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The inclusion of adults with intellectual disabilities in health research – challenges, barriers and opportunities: a mixed-method study among stakeholders in England

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Abstract

Background The study aims to understand system barriers to research participation for people with intellectual disabilities.

Methods A mixed-methods approach examined the inclusivity of people with intellectual disabilities (IDs) in a random sample of National Institute for Health and Care Research (NIHR) studies conducted in 2019–2020. An online questionnaire (stage 1) was sent to the selected studies lead investigators. An expert by experience panel of 25 people with intellectual disabilities (IDs, stage 2), discussed the stage 1 feedback. Descriptive statistics for quantitative data and thematic analysis for qualitative data was conducted.

Results Of 180 studies reviewed, 131 studies (78%) excluded people with IDs. Of these, 45 (34.3%) study researchers provided feedback. Seven (20%) of the 34 studies which included people with IDs gave feedback. Of all respondents over half felt their study had some relevance to people with IDs. A minority (7.6%) stated their study had no relevance. For a quarter of respondents (23.5%), resource issues were a challenge. Qualitative analysis of both stages produced four overarching themes of Research design and delivery, Informed consent, Resource allocation, and Knowledge and skills.

Conclusion Health research continues to exclude people with IDs. Researchers and experts by experience identified non-accessible research design, lack of confidence with capacity and consent processes, limited resources such as time and a need for training as barriers. Ethics committees appear reluctant to include people with cognitive deficits to 'protect' them. People with IDs want to be included in research, not only as participants but also through coproduction.

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Keywords Ethics, Intellectual Disability, (Global) Developmental Delay, Methodology in research

Introduction

People with intellectual disabilities (IDs) experience poorer physical and mental health outcomes than the general population (Carey *et al.* 2017). The England based Learning Disability Mortality Review (LeDeR) found men with IDs died on average 23 years younger than men in the general population. For females the difference was 27 years compared to the general population (Heslop *et al.* 2021).

To improve clinical outcomes in health care, there is a need for high-quality research that is representative of the population. However, some groups are often excluded from medical research, particularly people with IDs (Hamilton *et al.* 2017). A review of 300 randomly selected published research articles found only six of the studies clearly included people with IDs (Feldman *et al.* 2014). The review highlighted the potential harm in excluding from medical research a population group that experienced high health needs. It is well recognised that by excluding certain populations from research, the generalisability of the findings can be questioned (Shepherd *et al.* 2019a). Views of people with IDs when solicited has found that this population group want to participate in research and they feel that they can and should be allowed to make research participation decisions (Mc Donald *et al.* 2016; Mc Donald *et al.* 2018; McDonald *et al.* 2022).

One of the reasons for exclusion may relate to informed consent to participate. Informed consent is needed for ethical research (Health Research Authority 2017) and often participation in health research requires signed informed consent resulting in only those able to read and write being able to participate (Shepherd 2016). It was found 70% of the studies reviewed could have included people with IDs with simple changes such as low literacy level consent forms presented orally (Feldman *et al.* 2014). Other concerns around gaining informed consent from people with an ID relate to concerns of coercion and decision making with individuals who may tend to acquiesce to carers and professionals (Goldsmith & Skirton 2015).

People with an ID are often as a group assumed to lack capacity to consent despite no formal assessment on the subject. This assumption is a generic source of exclusion for people with an ID as studies must apply for ethical permission to be able to consent individuals who lack capacity (Russell 2022). While some individuals with an ID may lack capacity to give informed consent for research, there are guidelines in place for including participants who lack capacity to consent by seeking advice from a consultee or legal representative. Equally, these guidelines support enhancing decision making for those who might have borderline capacity. However, a study found that only a small number of UK trials were designed in this way, and within these trials, there were discrepancies in their approach (Shepherd *et al.* 2019b).

There are wider reasons why people with IDs might be excluded from research. First, a lack of suitable outcomes measures has been identified in health research (Russell *et al.* 2018). This problem identifies a further barrier to inclusion that needs addressing, not to be used as justification for exclusion. In a commentary on the exclusion of people with IDs in autistic spectrum disorder research, practical and methodological reasons are discussed with the conclusion that individuals with an ID should not excluded for convenience (Farmer & Thurm 2021).

The objective of this study was to understand the barriers which prevent suitable access to research participation for people with IDs by

1. Quantifying how many studies include or exclude adults with IDs using a pre-defined sample from the NIHR portfolio.
2. Survey the principal researchers involved in the sample studies on the reasons for exclusion or difficulties with including adults with IDs.
3. Present the survey results to a group of experts by experience, that is, people with IDs, and capture their views and impressions on the topic.

