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Redesigning trials to be inclusive of people with a learning disability – a practical example

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Abstract

Background

People with a learning disability are frequently excluded from clinical trials, with around two thirds of trials either directly or indirectly excluding this group. This contributes to the shocking health inequalities they experience, with people with a learning disability

having higher rates of long-term health conditions and dying on average 20 years younger than the general population. Improving inclusion of under-served groups in trials is a priority area for research funders and regulators. A UK-wide collaboration, 'No Research About Us, Without Us', was formed to explore and address the barriers to engaging and involving people with a learning disability in research. The project consisted of a number of intersecting work streams. This paper reports the findings from Working Group 3 which aimed to produce practical examples about how a trial could be redesigned to ensure it is more inclusive of people with a learning disability.

Methods

The redesign process consisted of three steps: 1) identifying an appropriate trial using predefined criteria, 2) selecting a tool to systematically review the trial, and 3) identifying barriers to inclusion of people with a learning disability and proposing alternative design approaches that could have widened access to the trial.

Results

Following review of a funder's portfolio, we selected a platform trial (PANORAMIC) which had sought to include people with a learning disability as a high-risk group for COVID-19 and yet had only made up 0.01% of those recruited. Using the INCLUDE Impaired Capacity to Consent Framework, our co-produced analysis identified practical strategies that could have ensured greater inclusion of people with a learning disability. This included involving people with a learning disability at the earliest design

stage, revisiting eligibility criteria, making reasonable adjustments (e.g., high-quality easy read versions of all documents) and simplifying overly complex study processes.

Conclusion

To achieve better health equity and improve the quality of clinical trials, researchers must pay greater attention to accessible study design and ensure appropriate accommodations are in place to enable inclusion of people with a learning disability. We outline some practical strategies that can inform the design and conduct of future trials to improve inclusion.

Keywords

Clinical trial; inclusivity; accessibility; learning disabilities; intellectual disability

Background

Clinical trials are essential for determining the safety and effectiveness of health and care interventions, enabling meaningful decisions to be made about whether and how these interventions should be used [1]. A major challenge for those who rely on the evidence generated by clinical trials to guide decisions about commissioning services or providing treatment or care, is that participants in clinical trials have often lacked

diversity, with under-representation of certain populations, resulting in them being underserved by research [1]. Unrepresentative trial populations means that the findings may not be generalisable to the actual clinical population, meaning that clinicians often have to make treatment decisions relying on evidence generated for different populations, and important findings specific to these under-served populations may be missed [2, 3]. As well as being 'bad science', exclusion from research exacerbates health inequalities and can worsen distrust in research [4] and reduce the willingness of people in those under-represented groups to accept treatment recommendations based on trial findings [1].

People with a learning disability (otherwise known as an intellectual disability) have been widely recognised as an under-served group [1, 2, 5] who experience profound disparities in their access to, and outcomes from, health services compared with the rest of the population [6]. A learning disability is defined by the UK Department of Health and Social Care as a significantly reduced ability to understand new or complex information, to learn new skills (impaired intelligence), with a reduced ability to cope independently (impaired social functioning), which started before adulthood [7]. People living with a learning disability have higher rates of long-term health conditions such as cardiovascular disease, respiratory disease, epilepsy, diabetes, and mental illness, and are more likely to be admitted to hospital as an emergency [8, 9]. This contributes to the stark statistic that people with a learning disability in the UK die on average 20 years younger than the general population, with 42% of these deaths considered avoidable compared with 22% of deaths in the general population [10]. The majority of people with a learning disability access routine (i.e non-specialist) services. Yet, people with a

learning disability are frequently excluded from research, which contributes to the health inequalities they experience [11]. For example, few clinical trials into Alzheimer's disease include people with Down syndrome, even though approximately 90% of people with Down syndrome will develop Alzheimer's disease or dementia by the age of 55 [12]. Similarly, even though 25% of people with epilepsy have a learning disability compared with <1% of the general population, people with a learning disability are under-represented in epilepsy studies [13].

Exclusion of people with a learning disability from clinical trials

A review of studies included on the UK National Institute for Health and Care Research (NIHR) portfolio found that only 1·4% of all studies were specifically related to learning disabilities, and 60% excluded people with a learning disability [14]. This picture is repeated internationally. A review of the US National Institute of Health (NIH) funded trials similarly found that three quarters excluded people with a learning disability, with little justification given [15]. However, the authors noted that 65% of studies may have indirectly excluded this group, and half of the studies excluded people based on research teams' perceptions of their inability to complete study procedures or their health status [15]. The most common reason for direct exclusion of people with a learning disability was due to concerns about lacking capacity to consent, with worryingly little explicit provision of modifications to support inclusion [15]. The authors suggested that more thoughtful attention to study design and making appropriate accommodations are critical to promoting equitable inclusion in clinical trials and health equity [15].

