropriate	
Funders should acknowledge the additional resources needed to recruit participants with impaired capacity, and ensure adequate provision for these 'missing' costs. This should also be considered when assessing the cost-effectiveness of applications involving under-served populations	
In addition to these trials being more resource intensive, they are often conducted in care settings with less access to research infrastructure support, such as care homes. The need for increased levels of research support in these applications should also be considered when setting funding ceiling caps/tiers	
Funders should ensure appropriate provision is made to support public involvement with people who have a cognitive impairment which may require additional resources such as accessible materials and activities, and additional funding for carers or other forms of support for the person with cognitive impairment.	

RECOMMENDATIONS FOR RESEARCH ETHICS COMMITTEES

The process for reviewing ethics applications for trials involving adults lacking capacity across the UK was particularly challenging for researchers. Recommendations include investigating whether the guidance currently available to research ethics committees (RECs) supports them in their reviews of trials involving adults lacking capacity. It also includes ensuring advice given by RECs to applicants is compliant with the legal frameworks governing research involving adults lacking capacity, ensuring consistency of review - both between RECs and within reviews of different applications conducted by RECs, and the need for greater communication between researchers and RECs

Recommendation	Category
All RECs (not only 'flagged' RECs) should consider whether issues around capacity and consent have been appropriately considered by applicants. This may include requesting justification for the exclusion of adults who lack capacity (rather than only justification for their inclusion as required by the legal frameworks)	
Organisations with responsibility for ethical review processes should seek to address inconsistencies in reviews of applications involving adults lacking capacity and the quality of the advice provided to researchers. Better guidance may be needed	
All RECs should consider whether researchers have appropriate arrangements in place in the event that capacity is lost or may change or fluctuate during a trial, which may include all trials not just those intending to recruit adults lacking capacity	
Enabling consultation and communication between RECs, the HRA, and research teams prior to submission of an application should be considered. This could ensure that any questions or issues are addressed at the earliest opportunity and reduce subsequent delays in applications receiving a favourable opinion	

RECOMMENDATIONS FOR POLICY, GOVERNANCE AND INFRASTRUCTURE

A systems-wide approach is needed to explore how the UK research infrastructure, policy and governance processes support trials involving adults with impaired capacity to consent, and identify modifiable barriers. There is also a need to build research capacity that can support future trials in populations affected by impaired capacity to consent and in the settings where they received care. This needs to be underpinned with a universal approach to training and guidance for all those who design, review, and conduct these trials

Recommendation	Category
Research governance and ethical review processes should be harmonised and streamlined across the UK to reduce the impact of a dual REC submission and ensure studies involving adults lacking capacity has parity in time to review with those involving people who are able to provide consent	
R&D infrastructure and support should be reformed to take account of the complexities encountered in the delivery of trials involving adults lacking capacity. For example, metrics and associated accruals should take account of the additional time and resources required to recruit adults lacking capacity.	
Co-ordinated and comprehensive training on the fundamental principles underpinning research involving adults lacking capacity to consent is needed for all those who design, review, and conduct these trials, with access to supplementary modules containing context-specific information where appropriate	
System-wide initiatives are needed to build capacity and competence in research involving adults lacking capacity. This requires investment to recruit and retain staff with appropriate skills, expertise, and experience and requires support for building long-term relationships	

RECOMMENDATIONS FOR RESEARCHERS

Researchers described a circular paradox where trials including adults lacking capacity to consent are relatively uncommon, therefore they have less experience and confidence in conducting trials with these populations and so are less likely to design trials to be inclusive of these populations. More detailed guidance is needed in relation to the design and conduct of trials involving adults lacking capacity, and for researchers to share their experiences e.g of using alternative consent processes such as those required in emergency and critical care research.

Recommendation	Category
Research teams should ensure they have access to methodological expertise/experience in the design and conduct of trials involving adults lacking capacity to consent and an understanding of how the legal provisions are implemented in practice	
Flexibility and inclusivity should be 'designed into' trials from the outset to facilitate recruitment and retention, such as enabling remote consultation with consultees and legal representatives, and planning ahead for the involvement of consultees/legal representatives should participants lose capacity during the trial	
Research teams should consider collecting additional data to identify any challenges and inform the rest of the trial, such as early qualitative work to enable changes to consent processes and/or enhanced consent training provided to recruiting staff	
Researchers should include additional resources (e.g enhanced research nurse time, accessible public involvement activities) in funding applications in order to provide tailored information and support to people with impaired capacity and their families	
Dissemination of findings must also be inclusive. For example ensuring summaries are cognitively accessible, and developing alternative dissemination pathways to ensure that information about the findings actually reach participants and their carers	

RECOMMENDATIONS FOR RESEARCH DELIVERY TEAMS

Research teams with experience of recruiting participants with impaired capacity made a number of practical suggestions that will be useful for other teams/members who may be less familiar with these populations . Some recommendations are generic although some will be more context or population specific.

Recommendation	Category
Additional training and support will improve staff skills and confidence in recruiting these populations. This may include assessing capacity, providing enhanced communication and supported decision-making, and optimising strategies to approach family members to act as consultee or legal representative	
Staff who are less familiar may benefit from peer support or the opportunity to shadow colleagues with greater experience with these populations. This might include learning from approaches used in speech and language therapy (SLT), with specialist input by SLT where required	
Where appropriate, staff should involve family members to discuss any concerns about capacity and help identify any additional communication needs the potential participant might have. Their involvement may help to support the person with cognitive impairment to make a decision about participation	
Prospectively planning for involving professionals as legal representatives or nominated consultees may reduce unnecessary delays e.g creating a list of clinical care team members who are willing to act as consultee or legal representative. This might be particularly important for emergency trials	
Staff should ensure regular communication with the participant and/or their care team so that any changes in capacity are recognised in a timely manner and consent and consultation can be revisited appropriately e.g if the participant regains capacity	

NEXT STEPS

The CONSULT-ENABLE Study forms part of a larger interdisciplinary programme of research exploring inclusivity in trials with a focus on populations with impaired capacity to consent. Whilst the study was conducted with researchers in the UK, many of the findings and recommendations will be applicable in international settings. The findings from this study will inform future work to address the challenges identified in a number of ways:

No. 01 — Disseminating findings

We will share the findings and key recommendations with a range of stakeholders to address the barriers identified in the study

No. 02 — Tools and guidacne

We are developing guidance and practical tools, such as the INCLUDE Impaired Capacity to Consent Framework to help researchers to design more inclusive trials

No. 03 — Methodological research

We will collaborate with others to increase the evidence base for conducting trials involving adults lacking capacity, including developing and evaluating interventions such as a decision aid for consultees and legal representatives (CONSULT Study)

Trials Methodology TMRP Research Partnership

ACKNOWLEDGEMENTS

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FURTHER INFORMATION

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CONSULT ENABLE Study

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