**Using a Delphi survey to gain an international consensus on the challenges of conducting trials with adults with intellectual disabilities.**

**Abstract**

**Background / Aims**: People with intellectual disability experience higher rates of multi-morbidity and health inequalities, they are frequently prescribed medications and more likely to have an avoidable or premature death. There is a recognised lack of randomised controlled trials, and subsequently a lack of evidence base, for many of the interventions and treatments provided to people with intellectual disabilities. Very few disability-specific trials are conducted and people with intellectual, and other cognitive, disabilities are routinely excluded from mainstream trials. There is an urgent need to facilitate more disability-specific trials or to encourage mainstream trialists to include people with disabilities in their studies. Obtaining a thorough understanding of the challenges inherent in these trials, and sharing this knowledge within the research community, may contribute significantly towards addressing this need. The aim of this study was to explore the practical and methodological challenges to conducting trials with adults with intellectual disabilities, and to reach a consensus regarding which are the most important challenges for researchers for inclusion in a resource toolkit.

**Methods**: A three-round modified Delphi survey was conducted with a panel of international trials researchers within the intellectual disability field. Items were assessed in terms of consensus level and stability of responses.

**Results**: A total of 64 challenges and barriers were agreed upon, across all aspects of the trial pathway, from planning through to reporting. Some challenges and barriers had been noted in the literature previously but many previously uncited barriers (both systemic and attitudinal) were identified.

**Discussion**: This is the first international survey exploring the experiences of researchers conducting randomised controlled trials with adults with intellectual disabilities. Many of the barriers and challenges reported can be overcome with creativity and some additional resources. Other challenges maybe harder to overcome, including attitudes towards conducting trials with disabled populations. These findings have implications for conducting trials with other populations with cognitive or communication difficulties. Implications for disability researchers, funding bodies and ethical review panels are discussed.

**Key Words:** Intellectual and Cognitive Disabilities, Randomised Controlled Trials (RCTs), Delphi Survey; barriers and challenges; identification, consent and recruitment; ethical approval; attitudes towards ID RCTs.

**Introduction**

Intellectual Disability (ID) is a wide class of disorders that may have genetic, biological or other aetiologies. People with ID have an IQ <70 typically have difficulties with communication, intellectual functioning (problem solving and reasoning skills), and adaptive functioning (self-care and social skills). They have poorer health profiles on a number of health markers, reduced longevity and poorer access to healthcare provision than the non-disabled population1-3. They also have higher rates of multi-morbidity than the general population3 and a higher proportion of avoidable and premature deaths2,4.

Clinical evaluation research within the ID field is at an early stage. A common note in ID systematic reviews is that there is a lack of evidence for many of the interventions commonly provided to people with ID5. RCTs are considered by many as the gold standard in intervention evaluation research6. Unfortunately, there has been a lack of RCTs in the ID field and people with ID are routinely excluded from mainstream trials7. There is a growing literature suggesting that when conducting RCTs with people with ID, or other cognitive disabilities, researchers may face additional ethical (e.g. obtaining written informed consent from people with communication difficulties), recruitment (e.g. needing to recruit through a series of ‘gatekeepers’), and practical challenges (e.g. adapting resources to match varying ability levels of participants, managing care providers schedules etc) not commonly experienced by those conducting mainstream trials8,9, 10. Both of these factors have contributed to the situation where research in the ID arena lags well behind the mainstream evidence-base11.

There is a growing bank of resources to support researchers in planning, conducting and reporting the results of clinical trials. The Medical Research Council (MRC) have developed a number of research hubs across the UK focused on enhancing trials methodology and they have produced guidelines on conducting clinical trials12. The Consolidated Standards of Reporting Trials (CONSORT) Statement provides clarity on how to report upon a trial after it is completed13. Until recently, the ID trials literature has focused mainly on reporting *results*, with little attention given to reporting *process*. The purpose of developing a scientific literature base is jointly to share knowledge of findings and to enable replicability of said findings. How can a trial be replicated if we do not know what was involved in conducting it? In a previous paper14 we differentiated between the sharing of an 'evidence base' and the sharing of an 'experience base' and proposed that the development of both were essential to addressing the health inequalities and inequities experienced by people with ID.

A number of trialists have produced reflective papers that report their experiences of conducting specific trials8 and have highlighted a number of common barriers: recruiting adequate sample sizes, obtaining ethical approval, a lack of ID-appropriate outcome measures, and ensuring intervention fidelity. The generalisability and commonality of these trial-specific papers have not been determined.