Other barriers to inclusion include the role of gatekeepers who decline access to potential research participants with learning disabilities [16], despite evidence that people with learning disabilities generally wish to participate in clinical trials [17]. Researchers report excluding people with a learning disability based on concerns about research ethics committees' views, a lack of confidence when assessing capacity and in communicating with people with a learning disability, and a lack of funding to make reasonable adjustments [13]. Lack of knowledge about the legal frameworks governing research involving adults with impaired capacity to consent also acts as a barrier to inclusion [18]. Researchers and other groups report that merely having concerns that a participant may lack capacity to consent raises fears about opening up the 'black box of horrendousness' of additional regulatory requirements, leading to exclusionary practices [19, 20].

Developing a collaborative partnership to address the barriers to inclusion

An international consensus statement on designing and conducting inclusive health research with people with a learning disability published in 2018 highlighted the need for more work to address the practical challenges, such as models of inclusive research that can be followed [21]. Inclusive research is key to ensuring that research is accessible by design [22]. To design and deliver meaningful and inclusive research, we need to bring together a diverse range of perspectives from people with a learning disability, academic researchers, funders, and other stakeholder organisations, with self-advocacy groups recognised as being central to building these networks and acting

as a catalyst for change [23].

Previous work, such as the NIHR's INCLUDE initiative, found that the way in which trials are designed and delivered is a significant barrier to the inclusion of under-served groups [2]. In response to a call by the NIHR to establish inclusive and collaborative models of partnership working with under-served groups, a group of 25 people including people with lived experience, self-advocacy organisations, community organisations, and academic researchers from across England, Scotland and Wales formed a partnership to explore and address the barriers to engaging and involving people with a learning disability in research. This collaboration, called 'No Research About Us, Without Us: Removing research barriers for people with learning disabilities', aimed to co-produce new knowledge about how research can be more inclusive of people with a learning disability. Throughout this article we use the term 'people with a learning disability' as team members with lived experience have selected this as the preferred term to be used in the project.

Further details about the No Research About Us, Without Us project, including information in easy read and video formats can be found on the Learning Disability England website (https://www.learningdisabilityengland.org.uk/no-research-about-us-without-us). The project consisted of five intersecting work streams: 1) Collaborative project design, 2) Mapping barriers to inclusion, 3) Addressing barriers to inclusion, 4) Ensuring research design is inclusive, and 5) Evaluating the collaboration.

As decided by the larger project team who collaboratively co-designed the project as a

whole, four smaller working groups (see ***Fig. 1***) were formed to facilitate a co-production approach. Members of the project team could choose which of the four working groups to join, depending on their preference and areas of interest.

Fig.1 Working groups from the No Research About Us, Without Us project

This paper reports on the findings from Working Group 3 (the 'orange group') which aimed to co-produce practical examples about how a trial could be redesigned to ensure it is more inclusive of people with a learning disability. The core working group consisted of four academic researchers, one member of a national learning disability organisation, and one supporter of people with a learning disability, with further input from two self-advocates with lived experience of a learning disability and one support worker who were part of the wider project team. Together, there were eight female and one male members, drawn from across the UK mainland (Scotland n=1, Wales n=1, England n=7).

Methods

The redesign process consisted of three steps: 1) identifying appropriate clinical trial(s) using predefined criteria, 2) selecting a tool that would enable us to review and then redesign the trial, 3) using the tool to systematically identify areas of the trial where the design was considered to act as a barrier to inclusion for people with a learning disability and propose alternative design approaches that could have widened access to the trial for people with a learning disability.

Identifying a clinical trial to review and redesign

We reviewed trials on the NIHR portfolio that either directly or indirectly excluded people with a learning disability in contexts where they would meet the INCLUDE definition being an under-served group, e.g. as a group they would be likely to need or receive the intervention in practice [2]. Trials were purposively sampled to include pragmatic trials evaluating interventions for general populations (e.g. prevention or management of diabetes), as well as those specifically intended for people with a learning disability (e.g. activity-based interventions), and other relevant trial design/contexts. We also contacted leading academics working in fields identified by the team as most relevant (e.g epilepsy and intellectual disability) and then discussed and refined their suggestions.