Methods

The STROBE guidelines for cross-sectional studies was used to guide the study and reporting (Supporting information S1).

Ethics

The project was approved by an UK medical school University Ethics board (reference: 2022-3203-2532) on 10/02/2022.

Stage 1

Sample

The first 200 consecutive studies on the NIHR portfolio for the financial year 2019–2020 was used for the study which included studies from every speciality. A review of the sample found 20 to be not applicable as they were studies on under 18s or health staff resulting in a final sample of 180.

Categorising the sample

The information on the NIHR portfolio includes the inclusion and exclusion criteria for the study. The criteria for each study were reviewed by the first author and the study was categorised as either including those with an ID, excluding or unclear.

Data collection – online questionnaire

Researchers involved in the studies in the sample were contacted by email and invited to take part in an online questionnaire. The questionnaire was opened in February 2022 for 6 weeks. For those who did not respond to the initial invitation, a further email was sent as a reminder.

Microsoft Forms was used to create the online questionnaire. The participants were sent a link to one of three versions of the questionnaire depending on whether their study was categorised as including people with IDs, excluding people with IDs or unclear (see Supporting information S2). The questionnaire included both open and closed questions that aimed to gather information around the challenges to inclusion and what could help increase inclusion of people with IDs in research.

Stage 2

Participants

The findings from stage 1 were taken to two experts by experience groups that included people with IDs and/or autism spectrum conditions. The groups were invited to take part in the study and were informed it was focused on the inclusion of people with IDs in research. All communication was directed through the group coordinators. The researchers had no direct contact or information about the individual members of the group to enable confidentiality.

Data collection

The themes from stage 1 were developed into discussion points (by the first author and the two experts by experience co-ordinators) and presented to the group by the group coordinator using both verbal description and easy read PowerPoint presentation (Supporting information S3). Some of the discussion points were developed into fictional examples to help communicate the concept. The discussion points were designed to gather the groups opinion on the perceived barriers and ways to increase inclusion. The group sessions were held over several weeks in July and August 2022. The group coordinators produced a written report to the study team summarising the discussion and the groups were paid for their time using NIHR rates.

Data analysis

Quantitative data gathered from the closed questions in the online survey was analysed using descriptive statistics to calculate the frequency and percentage of responses. The qualitative data was analysed using thematic analysis as described by Braun and Clarke (2006). They define thematic analysis as a method for identifying, analysing and reporting patterns (or themes) in the data and outline six phases to this analysis.

The responses from stage 2 were then combined with the findings from stage 1 to triangulate the findings. The aim of combining the two data sets was to look for areas of convergence, dissonance or complementary information (O'Cathain *et al.* 2010).

Results

Stage 1 categorisation of the sample and response rate to questionnaire

Table 1 shows the categorisation of the sample studies into include, exclude or unclear and the response rate

Table 1 Categorisation of the sample studies and response rate to online questionnaire

Sample categorised		Number of studies contacted (e.g., those with available email addresses)	Response rate
Exclude	140 (77.77%)	131	45 (34.3%)
Include	35 (19.44%)	34	7 (20.6%)
Unclear	5 (2.77%)	5	0 (0%)
Total	180	170	52 (30.6%)

to the online questionnaire. Supporting information S4 provides details of the clinical specialities of the responders who 'included' or 'excluded' people with IDs for their projects.

Stage 1 results from closed questions on questionnaire – quantitative data

When identifying the challenges to including people with IDs in their studies around a quarter of responders indicated resource issues (23.5%), while another 27.4% felt their study was not suitable for people with IDs. These results are in line with the results from the qualitative data.

Over half of the researchers felt their study had at least some relevance to people with IDs, with only a small minority (7.6%) stating their study had no relevance.

Stage 1 themes triangulated with stage 2 discussion responses

Analysis of the qualitative data produced from the questionnaires resulted in four overall themes, each with subthemes (Table 2). These themes have been combined with the data from the expert by experience discussion in stage 2. Supporting quotations for the themes can also be seen in the table. Each of the four themes will be explored here.

Research design and delivery

Research design. Researchers spoke of concerns that their study designs were not appropriate for people with IDs. This might be due to the method of data collection, examples given included designs that involved written tasks or being interviewed.

For some interventional studies it was the intervention that was seen as preventing people with IDs in taking part. Examples given included trialling a new talking therapy or attending multiple clinical appointments. Researchers recognised that more thought or planning may be needed in the design stage to enable a study to be more inclusive.