In an attempt to support the development of a robust evidence-base within the field of cognitive disabilities, we conducted a multi-stage, mixed-methods study to understand the challenges inherent in conducting RCTs with adults with ID, with the purpose of developing an on-line resource toolkit for researchers planning to conduct ID-RCTs, and for those conducting mainstream trials who wish to make their trials accessible to participants with ID. Stage 1 involved conducting a systematic review of the adult ID-RCT literature to ascertain which challenges and barriers were being reported in the literature14; Stage 2 involved a series of interviews with ID-RCT researchers to explore challenges and barriers that may not have been cited in the literature (Mulhall et al., Submitted); Stage 3 involved the use of an on-line modified Delphi Survey that synthesised, extended and triangulated the findings of the previous two studies and achieved a consensus concerning which of the challenges and barriers were considered important enough to be included in the resource toolkit (the toolkit will be presented in a separate paper). Thus, the overall larger study expands the ‘experience base’ by collating what is already known in the literature, extends this by exploring what was not previously cited, and then attains a consensus regarding what may be the most important challenges and barriers for researchers in this field. This paper details the planning and completion of the modified Delphi Survey (Stage 3).

Delphi surveys have been used extensively in the development of trials methodology. Sindhu et al. (1997)15 used a Delphi survey (n=8) for the development of a tool for rating the quality of a trial, while Cheung et al. (2017)16 reached a consensus (n=17) regarding optimal outcome measures to use in smoking cessation trials. They have also been used successfully in the implantation science field. For example, Abidi et al. (2016)17 explored the barriers to the implementation of brief alcohol interventions into primary practice. However, to the best of our knowledge, this is the first time that ID researchers have been surveyed internationally regarding the challenges and barriers they have faced while conducting an ID-RCT to inform the development of a resource toolkit.

This study had two aims:

1. To explore, both previously reported and unreported, methodological and practical challenges inherent in conducting RCTs with adults with ID.
2. To obtain a census about which of these challenges would be important to include in a toolkit for researchers planning ID-RCTs or who wish to include adults with ID into mainstream trials.

**Methodology**

This study employed a modified three-round Delphi survey, conducted between November 2017 and March 2018. A Delphi Survey is an iterative, systematic method for facilitating a panel of experts to reach a consensus on a given topic18-20. It consists of a sequential series of surveys (called ‘rounds’) with controlled, individualised feedback provided to respondents, between rounds. The Delphi method is commonly used when there is a lack of research regarding a particular topic20. This study is considered ‘modified’ because responses from an open-ended question in Round One were combined with information collated from two previous, related studies: a systematic review of the challenges14, and interviews with international ID-RCT experts.

*Survey Design*

*Panel selection.* Panel selection is a crucial factor in a Delphi survey design. It is important that panel members have sufficient experience and knowledge to make valid contributions21-22. It has been proposed that a heterogeneous panel with differing opinions, skills and perspectives can generate more robust results20-23, therefore, we sought the opinions of internationally renowned ID RCT researchers who come from a range of professional backgrounds, and with varying amounts of experience in the field.

### *Panel Identification.* A sampling frame of international ID-RCT researchers was devised from a previously conducted systematic review14.

*Panel Recruitment****.*** Potential panel members were individually sent an email invitation that included information about the study, a consent form and a request to forward the information to colleagues (snowball sampling), that they thought may have expertise in this area. A total of 61 invitations were sent (five were identified through snowballing) (see Figure 1).

In total, 22 respondents completed Round One (92% return rate), 21 completed Round Two (96% return rate) and 20 completed Round Three (95% return rate). Correspondence with respondents suggested that reasons for non-returning after Round One were due to external workload pressures.

INSERT FIGURE 1 HERE

*Panel profile.* Table 1 details the profile of the panel members. The panel consisted of 22 researchers from a range of professional backgrounds, with extensive experience researching in this field, and many of whom had also served on ethics or funding review panels. The panel included participants from Australia (n=5), England (6), Germany (n=1), Norway (n=1), Scotland (n=3), Sweden (n=3), USA (n=2) and Wales (n=1).

INSERT TABLE 1 HERE

*Consensus level for items*

There is no agreed standard for consensus levels within the Delphi literature24. Common consensus levels range from 70%25 to 80%26; although levels as low as 66%27 and as high as 90%28 have been used. A study aiming to determine a small number of key agreed items may benefit from using a higher consensus target than a study aiming to determine a more comprehensive list. Given the aims of the current study, an a priori decision was taken that our consensus target would be 70% (see Round Two Analysis).

