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COMMENT **Open Access**

Co-designing accessible trial information: lessons from designing an inclusive patient information leaflet in the RaCeR2 study

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Abstract

Background Informed consent is fundamental to ethical research, yet participant information leaflets (PILs) are often technical and difficult to understand. Although the importance of accessible study materials is widely recognised, practical guidance on how to develop them remains limited. For RaCeR 2, a randomised controlled trial evaluating different approaches to rehabilitation after shoulder rotator cuff repair, the baseline PIL was developed using Health Research Authority guidance. Early PPI consultation identified major concerns including dense formatting, overly complex language, and an unwelcoming tone, indicating the need for substantial redesign to support informed participation.

Description of Patient and Public Involvement Activity A diverse PPI group ($n = 5$) supported the development of an accessible PIL. Contributors varied in age, gender identity, ethnicity, preferred language, employment status, disability, and experience of shoulder surgery. Engagement methods were tailored to participant needs and included online discussions, written feedback, and in-person "think-aloud" sessions. Given the depth of insight provided during initial PPI consultation, we adopted an iterative, user-centred approach drawing on co-design principles to enable contributors to directly influence the content, structure, and presentation of the PIL.

Outcome of the Patient and Public Involvement Activity Contributors identified challenges with the original materials, including confusing layout, inaccessible formatting, technical terminology, and a tone that did not feel supportive. Through iterative cycles of review and refinement guided by co-design principles, the leaflet was substantially redesigned to include clearer headings, formatting aligned with British Dyslexia Association guidance, bullet-pointed and tiered information, simplified explanations of data protection, and a more conversational tone. Accessibility testing confirmed compatibility with freely available online screen-reading software. During the subsequent regulatory review, inconsistencies between legal requirements and participant preferences highlighted tensions that may limit the accessibility of study materials.

Conclusions This commentary provides a pragmatic example of integrating co-design principles within PPI to create a more accessible PIL. Early engagement, flexible methods, iterative feedback, and testing with screen reading

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software were central to the process. Our experience also highlights the need for continued dialogue between researchers and regulators to ensure that participant-facing materials meet ethical and legal requirements while remaining understandable to all potential participants.

Plain English summary When people take part in health research, it is important they understand what the study involves so they can make an informed choice. Researchers usually provide a written information leaflet, but many are difficult to read, particularly for people with lower literacy, disabilities, neurodivergent conditions, or for whom English is not their first language.RaCeR2 is a study comparing two approaches to helping people recover after shoulder surgery. When preparing to start the study, we drafted an initial leaflet using official guidance, but patients reported that it was hard to read, the images were confusing, it was long, and the tone felt "cold." In response, we collaborated with a group of patients and public contributors to make the leaflet more accessible. Some joined online meetings, others provided written feedback, and one participated in in-person sessions, sharing thoughts aloud while reading the leaflet. This led to major changes: simplified language, clearer layout, bullet points, improved fonts and colours, and testing with screen readers.However, when submitting the leaflet for Health Research Authority approval, several changes were requested, including additional legal information, making the document longer, more complex, and less aligned with patient preferences.Our experience shows that involving patients and the public makes information leaflets clearer and easier to use. But we also learned that current rules can make it difficult to keep the leaflet simple and accessible. We need better ways for researchers and regulators to work together so that study information meets legal requirements and is easy for everyone to understand when deciding whether to take part.

Keywords Patient and public involvement; PPIE, Participant information, Co-design, Accessibility, Informed consent, Clinical trials

Introduction and background

Informed consent is a central ethical and legal requirement for applied health research that aims to protect the autonomy of participants [1]. It has long been accepted that truly informed consent requires communication of the purpose of the study alongside a clear disclosure of the potential risks and benefits. This allows people to make an informed decision about whether they wish to be involved [2]. To facilitate informed consent, potential research participants must be provided with clear, accessible information about the study in a format that they can make sense of [3]; this is most commonly achieved via a written participant information leaflet (PIL). However, developing adequate written information resources presents a notable challenge for research teams given the varying level of health literacy and information accessibility needs amongst the general population [4, 5].