After reviewing the findings from stage 1, the experts by experience were left feeling that most researchers did not have the motivation to increase inclusion. They said the attitudes of researchers needed to change and they needed to make more of an effort.

Communicating the study to participants. It was recognised that communicating the nature and purpose of a study can be complex. There is often a large amount of information that needs to be shared with potential participants, so they understand the study and can decide if they want to take part.

Therefore, potential participants that have a severity of ID that would limit their ability to comprehend complex information would be excluded. Researchers recognise that this can be partly overcome making adaptations and having resources to explain complex study concepts.

The experts by experience groups gave numerous examples of how communication could be adapted, such as making materials easily read or delivering the information sheets in alternative formats. They spoke of the importance of people understanding what they are taking part in and giving them the opportunity to ask questions.

Protection of participant. For some of the researchers, there was a feeling that research participation would create an extra burden for those with an ID above that

Table 2 Themes and subthemes developed from questionnaire responses and expert by experience discussion

Theme	Subtheme	Quotes from stage 1 and stage 2 data
Research design and delivery	Research design	As the study used in-depth qualitative interview methodologies this could have been challenging to undertake with people with intellectual disabilities. (Stage 1 participant)
	Communicating the study to participants	There needs to be a certain level of comprehension in order for women to agree to and commit to the potential intervention in our study, as it involved physical treatment and multiple attendances. (Stage 1 participant)
	Protection of participant	This study involves many challenging and emotive subjects which would be challenging to a person with intellectual disability to understand and/or for their legally representative to take power of attorney of. (Stage 1 participant)
		A benefit rather than a burden. (Stage 2 participants)
Informed consent	Research ethics committees (RECs)	We're presenting them with often complex information in a written form (as is required by most Research Ethics Committees). (Stage 1 participant)
		We do our best to explain the PIS [Participant Information Sheet] in a straightforward way but the requirement to read the detailed PIS, and no guidance for what one might look like for patients with learning disabilities prevented us from writing one specifically for this group. (Stage 1 participant)
		From the way in which the questions in IRAS [Integrated Research Application System] are worded it makes it difficult to see how we could justify including people who could not consent for themselves. (Stage 1 participant)
		Accessible information should be in a standard policy for all future researchers to make sure everyone can be included in research projects. (Stage 2 participants)
	Support and guidance around assessing capacity and informed consent process for researchers	The difficulty and lack of understanding or clear documentation regarding how to access a person's capacity to consent if they have an intellectual disability would limit our ability to include people with intellectual disabilities in the study. (Stage 1 participant)
Resources	Funding	We did not have sufficient funding. (Stage 1 participant)
		Funders need to appreciate the reality of working with this population and embrace the opportunity to address health inequalities. (Stage 1 participant)
	Staff	Would require dedicated support workers who could make the participant fully understand the study. (Stage 1 participant)
		In order for this study to be conducted with people with intellectual disabilities we would need a different approach with a researcher/other person helping with the completion. (Stage 1 participant)
		Our potential participants are able to access a lot of support from social workers, specialist nurses and psychologists. We are fortunate to work in this multidisciplinary setting. (Stage 1 participant)
		Would help more people with disabilities not just those with intellectual disabilities. (Stage 2 participants)
	Time	More meetings, time to adapt materials and/or explain study. (Stage 1 participant)
Knowledge and skills	Staff experience	No one in research team with appropriate learning disability experience. (Stage 1 participant)
		To be quite honest, accommodating people with intellectual disabilities did not come into our thinking. (Stage 1 participant)

Table 2. *(Continued)*

Theme	Subtheme	Quotes from stage 1 and stage 2 data
	Coproduction	More consortiums and networks of researchers to enable nationwide recruitment and to 'pool efforts'. (Stage 1 participant)
		More representative PPI&E [Public and Patient Involvement & Engagement] teams to include people with intellectual disabilities …. Engagement and co-production with neurodiverse communities in research through PPI&E to better understand the hidden barriers to participation. (Stage 1 participant)
		Ask us to be co-producers in research – we have lots of skills to give. (Stage 2 participants)
		Having relationships with self advocacy groups and connecting with local communities can help change the attitude that it is hard to include people with intellectual disabilities in research. (Stage 2 participants)
	Training needs	Run by myself and a colleague and neither of us have had any training in working with this patient group (and I've no idea how to access any!). (Stage 1 participant)
		Lack of training in resources available related to participants with an intellectual disability. (Stage 1 participant)

experienced by participants without an ID. This burden was perceived to be an issue for both potential participants and their carers.