*Number of Rounds*

At the planning stage we anticipated a three round Delphi survey, however it was decided a priori that the survey would stop if consensus was reached for 90% of the items in Round Two. If consensus was not to be reached after Round Three, then outstanding items would be assessed in terms of stability with a weighted Kappa statistic. Items not achieving consensus after the third round but with very high levels of stability would be included as ‘cautionary items’ in the toolkit. There are no set standards for interpreting a Kappa statistic. In this paper we follow guidance from Landis & Koch (1977)29 who suggested the following: a Kappa value of 0.0 - 0.2 = Slight agreement; 0.21-0.4 = Fair agreement; 0.41 – 0.6 = Moderate agreement; 0.61 – 0.8 = Substantial agreement; 0.81 – 1 = Almost perfect agreement. The term ‘agreement’ refers to the stability of responses to an item by each individual respondent from Round Two to Round Three.

*Survey Administration*

The survey was conducted online using the Qualtrics software platform. Qualitative data were analysed manually, and quantitative data were analysed using SPSS for Windows (version 24) and Microsoft Excel.

*Survey Flow and Analysis process*

*Round One.* In the first round, participants were asked standard demographic questions followed by the following open-ended question:

“What are the main practical and methodological barriers or challenges that you have faced, or are aware of, when conducting RCTs with adults with ID. Please briefly note as many barriers or challenges that you can think of”.

There was no limit placed upon the length of possible responses.

*Round One Analysis and Initial Results*

The responses from Round One were coded using a four-phase Thematic Content Analysis approach similar to that of Braun & Clarke (2006)30. In Phase 1 each on the respondents’ answers were read and re-read by the primary researcher (PM) in order to become familiar with the data. In Phase 2 a semantic thematic analysis was conducted. Data from the Delphi responses were combined with barriers noted in the Mulhall et al. (2018)14 systematic review and the Mulhall et al. (submitted) interviews studies, and a series of seventy-nine (79) codes were produced. In phase 3 the codes were organised into a series of thirteen (13) categories relating to different aspects of the RCT research process. In phase 4 each of the seventy-nine codes were used to create 79 individual statements that would then be presented to respondents in Round Two. Table S1 in the online Appendix shows the thirteen categories, the corresponding number of items per section, and the source for each item. In total 61 items were derived directly from the Round One Delphi responses; eight items were from the Mulhall et al. (2018) systematic review; ten were from the Mulhall et al. (submitted) interviews report; thirty-five items were common to two or more sources, thus giving a total of 79 items (see also Figure S1 in the online Appendix).

*Reducing bias in coding.* To reduce the risk of bias at this stage, the wording of each item was kept as closely as possible to the verbatim wording of the original Round One responses. Each of the 79 items, 79 codes and the 13 sections were independently reviewed by two other members of the research team. This process led to one item being reworded.

*Round Two*

In Round Two respondents were given the following instruction “The responses you gave in Round 1 have been amalgamated with those provided by other respondents and have been collated into a list.  In this round of the survey you will be presented with the list of barriers and challenges and will be asked to rate whether it is important to include each barrier/challenge in a toolkit for researchers who are interested in conducting ID-specific RCTs, or who are interested in including people with ID into mainstream trials.  Please respond to all items”. Respondents were then presented with the seventy-nine items, with one category presented at a time. For example, the first section “Trial Planning” had two items and was presented as per Figure S2 in the online Appendix.

The respondents were asked to rate how important they thought it would be for each individual item (barrier/challenge) to be included in a toolkit for researchers interested in conducting trials with adults with ID. Reponses were on a 5-point Likert scale (1= Unimportant, 2= Not Important, 3= Neutral, 4= Important, 5= Very Important). An answer was required for each item.

*Round Two Analysis*

Participant responses were recoded into numerical form (e.g. “1= Unimportant” was recoded to “1” and “5= Very Important” was recoded to “5”). Consensus was measured by the percentage of respondents who rated a given item as “4 – Important” or “5 – Very Important”. Descriptive statistics were calculated for each item (mean, median, mode, and standard deviation). Those items that achieved a consensus level of ≥70% were deemed to be included in the toolkit at this stage. Those items that did not receive the required consensus level were re-presented in Round Three.

*Round Three*

Each respondent was presented with the items from Round Two that did not achieve 70% consensus, along with individualised feedback. The feedback consisted of a reminder of the respondent’s individual rating for each item in Round Two, along with the percentage rating from the overall survey panel. For example:

“In the previous round you rated this item [insert participant’s rating]. The overall group ratings were:

1=Unimportant – 5%; 2= Not Important – 10%; 3= Neutral – 60%; 4= Important 20%; 5= Very Important – 5%.

Please resubmit a rating for this item (you can use your previous rating or change to a new rating).

How important do you think it is to include this item in the toolkit?.”

*Round Three analysis*

In addition to descriptive statistics and consensus levels, the Round Three analysis also included a Weighted Kappa as an assessment of stability of responses from Rounds Two to Three.