According to statistics published by the National Institute for Health and Care Research (NIHR) [6], over seven million adults in the UK read at or below the level of an average nine-year-old, and around nine percent of the population cite a language other than English as their first language. Furthermore, up to 20% of the UK population are thought to live with a neurodivergent condition such as dyslexia, Attention Deficit/Hyperactivity Disorder (ADHD), or Autism Spectrum Disorder (ASD) (British Dyslexia Association (BDA) [7],), all of which may present challenges to information processing [8], including the interpretation of study-related information needed for informed consent. A commitment to promoting inclusivity in research requires that the needs of these groups are adequately considered; however, using plain language benefits all users, not just those with additional accessibility needs [9, 10] and is therefore a key component of inclusive study materials.

The Health Research Authority (HRA) provides guidance on the development of PILs for potential participants of NHS-based research to facilitate informed consent [11, 12]. This guidance clarifies the need for clear and appropriate language, a style and format that aids understanding, a clear statement of the risks and benefits of the study, and an adequate explanation of the approach to data protection. It is recommended that the length of the PIL reflects the study's complexity and burden, that text is broken up into sections to facilitate readability, and that researchers consider the use of flow diagrams or pictures to support understanding. Importantly, it is strongly recommended that the PIL is tested with a group of patient and public representatives to ensure it meets their needs [11, 12].

In addition to HRA guidance, organisations such as the British Dyslexia Association [13] and the UK Government [14] provide extensive resources on designing inclusive information materials. However, application of inclusive communication principles to the design of PIL is not consistent and the needs of those with accessibility challenges or low levels of health literacy may not always be adequately considered [15].

Our recent experience developing the PIL for a multi-centre randomised controlled trial highlighted substantial challenges in producing an accessible document and the limitations of current guidance in meeting the diverse accessibility needs of potential research participants. In this commentary, we describe our work with a patient and public involvement (PPI) group to co-design an accessible PIL, outlining the practical challenges encountered during regulatory review and the adaptations required. By sharing these insights, we aim to support ongoing improvements in informed consent processes. This commentary has been collaboratively written by the academic team and our PPI co-applicant, reflecting our shared experiences throughout the process.

Context

The following sections describe activities undertaken to develop the PIL for our RaCeR2 study, regarded as a low-risk study, in preparation for submission to the HRA and Research Ethics Committee (REC). RaCeR2 is a two-arm parallel group randomised controlled trial (RCT) comparing individualised patient-directed rehabilitation versus standard rehabilitation following shoulder rotator cuff repair surgery. Recruitment for the RaCeR2 study took place in NHS Trusts across the UK that serve diverse communities with a range of accessibility needs. During the active recruitment period, all adults aged 18 years and over who were awaiting keyhole surgery to repair a torn rotator cuff at one of our recruiting sites were eligible to take part. Ensuring accessible patient-facing materials was therefore crucial to facilitate inclusive recruitment and ensure that all eligible individuals have the opportunity to understand the study and provide informed consent. Full details of the RaCeR2 RCT have been published elsewhere.[16].

Ethical approval

Approval for the RaCeR2 trial was provided by the London – Stanmore Research Ethics Committee on 13/04/2023 (REC reference number: 23/LO/0195). The PPI activities described in this commentary took place prior to submitting the application for ethical approval. As these activities were undertaken to inform study materials rather than as part of a formal research study, ethical approval was not required. All PPI contributors provided verbal agreement to the group's terms of reference, which outlined the purpose of the activities and what participation would involve.

Aim of the PPI activities

The aim of our PPI activities was to ensure that participant-facing materials for the RaCeR2 trial, particularly the PIL, were not only compliant with HRA standards but also usable, accessible, and acceptable to a diverse group of potential participants.

Description of the PPI activities

As we prepared our application for review by the HRA and REC (October - December 2022), we initially followed an approach to PPI that the NIHR would classify as an "advisory" or "consultative" approach to involvement [17]. This meant that our trial manager led the development of the initial PIL, based on examples used in previous studies and guidance available from the HRA at the time. Once the initial draft was ready, we sought feedback from our PPI group (see supplementary file 1).