We selected a trial based on our three pre-defined criteria, that the trial was:

a) **relevant to** people with a learning disability, as determined by the researchers who led the study and members of our project team with lived experience. It was considered relevant if the intervention, should it be implemented, would be part of services accessed by people with a learning disability.

and

b) **should have included** people with a learning disability but did not, or included only insufficiently small numbers, as determined by the researchers who led the study and members of our project team with lived experience. Trials that should have included people with a learning disability were those which related to a condition that has a high prevalence (e.g. epilepsy) in people with a learning disability or is noted to exacerbate health inequalities for people with a learning disability.

and

c) there was **sufficient available information** to enable us to reconstruct the trial (e.g. the protocol and study information were publicly available) as determined by our working group.

As a working group we shortlisted two potential trials that met the criteria and sought consensus from the wider project team members about which to focus on. The working group prepared an easy read presentation outlining the 'pros and cons' of each trial that

was presented at a project team meeting for discussion as group. In line with the co-production approach to the project, a number of practical steps (outlined in our co-produced guide https://www.learningdisabilityengland.org.uk/wp-content/uploads/2025/05/Practical-principles-for-including-people-with-learning-disabilities-in-research-final.pdf) helped ensure the meeting was accessible. No formal definition of consensus was used, but the decision about which trial to select was made using the approach outlined in our co-produced terms of reference (titled 'How we will work together' [24]).

After discussion, we selected a trial that evaluated the effectiveness of antiviral treatments for COVID-19 in the community (PANORAMIC) [25]. Organisations such as MENCAP have highlighted the appalling rate of disproportionate COVID deaths of people with a learning disability compared to the general population in the UK, with 45% of deaths reported to the Learning Disability Mortality Review (LeDeR) being COVID related [26]. This was exacerbated due to the inequalities in access to COVID vaccines, with only those with a severe or profound learning disability and adults with Down syndrome being on the priority list for vaccines at the time when PANORAMIC was being designed, despite data showing that 68% of those with a learning disability who died from COVID in the first wave in England had a mild or moderate disability [27].

Summary of the clinical trial selected for review and redesign

The trial was a multicentre, UK-based, platform randomised controlled trial involving people aged 50 years or older (or aged 18 years or older with relevant comorbidities)

who had been unwell with confirmed COVID for 5 days or fewer in the community [28]. As a platform trial it was designed to test multiple treatments, with two antiviral treatments (Molnupiravir and Paxlovid) selected. It aimed to include adults at increased risk of an adverse outcome from COVID aged 50 years and over, or 18-49 years and considered clinically vulnerable as defined by UK Government guidance at the time. That included people with severe and profound learning disability, Down syndrome, severe mental illness, or who were a care home resident.

It was developed at an unprecedented pace due to the COVID pandemic and was designed to be an inclusive trial with a proactive outreach strategy. To maximise recruitment, participants were recruited via General Practice hubs, online, and by telephone via the central trial team. Once recruited, participants were randomly assigned to receive antiviral treatment plus usual care or usual care only, and the adaptive trial design meant that it tested several different antiviral medications during the three years it ran for. If randomised to the treatment arm, participants were couriered a pack containing the antiviral medication (along with dosing and safety information) and a pregnancy test (only for use by participants of childbearing potential)[28]. Data were collected through an online daily diary for 28 days, with regular telephone calls if they didn't respond, and via their health-care records. Participants could nominate a trial partner to help to provide follow-up data.

PANORAMIC was selected as the focus for this project as it met the three criteria for inclusion:

a) people with a learning disability were identified as a clinically vulnerable group and hence the trial specifically aimed to recruit this group. People with learning disabilities experienced significant impact from COVID [29], and therefore PANORAMIC was considered to be highly relevant by project team members with lived experience.

b) mortality rates from COVID during the pandemic were 3–6 times higher for people with a learning disability compared to people without a learning disability [30, 31], and people with a learning disability were less likely to receive intensive medical treatment if hospitalised for COVID [32]. However, in PANORAMIC, out of the 26,411participants recruited to the trial of the first treatment (Molnupiravir) only 63 participants were recorded as having a learning disability and 29 as having Down syndrome, making up less than 0.01% of the study population [28].

and

c) accurate reporting of the study population, ability to access a wide set of study documents via the study website (https://www.panoramictrial.org/), and the publication of a 'review and learning exercise' reflecting on the lessons learned [33] meant that there was sufficient information available to enable us to reconstruct the trial to a reasonable degree.