*Ethical Considerations*

As Delphi studies are iterative and require the provision of individualised feedback to each participant, complete anonymity of survey responses was not possible. However, pseudo-anonymity was assured as participants were not aware of the identities, or responses, of the other participants, nor how many other respondents were in the panel.

This study was reviewed, and approved, by the Ulster University Nursing & Health Research Ethics Filter Committee.

**Results**

*Round Two Results*

For reasons of brevity the descriptive statistics, Round Two & Round Three consensus levels and Kappa statistics for each of the 79 items, are presented in Table S2 in the online Appendix. Table 2, below, shows the 13 sections, the number of items in each section, the number of items presented at each round and the number of items which achieved the target level of consensus. For example, the section titled “Service Factors” had twelve items presented at Round Two, of which nine items achieved the target consensus level of 70%. From the pool of 79 items, 56 items achieved the target level of consensus in Round Two. Those items that did not achieve the target level of consensus were re-presented in Round Three.

INSERT TABLE 2 HERE

*Round Three Results*

Of the 23 items re-presented in Round Three, eight (34.8%) achieved consensus. For example, the Funding section had six items at Round One. At Round Two, two items achieved ≥70% consensus. The other four items were re-presented in Round Three of the survey. At this stage, a further one of the four items achieved ≥70% consensus. Therefore, after Round Three the Funding section consisted of three items, with an average consensus level across the section of 62.8%.

Of the remaining fifteen items, six achieved substantial levels of stability (>0.81) (Table S2 in the online Appendix). This means that although the *majority* of respondents may not have agreed that each of these items were important enough to be included in a toolkit, those who did were consistent in their opinion.

**Discussion**

In this survey an international panel of ID researchers were asked about their experiences of conducting ID RCTs, building on a previous review of challenges in the published literature14. This study is the first time that the Delphi technique has been used to survey a group of ID-RCT trialists to reach consensus on this subject. The diversity within the panel, in terms of world-wide location, multi-disciplinary professional background, and significant experience within the field of ID-RCTs, adds considerable weight to the findings highlighting a number of challenges that have not been well discussed in the literature.

In order to facilitate and encourage the development of RCTs within the ID field, and to encourage mainstream trialists to encourage participation from people with ID into their trials, it is important that prospective trialists are fully informed about the potential challenges that they may face when conducting ID trials.

Researchers conducting ID RCTs face a number of practical and methodological challenges14. The Delphi survey identified 64 barriers and challenges across 12 sections of an RCT pathway. It should be noted that the extent of the potential impact of these challenges on a trial has not been assessed, and the fact that the items are reported, or will be included in the toolkit, does not guarantee that a researcher will face each barrier and challenge. However, the sixty-four challenges and barriers were included in the toolkit as 70% of the panel of ID-RCT experts considered them important enough for other researchers to be made aware off.

Some of the barriers and challenges identified may be expected in any clinical trial, such as challenges recruiting adequate numbers31. However, there are a large number of nuanced barriers that may be faced when including disabled, or hard to reach, populations. Many of these nuanced barriers have not been thoroughly reported or discussed in the trials literature. Panel members considered it important that prospective researchers know that they may encounter varying degrees of resistance from other clinical or research staff regarding the utility of RCTs with this population.

Due to the challenges of identifying and recruiting adequate numbers, there has recently been a shift towards multi-centre ID studies. This, coupled with the need to make reasonable adjustments to measures and interventions, means that ID trials have added costs. Future research providing actual cost implications would be useful as there was a perception among some of the respondents that some funders may not consider ID trials cost-effective.

The process, and costs, of recruitment may be exacerbated by the requirement to recruit via gatekeepers. This can also introduce a degree of sampling bias that is not often acknowledged, and can threaten the external validity of a trial32. Adults with ID often rely on a number of people for their health and social care needs, similarly with research, they may rely on others for their consent, participation and data collection14, thus we propose that the gatekeepers and the caregivers are crucial to the success of clinical trials that have participants with cognitive disabilities.

This survey contributes to the international research literature; forty-four (56%) of the Round One items had not been reported in our earlier systematic review14 and 39 (49%) had not been reported in the earlier series of one-to-one interviews(Mulhall et al., Submitted). This suggests that many of the methodological and practical challenges faced by ID-RCT researchers are not being reported in the trials literature. To date, most of the literature on ID trials has focused on outcomes – what was done and what was the result. There is now a growing recognition that if the standard / quality, frequency and impact of trials is to increase then researchers will also need to share their ‘experience base’ as well the ‘evidence base’. It is hoped that endeavours such as the MRC Research Hubs and the MRC guidelines for conducting process evaluations33 will encourage the development and sharing of this ‘experience base’.