To capture a broad range of perspectives and ensure the PIL was relevant to the cohort of potentially eligible patients, we engaged a diverse group of five contributors aged 26–54. Contributors were recruited through multiple channels: via NHS colleagues within the research team's clinical networks, an advert posted on the "People in Research" website, and internal communications at the Chief Investigator's host Higher Education Institution. The group included three women, one man, and one transgender man; three White British participants, one White European participant for whom English is a second language, and one British Asian participant. Two were in employment, one was a university student, and two were not in employment at the time of involvement. Two participants disclosed disabilities, including visual impairment, wheelchair use, dyslexia, and ADHD. Four had experience of shoulder pain and two had undergone rotator cuff repair surgery. All demographic and medical information reported in this commentary was self-reported by PPI group members upon joining, and medical diagnoses were not independently verified.

Our PPI representatives had differing preferences for how they contributed to the feedback process. To accommodate these preferences and support effective involvement, two participants joined a 90-minute online discussion, two provided detailed written feedback via email, and one took part in an individual, in-person session with the PPI lead (first author, MM, a member of the core research team funded to coordinate all PPI activity). At the participant's request, this in-person session was conducted as a "think-aloud" activity, during which she reviewed the first draft of the PIL in real time, verbalising her thoughts as they arose, with support from the PPI lead.

Findings from this initial involvement phase highlighted significant limitations in the first draft of the PIL, particularly regarding accessibility, tone, and usability (described below). Based on this extensive feedback, group members explicitly suggested discarding the original draft and collaboratively developing a new version that better reflected their needs. We actioned this suggestion, marking a clear shift from a consultative to a co-design-informed approach [18, 19], while noting that the process did not constitute a formal co-design study. A formal definition and the key principles of co-design can be found in Table 1 below.

In the "co-design" phase, a 60-minute online meeting was held with two contributors to begin developing the second draft of the PIL. Following this session, these contributors provided further written feedback via email, and either made amendments directly to the developing draft or reviewed and approved revisions proposed by the research team based on their suggestions. Two additional group members also provided iterative written feedback on developing drafts. One contributor, who requested individual support, participated in two in-person meetings with the PPI lead: the first to discuss her views on the required content and structure, and the second to review and refine the updated draft. Feedback was incorporated iteratively, with the research team proposing revisions solely in response to contributors' suggestions and implementing them only following PPI group approval. In this instance, no conflicting feedback emerged; however, had differences of opinion arisen, we had planned to resolve them through constructive discussion facilitated by the PPI lead to reach consensus.

Outcomes of PPI activities

Feedback on the first draft of the PIL

Our patient and public representative group identified several key issues related to accessibility, tone, and content of the initial PIL draft:

- Text within decorative text boxes was not read aloud by some screen reading software, creating accessibility barriers.
- The chosen colour contrast posed challenges for dyslexic group members, as some shades unintentionally suggested that certain information was more important.
- Text boxes conveyed the impression that the information inside them was "the most important bit", which was not always accurate and caused confusion.
- Decorative icons (such as a figure flipping a coin to denote the notion of randomisation), though intended to aid understanding, were misinterpreted by different group members and not recognised by screen readers, reducing clarity.
- Single-line spacing and narrative-style paragraphs made the document difficult for dyslexic group members to read.
- Despite using plain language, the tone was described as "cold" and "unwelcoming". For example, the opening line of the original PIL was criticised; this read "We are conducting a study focussing on the rehabilitation following surgery to repair the muscles and tendons of the shoulder (the rotator cuff).".
- The leaflet was perceived as excessively long (at seven pages and around 2081 words), with overly detailed explanations about data management and General Data Protection Regulation (GDPR) described as "unnecessary and boring". However, aspects of data management were deemed important to our PPI group; they emphasised the importance of clear communication about data management, particularly regarding withdrawal of consent. They wanted reassurance that their data could be removed up to the point of analysis, with an explanation of why data cannot be withdrawn once analysis is complete, and that all data would be handled appropriately and sensitively.