It was not only a concern about creating burden but also for doing harm. People with IDs are being protected from potential harm and as a result are excluded. This exclusion may not be due to the researchers, but also to those connected to people with IDs becoming gatekeepers. This quote also indicates a conflation of different legislation, which would result in problems interpreting the Mental Capacity Act regarding the legal role of a supporter in a research context.

In contrast to the researchers' responses, the experts by experience highlighted the importance of asking people with IDs if they want to take part and not assuming that they do not. They also spoke of the importance of seeing the positive aspects of including people with IDs in research.

Informed consent

Research ethics committees. Researchers said they were restricted due to the requirements of research ethics committees (RECs), which made inclusion harder.

One responder wrote that having guidance around what would be acceptable to a REC would help researchers understand how to adapt information so it is accessible.

The expert by experience groups took this a step further by suggesting that accessible information should be a standard requirement of research, to make sure everyone can be included.

There is a feeling of restriction that including people without capacity is not the right thing to do. This is preceived to be fed down from RECs.

Support and guidance around assessing capacity and informed consent process for researchers. Respondents indicated a need for support when ascertaining whether a person with an ID had capacity and how to document this, when traditional written consent requires literacy.

The experts by experience highlighted the importance of not assuming someone with an ID cannot consent for themselves; even when there is an issue with capacity, researchers still need to talk to the participant.

When a potential participant lacks capacity to provide informed consent, a consultee or legal representative can be used to support the process; however, this process was only mentioned a few times in the responses.

Resources

Funding. Funding was frequently mentioned in the questionnaire responses and was seen as a barrier to inclusion. Researchers described ways in which increased funding would support inclusion such as being able to employ experts in IDs to provide advice or create accessible research materials.

There was a critical view of the bodies providing funding for research and the need for funders to acknowledge that increased funding can help increase research participation and help address health inequalities.

Staff. The need for additional staff to support participation was highlighted by several researchers. For some, this was in relation to consenting and explaining the study.

For others, it was around supporting participation in data collection or intervention.

Participants spoke of how the staff team enabled inclusion, especially when those staff members had appropriate experience.

The expert by experience agreed that more resources would support inclusion in research for everyone, not just those with IDs.

They felt that having people with a good understanding of people with IDs would be beneficial such as employing experts by experience to support recruitment.

Time. Having more time was seen as a facilitator to inclusion. It was felt that studies would take more time to design and deliver when making it more accessible for people with IDs.

Limited time for research delivery appears to have resulted in reducing opportunity for research participation for people with IDs.

The experts by experience highlighted how this would also have wider implications by enabling studies to recruit a larger and therefore more diverse population.

Knowledge and skills

Staff experience. Participants frequently spoke of their lack of experience and knowledge in the area of IDs being a barrier to inclusion.

Limited experience also affected researchers' awareness of including people with IDs in research and this was reflected in several responses.

By not having experience of involving people with IDs, there was a feeling of not knowing where to start. There were concerns about not knowing any potential participants with IDs or how to support their participation. Some responders provided ideas to improve inclusion in research by using the experience and knowledge of others.

Coproduction. Coproduction was raised several times by the expert by experience groups as a solution to many of the issues raised by the researchers. Researchers themselves spoke of coproduction and the value of including people with IDs in public and patient involvement and engagement (PPIE). PPIE is already established as a method of enabling members of the public to have a say about research. Using this approach to include people with IDs was seen as a positive approach to increase inclusion in research participation.

Coproduction was felt to be valuable in various stages of research including research design and developing communication methods. The experts by experience highlighted the importance of developing connections between researchers and expert by experience/advocacy groups so they can support research and change the view that it is hard to include people with IDs in research.

Training needs. The need for training in this area was raised several times as a way to increase inclusion.

Training would be to raise knowledge and awareness within the research team and practical guidance on to how to make a study more inclusive.

The experts by experience felt that the training should cover communication and making reasonable adjustments and needs to be delivered by people with IDs.

Discussion

The findings from this study support existing evidence that people with IDs are excluded from health research. The majority of the studies in the NIHR portfolio sample were found to likely exclude people with IDs, which is in line with the findings

from Feldman *et al.*'s (2014) review almost a decade ago. There were several reasons for this continued exclusion discussed by both the researchers and experts by experience in this study.

There were issues with research design, such as data collection methods and interventions, resulting in studies not being accessible. The exclusion of people with IDs can be partly explained by the need for capacity to provide informed consent to participate in research. A range of populations with assumed impaired capacity are often excluded for this reason, without any reported forms of capacity assessment. There was little evidence of attempts to support participants to gain an understanding of research studies.