One of the most concerning findings of the survey was the perception amongst some respondents that many people (relatives, care staff, clinical staff and even fellow researchers) do not agree with the utility, or understand the process, of an RCT. There appears to be a lack of technical understanding amongst researchers about concepts such as randomisation, and fear amongst some gatekeepers about being responsible for any harm that might come to the person with ID – these issues are not being discussed in the ID trials literature.

*Limitations and Strengths of the study*

A potential limitation of the study is the small sample size, which may question the generalisability of the results. Recent studies suggest that many healthcare Delphi surveys have small samples35, however panels with more than twenty members produce stable findings24. A potential criticism of the Delphi methodology is that the provision of group responses during the feedback may lead to social desirability and group influence. However, the high Kappa statistics found in the study suggest that this was not the case. Qualitative data regarding the respondents’ choice of ratings were not collected. This may have added further insights.

Although Delphi surveys have been used before in the ID field35, this is the first time an international group of researchers have been surveyed to collate the range of challenges that they have faced when conducting RCTs with adults with ID. The high levels of consensus and stability suggest that the challenges highlighted in this study are common across many jurisdictions, thus are of international relevance. A further strength of this study is the rich experience base of the international panel. In addition to the wide range of professional backgrounds, a large portion of the panel also had experience serving on ethics committees and funding review panels. Thus, many of them are in a unique position to a share a wealth of experience over and above what may appear in a single 'methods' paper.

Another strength of the study is that we did not limit analysis to consensus. We also included a weighted Kappa as a measure of stability of responses. A number of papers have suggested that stability can be equally as important as consensus in Delphi surveys36.

*Wider Implications*

Although this study focused on the field of ID, the findings have important global relevance and are transferable to other fields where potential trial participants have cognitive or communication disabilities. Clinical trials with adults with dementia, Alzheimer’s Disease, acquired brain injuries or Autistic Spectrum Disorders are rare and may all face potential barriers concerning communication, information processing abilities and ability to provide informed consent. With an estimated 10% of the world’s population living with a disability37 (many of whom will have a cognitive disability), addressing the health inequalities faced by people with disabilities is of global importance. With the number of people living with cognitive disabilities likely to increase38, the need for RCTs in the disability field has never been greater.

There is a challenge in these results for the ID-RCT field: there is much work to be done in improving the communication and collegial working arrangements between the ID RCT research community and the wider academic/researcher/professional communities at large. We propose that the time is right for discussions to re-evaluate the current ethical guidelines regarding the almost universal automatic requirement to recruit in-directly through gatekeepers, or more accurately the inability to recruit directly. Current mental health legislation, such as the UK’s Mental Capacity Act39, states that a person’s ability to make their own decisions should be assumed in the first place, until found otherwise. The experiences cited in this survey would suggest that this may not always happen in practice.

**Conclusions**

Researchers conducting RCTs with cognitively disabled adults are likely to experience a number of methodological and practical barriers, the majority of which are not often reported in the trial’s literature. Many of these challenges can be overcome with creativity and an appreciation of the rights of people with ID to actively partake in research. These challenges require additional planning, time and costs in order to make adaptations that take into account this population’s unique needs and abilities. We propose that the hardest challenges to overcome are those that are rarely reported: the attitudes towards the utility of conducting RCTs with people with ID; the lack of technical understanding of processes such as randomisation amongst research and clinical staff; the inability to directly recruit people with ID; and the perception that such trials are not a cost-effective use of funding. If ID-RCT researchers do not find a platform for sharing their 'experience-base' as well as their 'evidence-base' then the development of the evidence base in the field is likely to remain slow and mainstream researchers will continue to avoid including people with ID in their trials.

**References**

01 NHS Health Scotland. People with Learning Disabilities in Scotland: The Health Needs Assessment Report. Scotland, Glasgow: NHS; 2004

02 Ouellette‐Kuntz, H. Understanding health disparities and inequities faced by individuals with intellectual disabilities. *Journal of Applied Research in Intellectual Disabilities*, 2005; *18*(2), 113-121.

03 Cooper SA, McLean G, Guthrie B, et al. Multiple physical and mental health comorbidity in adults with intellectual disabilities: population-based cross-sectional analysis. *BMC Fam Pract*, 2015; 16:110

04 Heslop, P., Blair, P. S., Fleming, P., Hoghton, M., Marriott, A., & Russ, L. The Confidential Inquiry into premature deaths of people with intellectual disabilities in the UK: a population-based study. *The Lancet*, 2014; *383*(9920), 889-895.