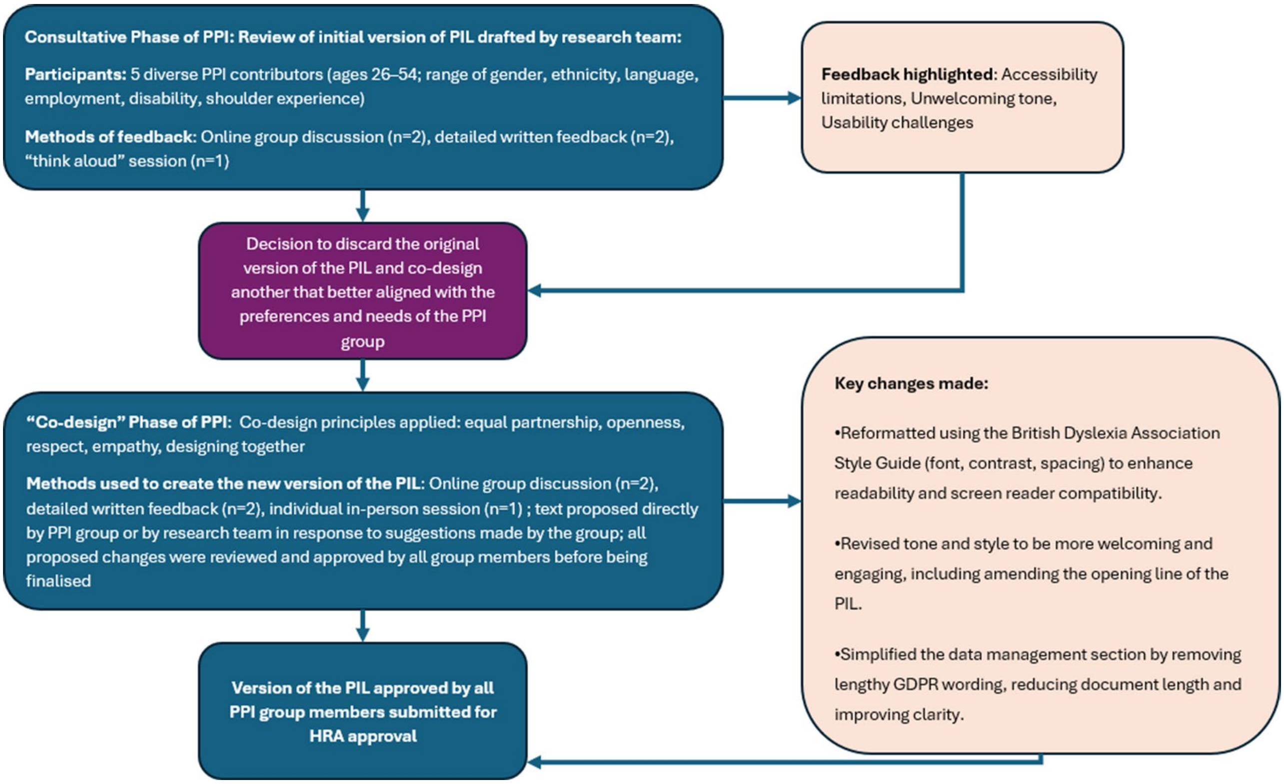
Table 1 Definitions and key features of co-design taken from [19]

Involvement approach	Definition	Key principles
Co-design	Co-design describes active collaboration between stakeholders in the design of solutions to a pre-specified problem	Equal partnership Openness Respect Empathy Design together

Group-driven improvements to the PIL

Following the co-design-informed approach described above, the following changes were made:

- We removed text boxes and reformatted the content into bullet points, largely following the British Dyslexia Association Style Guide (BDA, [13]). This informed our choices on font type and size, line spacing, and appropriate colour contrast to enhance readability for dyslexic users and screen readers.
- Decorative icons and images were eliminated to prevent confusion and ensure better compatibility with screen reading software.
- We adopted a hierarchical approach to presenting information, placing the most important details at the beginning of each section, followed by supplementary or more detailed content.
- The tone and style were revised to be more welcoming and engaging, directly responding to PPI group members' concerns about coldness. For example, the opening line of the PIL was amended to read "Thank you for considering taking part in this research study, called "RaCeR 2" which was deemed more welcoming.