The legal frameworks designed to support participation in research for those who lack capacity were only mentioned by a few of the responders to survey. This could indicate a lack of knowledge of this legislation, which previous research has highlighted in both researchers and RECs (Shepherd *et al.* 2018; Shepherd *et al.* 2022).

Both the researchers and the experts by experience agreed that more resources in the form of money, time and staffing would support inclusion. Designing and delivering studies that can be inclusive to not only people with IDs, but all underserved populations will require more resourcing to meet the needs of a wider population. This is echoed in the findings by Wroe *et al.* (2022) who also found researchers identified resourcing as a major barrier to inclusive research. This study found that not all researchers have the knowledge and experience needed to make their study inclusive or consider inclusion. The experts by experience in this study felt that this could be addressed by coproduction in research and sufficient funding for accessible information and accessible data collection.

The views of people with IDs were included in this study, and this provided an important interpretation of the researcher responses. They spoke of the importance of making studies inclusive and that there was a desire to be included, not only as participants but also through coproduction. Recent work in Scotland exploring the views of people with IDs on health research has also shown this desire to be included and involved in research as all stages, not just as participants (Scottish Learning Disability Observatory 2021).

There is now an increasing awareness of underserved populations, but it may not be people with IDs that research bodies have in mind. An outcome of this study is to put this population on the radar and raise awareness about their passive exclusion. The equality, diversity and inclusion strategy of the NIHR needs to be aware of the needs and desires of people with IDs to be included in health research. There are signs that the NIHR is becoming more open to opportunities for addressing the issues of exclusion of people with IDs in research, but this needs to be combined with sustainable funding.

The current study highlights an important issue, but more research is needed to develop ways to improve the situation. Future work needs to consider strategies to improve inclusion such as training and system level approaches. These strategies could target research areas with relevance to people with IDs such as epilepsy or social care (Shankar *et al.* 2018; Gabrielsson *et al.* 2023; Newman *et al.* 2023). Future research could investigate the views of wider stakeholders such as ethics boards and funding bodies.

Limitations

Due to the small scope and scale of this study, a key limitation relates to resource and time restraints. For example, judgement on whether a study included or excluded people with IDs was made using the inclusion and exclusion criteria available on the NIHR portfolio. There were not the resources to follow up with authors whether they did actually include people with IDs.

The response rate to the questionnaire was 30.6% and therefore can be viewed as a limitation. A higher response rate would have enhanced and strengthened the findings of the study.

The data collection for stage 2 did not directly involve a researcher from the study team. The benefit of not having a researcher present when the experts by experience had their discussion means that the participants may have been more open and comfortable discussing their views. It also helped to ensure that responses from the experts by experience were not influenced by the views and experience of the researcher, who may have had a bias towards the views of the researchers in stage 1 as a result of being a

researcher themselves. It was therefore decided not to have a member of the research team present for the discussions, but the team were available if any clarification was needed about the results from stage 1 and the related discussion points. However, it is also recognised that this could be a limitation of this study. By not having a research team member present, elements of the conversation may have been lost in the final summary given to the researcher by the group facilitator. The experts by experience may have preferred a researcher to be present to support understanding and context of the stage 1 results.

Conclusion

There is a growing awareness of the need to include a wide range of people in health research. This study demonstrated the exclusion of people with IDs by reviewing the NIHR portfolio and highlighting the small number of studies that clearly included people with IDs. This study was able to consider the reasons to this exclusion by asking researchers and allowing their responses to be reflected on by experts by experience. Issues with designing studies, consent procedures, resources and skills were all identified as both the reasons for exclusion and areas that can be targeted to improve inclusion. The findings raise awareness of the current exclusion of people with IDs in health research. Further work is needed to develop focused strategies to increase inclusion for this underserved population group.

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Conflict of interest

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Author contributions

All authors satisfy the ICMJE guidance by substantially contributing to the design, analysis and interpretation of the work, drafting of the manuscript, final approval of the manuscript and all agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work is appropriately investigated and resolved.

Ethics statement

University of Plymouth Ethics board (reference: 2022-3203-2532) on 10/02/2022.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional Supporting Information may be found online in the supporting information tab for this article.

Supporting information S1. STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Supporting information S2. Questionnaires (variations 1–3).
Supporting information S3. Materials developed to discuss with experts by experience.
Supporting information S4. Clinical specialties of those who responded to the 'Exclude' questionnaire. Clinical specialties of those who responded to the 'Include' questionnaire.