05 Koslowski, N., Klein, K., Arnold, K., Kösters, M., Schützwohl, M., Salize, H.J., Puscher, B. Effectiveness of interventions for adults with mild to moderate intellectual

disabilities and mental health problems: systematic review and meta-analysis. *Br. J.*

*Psychiatry*, 2016; 209 (6), 469–474.

06 Wessely, S. Randomised, controlled trials. In *Choosing methods in mental health research: Mental health research from theory to practice*. New York: Psychology Press, 2007; pp.85-98.

07 Feldman, M.A., Bosett, J., Collet, C., Burnham-Riosa, P. Where are persons with

intellectual disabilities in medical research? A survey of published clinical trials. *Journal of Intellectual Disability Research*. 2014; 58 (9), 800–809.

08 Lennox, N., Taylor, M., Rey-Conde, T., Bain, C., Purdie, D.M., Boyle, F. Beating the barriers: recruitment of people with intellectual disability to participate in research.

*J. Intellect. Disabil. Res*. 2005; 49 (4), 296–305.

09 Oliver, P. C., Piachaud, J., Done, J., Regan, A., Cooray, S., & Tyrer, P. (2002). Difficulties in conducting a randomized controlled trial of health service interventions in intellectual disability: implications for evidence‐based practice. *Journal of Intellectual Disability Research*, *46*(4), 340-345.

10 Brooker, K., van Dooren, K., Tseng, C. H., McPherson, L., Lennox, N., & Ware, R. (2015). Out of sight, out of mind? The inclusion and identification of people with intellectual disability in public health research. *Perspectives in Public Health*, *135*(4), 204-211.

11 Hastings, R. Running to catch up: rapid generation of evidence for interventions in

learning disability services. *Br. Med. J*., 2013; 203, 245–246.

12 Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj*, 2008; *337*, a1655.

13 Schulz, K.F., Altman, D.G., Moher, D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. I. 2010; 8 (1), 18.

14 Mulhall, P., Taggart, L., Coates, V., McAloon, T., Hassiotis, A. A systematic review of the methodological and practical challenges of undertaking randomised-controlled trials with cognitive disability populations. *Social Science & Medicine*. 2018 Mar 1;200:114-28.

15 Sindhu, F., Carpenter, L., & Seers, K. Development of a tool to rate the quality assessment of randomized controlled trials using a Delphi technique. *Journal of advanced nursing*, 1997, *25*(6), 1262-1268.

16 Cheung, K. L., de Ruijter, D., Hiligsmann, M., Elfeddali, I., Hoving, C., Evers, S. M., & de Vries, H. Exploring consensus on how to measure smoking cessation. A Delphi study. *BMC public health*, 2017, *17*(1), 890.

17 Abidi, L., Oenema, A., Nilsen, P., Anderson, P., & van de Mheen, D. Strategies to overcome barriers to implementation of alcohol screening and brief intervention in general practice: a Delphi study among healthcare professionals and addiction prevention experts. *Prevention Science*, 2016, *17*(6), 689-699.

18 Dawson, M. D., & Brucker, P. S. The utility of the Delphi method in MFT research. *American Journal of Family Therapy, 2001; 29,* 125–140.

19 Fletcher-Johnston, M., Marshall, S. K., & Straatman, L. Healthcare transitions for adolescents with chronic life-threatening conditions using a Delphi method to identify research

priorities for clinicians and academics in Canada. *Child: Care, Health and Development, 2011; 37,* 875–882.

20 Wester, K. L., & Borders, L. D. Research competencies in counseling: A Delphi study. *Journal of Counseling & Development*, 2014; *92*(4), 447-458.

21 Balasubramanian, R., & Agarwal, D. Delphi technique-A review. *International Journal of Public Health Dentistry*, 2013; *3*, 16–25.

22 Weise, J., Fisher, K. R., & Trollor, J. N. Establishing core mental health workforce attributes for the effective mental health care of people with an intellectual disability and co‐occurring mental ill health. *Journal of Applied Research in Intellectual Disabilities*, 2017; *30*, 22-33.

23 Murphy, M. K., Black, N. A., Lamping, D. L., McKee, C. M., Sanderson, C. F., Askham, J., & Marteau, T. Consensus development methods, and their use in clinical guideline development. *Health Technology Assessment, 1998; 2,* i–iv, 1–88.

24 Jorm, A. F. Using the Delphi expert consensus method in mental health research. *Australian & New Zealand Journal of Psychiatry*, 2015; *49*(10), 887-897.

25 Bisson, J. I., Tavakoly, B., Witteveen, A. B., Ajdukovic, D., Jehel, L., Johansen, V. J., ... & Sezgin, A. U. TENTS guidelines: development of post-disaster psychosocial care guidelines through a Delphi process. *The British Journal of Psychiatry*, 2010; *196*(1), 69-74.