Selecting a tool for reviewing the trial

There are a broad range of approaches and tools that can potentially be used to explore

the inclusivity of a trial, including from a disability perspective, such as inclusivity checklists to be used when designing a trial (e.g a checklist developed by the National Cardiac Surgery Clinical Trials Programme [34]), frameworks to identify and categorise barriers to participation across different dimensions (e.g Ford framework [35]), and resources to help implement accessibility (e.g Accessibility By Design toolkit [36]). However, most do not include the issues that were considered by the project team to be particularly relevant to the inclusion of people with a learning disability in this context.

In recent years, the NIHR INCLUDE initiative created a strategic roadmap intended to act as a guide to addressing the needs of under-served groups in research [2]. It provides a structure to address barriers to participation and identifies key points for considering inclusion over the life course of a study with a number of 'check points' for decision-making. Building on this work, a series of INCLUDE frameworks have been developed to support researchers to design and conduct trials involving particular under-served groups, such as the INCLUDE Ethnicity Framework [37]. The working group selected one of these frameworks, the INCLUDE Impaired Capacity to Consent Framework, as it is a structured tool to help identify the key points for considering inclusion of this group [38]. Whilst recognising that having a learning disability should not be conflated with lacking capacity to consent, it covers relevant issues such as accessibility of information and supported decision-making that are key to reducing barriers to involving people with a learning disability in research [13].

The INCLUDE Impaired Capacity to Consent Framework consists of a set of four key

questions to help researchers identify who should be included in their trial, and a series of worksheets covering intervention design, recruitment and consent processes, data collection and analysis, and public involvement and dissemination [38]. The final section encourages researchers to summarise the actions and resources needed to ensure their trial is inclusive of people with impaired capacity to consent. The framework is supported by an accompanying website for researchers containing resources on capacity and consent [39].

Identifying barriers to inclusion and alternative designs to support inclusion

The INCLUDE Impaired Capacity to Consent Framework [38] encourages researchers to first consider who the trial results should apply to (Q1), whether those group(s) are likely to respond to the intervention and/or comparator in different ways (Q2), and whether the intervention and/or comparator itself might make it harder for these group(s) to respond to or engage with it (Q3), before considering whether the design of the trial might make it harder for any of the groups to consider taking part and remain in the trial (Q4).

Using the structure of the INCLUDE Impaired Capacity to Consent Framework [38], the members of the working group reviewed a core set of documents from PANORAMIC including the study protocol, easy read and non-easy read versions of participant information sheets, consent forms, information booklet and other supporting information, supplemented by publications reporting the findings (e.g. [28]) and lessons

learnt [33]. Each member then systematically completed their own version of the INCLUDE framework document with the key barriers to inclusion they had identified and proposed where a redesign of these elements may help overcome them. The findings were collated in the form of a shared Excel spreadsheet, with any replications removed, and the text was then refined for clarity and consistency.

Alongside this, the easy read version of the participant information sheet (https://www.panoramictrial.org/files/pis/panoramic_pictorial_pis_v3-0_15nov2022_clean.pdf) was reviewed by three members of the wider project team who are from self-advocacy groups, including two members with lived experience of a learning disability. As the easy read information sheet was describing a clinical trial which involves regulatory aspects and other features less commonly seen when developing easy read documents for other types of studies (e.g., pregnancy testing as a safety requirement, optional clinical procedures, reporting side effects), they reviewed it alongside an easy read information sheet and consent form that had been co-designed by members of the wider project team as part of another trial (https://indd.adobe.com/view/b2985c90-187c-463f-b35a-f9deda03ced4). The feedback from this review was then added to the relevant section in Excel spreadsheet, which was then summarised.

Findings

The findings from our analysis using Q1-3 of the INCLUDE framework are summarised

here.

Who should the trial results have applied to?

The trial website acknowledges that underserved communities, such as those from ethnic minority backgrounds and people with learning disabilities, were disproportionately affected by the COVID pandemic and are traditionally under-represented in medical research. The trial team wanted to ensure that the PANORAMIC trial was accessible to all communities in all four countries of the UK, regardless of background, location, ethnicity, or socioeconomic status. The health inequalities experienced by people with a learning disability are well documented, and people with a learning disability were dying at disproportionately higher rates from COVID compared to people in the general population [30, 31]. Therefore, they were likely to benefit from effective medications to treat COVID. However, eligibility for the trial was restricted to:

- Those living in care homes
- People who have Down syndrome and can consent to take part
- Those who have severe and profound learning disabilities and live in a care home

NHS England data also shows that approximately 11% of people with learning disability have Down syndrome [40]. The protocol states that people who lack capacity to consent for themselves could only be recruited from care homes, which meant that adults who lack capacity to consent but were living elsewhere could not be recruited. This prevented recruitment of the estimated 76% of adults with severe and profound learning disability who are living in a family home [41]. Therefore, the criteria excluded the majority of people with learning disabilities who were not eligible to participate in

the trial.