26 Berk, L., Jorm, A. F., Kelly, C. M., Dodd, S., & Berk, M. Development of guidelines for caregivers of people with bipolar disorder: a Delphi expert consensus study. *Bipolar disorders*, 2011; *13*(5‐6), 556-570.

27 Loeffen, E. A. H., Mulder, R. L., Kremer, L. C. M., Michiels, E. M. C., Abbink, F. C. H., Ball, L. M., ... & Vd Wetering, M. D. Development of clinical practice guidelines for supportive care in childhood cancer—prioritization of topics using a Delphi approach. *Supportive Care in Cancer*, 2015; *23*(7), 1987-1995.

28 Hart, L. M., Jorm, A. F., Kanowski, L. G., Kelly, C. M., & Langlands, R. L. Mental health first aid for Indigenous Australians: using Delphi consensus studies to develop guidelines for culturally appropriate responses to mental health problems. *BMC psychiatry*, 2009; *9*(1), 47.

29 Landis, J.R, Koch, G.G. The measurement of observer agreement for categorical data. *Biometrics, 1977;* 33:159–174

30 Braun, V. & Clarke, V. Using thematic analysis in psychology. *Qualitative Analysis in Psychology*, 2006; 3:2, 77-101.

31 Mills, N., Gaunt, D., Blazeby, J. M., Elliott, D., Husbands, S., Holding, P., ... & Smith, C. T. Training health professionals to recruit into challenging randomized controlled trials improved confidence: the development of the QuinteT randomized controlled trial recruitment training intervention. *Journal of clinical epidemiology*, 2018; *95*, 34-44.

32 Pakozdi, A., Rajakariar, R., Pyne, D., Cove-Smith, A., & Yaqoob, M. M. Systematic Review and the External Validity of Randomized Controlled Trials in Lupus Nephritis. *Kidney international reports*, 2018; *3*(2), 403-411.

33 Moore, G.F., Audrey, S., Baerker, M., Bond, L., Bonell, C., Hardeman, W., et al.

Process evaluation of complex interventions: medical Research Council guidance.

I. 2015; (350), h1258.

34 Trevelyan, E. G., & Robinson, N. Delphi methodology in health research: how to do it?. *European Journal of Integrative Medicine*, 2015; *7*(4), 423-428.

35 Bakker-van Gijssel EJ, Lucassen PL, Assendelft WJ, van Schrojenstein Lantman-de Valk H. Development of a health assessment instrument for people with intellectual disabilities: a Delphi study. Family practice. 2018 Feb 17.

36 von der Gracht, H.A. (2012). Consensus measurement in Delphi studies: review and implications for future quality assurance. *Technol. Forecast. Soc. Change*, 2012; 79 (8) 1525–1536

37 UN Fact sheet on Persons with Disabilities, https://www.un.org/development/desa/disabilities/resources/factsheet-on-persons-with-disabilities.html last accessed 01/05/19.

38 Mavrodaris, A., Powell, J., Thorogood, M. Prevalences of dementia and cognitive

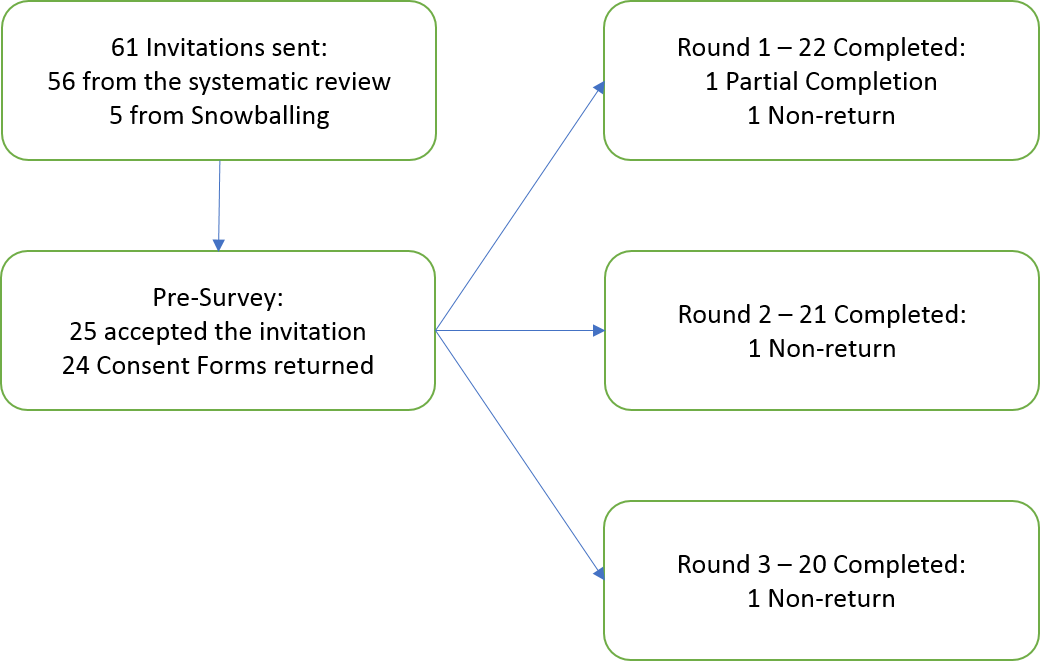
impairment among older people in sub-Saharan Africa: a systematic review. Bull.

World Health Organ. 2013; (91), 773–783. https://doi.org/10.2471/BLT.13.118422.

39 Mental Capacity Act, (2005). UK: the Stationary Office Ltd. See also. https://www.

legislation.gov.uk/ukpga/2005/9/contents, Accessed date: 26/06/2018

**Figure 1: Flow diagram of survey participation**



**Table 1 Expert Panel Profile**

|  |  |  |  |
| --- | --- | --- | --- |
| Profile | Category | N\* | %\*\* |
| Professional Background | Academic Researcher | 7 | 32 |
|  | Psychiatry | 3 | 14 |
|  | Nursing | 2 | 9 |
|  | Psychology | 2 | 9 |
|  | Psychology/Academic | 2 | 9 |
|  | Psychology/Medicine | 1 | 5 |
|  | Physiotherapy | 1 | 5 |
|  | Health Promotion | 1 | 5 |
|  | Health Promotion/Academic | 1 | 5 |
|  | Medicine | 1 | 5 |
|  | Other | 1 | 5 |
| Current Employment | Academic Staff | 14 | 64 |
|  | Joint Academic/Clinical | 7 | 32 |
|  | Clinical Staff | 1 | 5 |
|  |  |  |  |
| Gender | Male | 9 | 41 |
|  | Female | 13 | 59 |
|  |  |  |  |
| Years of Experience | 1-5 | 2 | 9 |
| In ID Research | 6-10 | 8 | 36 |
|  | 11-15 | 4 | 18 |
|  | 16-20 | 4 | 18 |
|  | 20+ | 4 | 18 |
|  |  |  |  |
| Number of RCTs | 10+ | 3 | 14 |
| Conducted? | 10 | 1 | 5 |
|  | 6 | 2 | 9 |
|  | 5 | 1 | 5 |
|  | 4 | 1 | 5 |
|  | 3 | 2 | 9 |
|  | 2 | 3 | 14 |
|  | 1 | 9 | 41 |
|  |  |  |  |
| Ethics Panel Member\*\*\* |  | 2 | 10 |
| Funding Panel Member\*\*\* |  | 6 | 29 |
| Both Ethics & Funding\*\*\* |  | 2 | 10 |

\*Sample Size N= 22 at Round One; \*\*Percentages are rounded to nearest whole number; \*\*\*Data collected at Round Two

**Table 2: Results from Round Two, Round Three and the final number of items with consensus**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Round 2 |  |  | Round 3 |  | Final |
| Section | Number of items presented at  Round 2 | Average consensus level reached at Round 2 | Number of  items reached consensus at Round 2 | Number of items  Re-presented at Round 3 | Number of items achieved consensus at Round 3 | Final Number  of items with consensus |
| Trial Planning | 2 | 74% | 1 | 1 | 1 | 2 |
| Team Planning | 2 | 62.5% | 1 | 1 | 0 | 1 |
| Funding | 6 | 60% | 2 | 4 | 1 | 3 |
| Ethics & Consent | 9 | 82.1% | 8 | 1 | 0 | 8 |
| Recruitment | 12 | 78.2% | 10 | 2 | 1 | 11 |
| Participant Factors | 6 | 77.8% | 5 | 1 | 0 | 5 |
| Service Factors | 12 | 69.2% | 9 | 3 | 1 | 10 |
| Co-Participant Factors | 8 | 80.3% | 6 | 2 | 2 | 8 |
| Fidelity Challenges | 7 | 69.4% | 5 | 2 | 0 | 5 |
| Technical Understanding | 3 | 76.3% | 2 | 1 | 0 | 2 |
| Outcome Measures | 8 | 79.8% | 7 | 1 | 1 | 8 |
| Attitudes & Perceptions | 2 | 62% | 0 | 2 | 1 | 1 |
| Publishing Difficulties | 2 | 43.5% | 0 | 2 | 0 | 0 |
| Totals | 79 |  | 56 | 23 | 8 | 64 |