Are people with a learning disability likely to have responded to the intervention and/or comparator in different ways?

The study medication (Molnupiravir) consisted of four capsules taken orally twice a day, twelve hours apart (example, first daily dose at 8:00 am, second daily dose at 8.00 pm), for five days. Participants with a learning disability may have needed additional informational support to adhere to this complex medication schedule, however information to support participants to take the medication was somewhat limited, and the instructions were not available in easy read or alternative formats. The interaction between the study medication and other medications, such as for epilepsy, which is more common in people with a learning disability, is not clear.

Did the trial intervention and/or comparator make it harder for people with a learning disability to engage with the intervention and/or comparator?

The medication was delivered to the participant directly by courier along with instructions about how to take it and for how long. They were required to confirm receipt of the medication via text or telephone call. If the participant was of child-bearing potential and was allocated to an antiviral treatment, the trial pack would also contain a pregnancy test with instructions on how to perform the test. Neither the pregnancy test instructions nor the participant 'card' that was required to be carried as

part of the safety arrangements for medication were available in an accessible format. The medication was only available in a tablet format, and it was not clear if it could be crushed or was available in liquid format for those who were unable to take tablets.

Did the trial design make it harder for people with a learning disability to take part, and how could it have been redesigned to be more inclusive?

The findings from Q4 are shown in ***Table 1***. The analysis indicated that there were three key aspects of the design that would have considerably improved the opportunities to include people with a learning disability in larger numbers:

(1) Not restricting eligibility to people with a single named genetic syndrome and one level of learning disability severity, or to people in specific types of accommodation/receiving specific types of care and support such as those living in a care home. This led to the inadvertent exclusion of the majority of people with learning disability.

(2) Ensuring **all** study information and instructions are available in easy read format. This would have benefited not just the inclusion of people with a learning disability but also larger numbers of other under-served groups (e.g. people with lower literacy levels) or participants with intersectional characteristics.

(3) Ensuring the teams involved in recruiting participants were sensitive to the need to ensure people with a learning disability had opportunities to take part in the trial. For example, being aware that people with a learning disability would often be visiting places that acted as recruitment hubs in the trial (e.g., GP practices) and could have been approached for recruitment. This could also have been

facilitated by ensuring that staff have better skills, knowledge and understanding about the needs of people with a learning disability (e.g. Oliver McGowan Training https://www.olivermcgowantraining.com/), and are trained and encouraged to recruit these groups.

[*Table 1. INCLUDE Impaired Capacity to Consent Framework questions applied to the design of PANORAMIC to identify barriers to inclusion and the actions required to address them*]

Review of easy read study documents

When reviewed alongside a co-designed easy read information sheet and consent form that was developed for another trial, the members of the project team with lived experience of a learning disability identified a number of issues with the quality of the easy read information sheet that was used for the PANORAMIC trial. They also made several practical recommendations which could inform the development of easy read documents in future trials. The feedback on both sets of documents is summarised in **Table 2** below.

Table 2. Summary of feedback on the easy read participant documents and recommendations to improve the quality of documents in future trials

Content area	Issues raised and recommendations for future trials
Language	• Some of the language used was considered to be difficult to understand, for example “Participant Pictorial Information, “symptoms” and “Research Governance Ethics and Assurance Team” and should be reconsidered. • Language about the use of randomisation, such as “randomly” which was explained in one information sheet as being “like rolling a dice”, was considered to need more explanation. This reflects the literature reporting that participants often struggle to understand the concept of randomisation (e.g [42]). • It was suggested that using "doctor" instead of “Dr” or “GP” and “worries” instead of “concerns” would be more accessible. • The use of ‘study Dr’ and ‘your Dr’, was also found to be confusing.
Font	• The font used was not considered to be accessible. It was suggested that Century Gothic (a sans serif font) could be used as an alternative. • Use of italics and capital letters in the middle of words was also not considered to be accessible.
Content and order	• It was felt that the information about consent wasn’t at the forefront in documents. This led to concerns about whether

	consent would be in place for the procedures and processes that were described as being part of the study, such as accessing medical records. It was recommended that there should be clear statements about consent at the start of the information sheet. • Information about stopping participation during the study was thought to be confusing. For example, it was suggested that if the information which had already been provided by participants was still going to be used as data, then they were still technically 'taking part' in the study. • It was suggested that information about what would happen if they decided to stop taking part should be at the beginning of the document alongside information about consent. • For study activities that are optional, researchers should make it clear early on in the documents that these are optional and should be aware that some individuals might find specific activities more challenging. For example, some autistic people may find nose swabs and finger pricks more difficult due to their disability and/or fear of tests or blood.
Use of images	• The images used didn't always show clearly what the text is about. For example, when describing a clinical procedure it

	may be helpful to show that. In addition, some images were viewed as a bit 'childish'. It was suggested that using real life photos or photosymbols may be preferable to other types of images. The use of photographs of the research team was particularly welcomed.
Layout and design	• Having text at the bottom of each page as part of the document footer, which is common in study documents to enable version control, was considered to be inaccessible and distracting. • Having multiple statements within a section of the consent form with only one corresponding box in which to confirm agreement was considered confusing. • The use of coloured text against different background colours was considered difficult to read, and there were concerns that it was not necessarily accessible for some groups of people. For example, the use of white text against a blue background may be less accessible for people with dyslexia.

Discussion

Evidence that people with a learning disability are systematically excluded from clinical trials is mounting [13, 15, 43]. The stark inequalities in health outcomes and mortality for people with a learning disability call for including them in the generation of evidence on 'what works' so that treatments and medications are immediately available. In this project, we aimed to support researchers to design more inclusive trials. We analysed a very large trial testing medications for the treatment of COVID and identified aspects of the design that inadvertently excluded (more) people with a learning disability from taking part. A co-produced easy read report of this paper can be found at (https://indd.adobe.com/view/5db07804-c67c-48d0-8f11-f77453385385).

The innovative design of PANORAMIC, conceived and delivered during a pandemic, allowed for remote recruitment of participants from all four UK devolved administrations, irrespective of where people lived or received their health care [28]. Using a pragmatic trial design, PANORAMIC was designed to mirror real-world practice as closely as possible. It strove hard to be a democratic trial, with a proactive outreach strategy led by the trial's national pharmacy and inclusion and diversity lead [28] and its strong commitment to embracing diversity has been described as 'setting a new standard for clinical trials' [44]. Our review was only possible because the trial team made all trial documents publicly accessible on the trial website and, together with the NIHR research delivery team, had engaged in a collective review and learning exercise with the aim of influencing the design and delivery of future studies. [33]. However, people with a learning disability - a key population at high risk of adverse outcomes from COVID - were largely excluded from the trial. There were two main phases of the trial that excluded, indirectly, people with a learning disability: the recruitment process

and the implementation of study activities.

The recruitment process, albeit initially designed to include people with Down syndrome and people with severe-profound learning disability, inadvertently excluded the majority of people with a learning disability; those with mild or moderate learning disability and those with other genetic syndromes associated with a learning disability. Indirect exclusion at recruitment was enabled by (a) inclusion criteria that allowed proxy consent only for those in care homes - many people with learning disability live at home with their families, while many in residential settings are able to provide independent consent, and (b) by recruitment processes that did not make allowances for people with reduced independence or cognitive capacity (e.g., online opt in to the trial, technical language in the consent form, not aiming to recruit people with a learning disability in hubs where face to face recruitment was taking place). These aspects of the design likely resulted in the very small number of people with a learning disability eventually recruited in the trial – just 0.01% of over 26,000 participants [28].

The cohorts that were eligible for PANORAMIC were determined by an independent expert group commissioned by the Department of Health and Social Care and reflected the UK Government guidelines for priority groups eligible for COVID vaccines, which were heavily critiqued at the time by the health research community because of the impact on people with a learning disability [45]. Engagement with other stakeholders with experience of living with/supporting people with a learning disability may have highlighted to policymakers and to the research team that these eligibility criteria would result in an inability to include this key population, thus exacerbating the health

inequalities they were (and continue to) experiencing.

Our co-produced analysis, using the INCLUDE framework which enabled a systematic approach and encompassed all stages of a trial, suggested that including more people with a learning disability and their carers in the advisory group and having easy read information for all study documents could have made a significant difference to numbers of people recruited. Co-production and easy read have been identified as facilitators of inclusion in many other studies [13, 46]. There are several guides on how to carry out co-produced research and our team recently published a video including top tips for co-production (https://youtu.be/ursIiKPMuV4). Easy read further constitutes 'reasonable adjustments', a legal requirement in the UK under the Equality Act (2010) and the Accessible Information Standard (2016).

Beyond recruitment, trials need to ensure their procedures do not lead to differential drop out of this group of participants [47]. Our co-produced analysis identified key aspects of the implementation that would have benefitted from adaptation to ensure participants with a learning disability can take their medication and complete the planned assessments. Trials the size of PANORAMIC are designed, by necessity, to minimise research resource needed for delivery and also, crucial during COVID, to minimise contact with participants. These two essential design features can negatively impact retention of participants with a learning disability. However, our analysis identified two adaptations likely to facilitate retention: easy read information for intervention adherence (e.g., how to take the medication) and inclusion of the support person (staff or family carer) to help the participant with a learning disability to self-

report or provide a proxy report. There are, of course, limitations with this approach: some assessments that are essential in trials, e.g., health-related quality of life, using standard tools such as EQ-5D are not considered reliable for self-reporting participants with a learning disability [48], while they are altogether not possible for those with more severe disability. Accessible versions of the EQ-5D-3L for adults with mild to moderate learning disabilities are available [49]. The reliance on proxy reporters may lead to biases in measurement [50]. In most instances, such obstacles are not insurmountable, and, in all cases, incomplete assessments are preferable to exclusion of large segments of the population where there is an established clinical need to generate evidence on effective interventions. Our co-produced analysis highlighted specific actions (***Tables 1*** and ***2***) that could have enabled participation for people with learning disability. Using tools other than the INCLUDE framework, such as an equality impact assessment (e.g as developed by NIHR Allied Research Collaboration [51]) may have identified other actions to be identified, although they may be more general in nature. Our approach to identifying a suitable trial to review and 're-design' was intended to be pragmatic and so did not use a systematic process. Other trials may have met our criteria, and these may have identified other practical recommendations.

Several of the adaptations proposed here have resource implications for study designers. Co-production and easy read require additional costs in the research budget that are currently missing from funding applications. Adaptations to include carers to support participation have indirect costs in the form of increased research time (e.g., to assess capacity to consent or identify consultees who can provide best interests consent), or occasionally direct costs (e.g., to compensate direct social care costs).

Resource implications of including participants with a learning disability are often cited by researchers as reasons for exclusion [13, 43]. The ethical, scientific and legal imperatives to do more to include under-represented groups, including people with a learning disability, in clinical research suggest the increased resources can be well justified to research funders, who, in turn, are increasingly aware of this inequality: in the UK, the NIHR has funded the development of frameworks to support diverse inclusion (e.g., INCLUDE) and, as a small example, funded our co-produced study and other similar ones actively seeking solutions to this problem. As a funder of the PANORAMIC trial, they also clearly supported its focus on striving to be inclusive and recruit diverse populations.

There are also time implications for co-designing a trial and co-producing components such as participant facing documents and ensuring that people who may require additional support are able to be recruited. This is particularly relevant to PANORAMIC which was rapidly set up during a pandemic. Whilst early involvement of people with lived experience is strongly encouraged, in time-sensitive situations such as this where it may not be possible at the outset, engaging with under-served communities at the earliest opportunity and incorporating changes via amendments may enable greater inclusion. Importantly, lessons learned from this COVID pandemic will be key to ensuring more inclusive trials in future pandemics. PANORAMIC's successful inclusion of people from minority ethnic backgrounds also demonstrates that it is possible to improve inclusion during a pandemic, given the right resources and focus. We hope that the practical tools and suggestions we have provided can ensure that future trials and collaborations are not 'starting from scratch' when it comes to inclusion of people

with a learning disability. Future work could include co-designing templates for accessible documents that could be co-adapted as needed and developing more accessible versions of standardised text such as statements about data protection regulations.

The appetite for change is further evident in whole system change in health and social care where, as of 2022, all staff are required to complete mandatory training on learning disability (such as the Oliver McGowan Mandatory training on learning disability and autism). These examples are evidence that, at the systems-level, attitudes have not only changed but vehicles for practical change are being funded and implemented. Some of these systemic changes (e.g., all staff receiving training on learning disability as part of their clinical role) can support the implementation of our recommendations (staff training on how to recruit people with a learning disability in research), thereby mitigating some of the additional costs. However, this is primarily a workforce capacity issue as we need to improve confidence in our research workforce to recruit people with a learning disability, including becoming more confident in diverse forms of communication. This echoes other study findings such as the recommendation by McDonald et al that research teams develop the skills necessary to interact appropriately with people with a learning disability, in particular with respect to presumption of capacity, demonstrating respect, fostering choice, and enhancing communication and understanding [52]. These systemic facilitators will no doubt increase awareness outside the learning disability research community and improve skills across a large intersection of staff directly or indirectly involved with research.

Our analysis aimed to provide an example of how a significant trial could be re-designed to achieve greater inclusion of people with a learning disability. We propose that easy read materials, co-production at the design stage, inclusion of carers to support participation, recruitment and participation processes that allow for – legally required – adaptations to enable participation of people with a learning disability are likely to lead to higher numbers of people with a learning disability being included, and retained, in trials. Their continued exclusion is discriminatory and unethical and actively perpetuates the well-established inequalities in health outcomes and mortality. Our study proposes some specific, practical and feasible adaptations. Whilst only one trial was used to articulate and illustrate the barriers to inclusion, our recommendations have been co-produced with experts by experience. As a multiply disadvantaged group, any steps taken to support inclusion of people with a learning disability in trials will enhance, by extension, participation of other groups of people with reduced independence or cognitive capacity, making our proposed adaptations relevant and justified beyond the world of learning disability research. Although the trial we selected evaluated treatments for COVID-19, we believe the lessons are transferable to trials in other conditions and settings which are relevant to (and therefore should include) people with a learning disability. Arguably this would be all trials, given that people with a learning disability access general healthcare services and develop health conditions just as people without a learning condition do, yet often experience much poorer outcomes [6, 9].

Conclusions

The exclusion of people with a learning disability from research exacerbates the health inequalities experienced by this group, as demonstrated during the COVID pandemic with devastating consequences. Whilst more research is needed to improve evidence-based care specifically for people with a learning disability, clinical trials that investigate interventions that are relevant to people with a learning disability *must* consider how their trial design will prevent this under-served group from being able to access the trial. Our analysis of a large community-based platform trial has demonstrated how a trial could be re-designed to achieve greater inclusion of people with a learning disability. Involving people with a learning disability (and carers, supporters, and advocates if required) at the earliest design stage will help to ensure that recruitment and participation processes are designed in ways that support people with a learning disability being included and retained in trials.

This 're-design' needs to include fundamental aspects of a trial such as the eligibility criteria which often directly or indirectly exclude people with a learning disability. This requires greater awareness amongst the wider trials community (not just those who work specifically in learning disability research) about the need to ensure that this under-served population is not excluded from trials, as is the case for all under-served groups. Alongside this, reasonable adjustments, such as having easy read versions of all documents (not just information sheets) and flexible options for taking part (e.g. via 'non-digital' routes), are vital if we are to deliver the person-centred research that

policymakers, research funders and regulators now require. Research inclusion costs must pay attention to this, in addition to the current focus on language translation and other strategies to support inclusion of under-served groups. In all trials, efforts to improve the accessibility of study information must not solely focus on participant information sheets – requiring participants to sign a consent form or to follow instructions that are not accessible to them is neither ethical nor safe. Research ethics committees, sponsors, and other regulatory organisations also play a key role in supporting inclusivity throughout a participant's time in a trial, and not just at the point of recruitment and consent.

Ensuring a trial is accessible for people with a learning disability will help ensure the trial is more accessible for all groups for whom language, literacy, and the (in)ability to navigate overly complex processes currently act as barriers to inclusion, and those for whom intersectionality further compounds their exclusion. A range of tools and resources have been developed to support researchers to design more inclusive trials (e.g Trial Forge https://www.trialforge.org/improving-trial-diversity/, STEP UP https://step-up-clinical-trials.co.uk/), and public involvement activities and co-production projects such as ours can provide valuable additional learning [53]. We hope that this paper outlining a number of strategies that could have led to a more inclusive trial is a useful contribution for researchers who are seeking practical examples of inclusive trial design when developing future trials.

Declarations

Ethics approval and consent to participate

Ethical approval was not required for the 'No research about us without us' project as it is a co-production project and not a research study. No data were collected for this review of a clinical trial.

Consent for publication

Not applicable.

Availability of data and materials

No data were collected for this review of a clinical trial.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

The ‘No Research About Us, Without Us project was conceived by the project team and led by AR and GB. RR and VS led the ‘Orange’ working group. VS and VT drafted the manuscript. All authors critically revised the manuscript and approved the final version.

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