Consultative Phase of PPI: Review of initial version of PIL drafted by research team:

Participants: 5 diverse PPI contributors (ages 26–54; range of gender, ethnicity, language, employment, disability, shoulder experience)

Methods of feedback: Online group discussion (n=2), detailed written feedback (n=2), "think aloud" session (n=1)

Feedback highlighted: Accessibility limitations, Unwelcoming tone, Usability challenges

Decision to discard the original version of the PIL and co-design another that better aligned with the preferences and needs of the PPI group

"Co-design" Phase of PPI: Co-design principles applied: equal partnership, openness, respect, empathy, designing together

Methods used to create the new version of the PIL: Online group discussion (n=2), detailed written feedback (n=2), individual in-person session (n=1) ; text proposed directly by PPI group or by research team in response to suggestions made by the group; all proposed changes were reviewed and approved by all group members before being finalised

Key changes made:

•Reformatted using the British Dyslexia Association Style Guide (font, contrast, spacing) to enhance readability and screen reader compatibility.

•Revised tone and style to be more welcoming and engaging, including amending the opening line of the PIL.

•Simplified the data management section by removing lengthy GDPR wording, reducing document length and improving clarity.

Version of the PIL approved by all PPI group members submitted for HRA approval

Fig. 1 Overview of the PPI activities undertaken to develop the PIL for RaCeR2. Abbreviations included are as follows: HRA health research Authority; GDPR general Data Protection Legislation; PIL participant information Leaflet; PPI patient and public involvement

- We tested the revised PIL using several free online screen readers to confirm that all relevant text was read aloud correctly and in the intended order.
- The section on personal data management was simplified by removing lengthy GDPR wording while clearly assuring participants that their personal information would be kept confidential and including the requested detail about withdrawal of data. This reduced the document's length (by around 400 words) and improved clarity in line with the group's preferences.

A visual overview of the process described above is provided in Fig. 1.

Challenges encountered during PPI and regulatory approval

During submission of the co-designed PIL to the HRA for review, the RaCeR2 research team encountered multiple challenges where requested changes from regulatory bodies conflicted with the preferences of our PPI group.

Most notably, the full standard GDPR wording [11, 12], was a mandatory reinstatement, despite our PPI members identifying it as excessively long, boring, and unnecessary. This had a significant impact on the overall word count.

The HRA requested further information about specific aspects of the trial, including the Quintet Recruitment Intervention, which involved audio-recording discussions between patients and healthcare professionals about recruitment into the study. They also asked for additional background on the pilot study and more detailed explanations of the potential disadvantages of the new "non-standard" rehabilitation approach being evaluated in the trial. Initially, the committee requested that we replace the short, lay-friendly title used in the PIL (which was designed to aid comprehension) with the full, technical version to ensure consistency across documents. However, after we explained our rationale, this request was withdrawn.

The final approved PIL extended to 10 pages and approximately 2,200 words (see supplementary file 2). These mandated additions significantly lengthened the document, undermining the accessibility improvements that had been co-designed with the group. While key formatting and layout changes, such as the use of clear headings, bullet points, and screen-reader friendly design, were retained, the increased length arguably reduced the document's overall digestibility, despite our efforts to make it as clear and concise as possible.

This challenge highlights a tension between the priorities of our PPI group - who valued clarity, brevity, and accessibility - and the regulatory requirements enforced by the HRA [11, 12]. While both perspectives are important, this experience underscores the need for increased flexibility in how essential regulatory information is presented, so that accessibility is not compromised.

Discussion

Our experience highlights both the successes and challenges of developing accessible participant-facing study materials for a diverse NHS service user population. Several aspects of the process worked well, including establishing a PPI group, scheduling engagement sessions, and accommodating group members' engagement preferences. However, our experience also underscored the limitations of a purely consultative approach to PPI: although the initial draft of the PIL was developed in accordance with regulatory guidance [11, 12], our PPI representatives identified significant concerns regarding its accessibility, tone, and content. Addressing these issues effectively required a more collaborative approach, demonstrating the added value of co-design in producing materials that are fit for purpose.

Our experience echoes wider concerns in the literature about the utility of participant-facing materials in supporting informed consent. A survey from 2021 [20] reported that 63% of research staff recruiting to clinical trials felt that PILs were too long and 56% were concerned that participants may not have adequately understood complex information. These concerns were supported by the findings of a systematic review published in the same year [21]. This review demonstrated that a small minority of research participants understood concepts such as randomisation and placebo, and most were unaware of the risks and side effects involved in their studies. This evidence highlights the ongoing need to enhance informed consent practices to better serve researchers and participants.

The expert consensus process reported by Coleman et al. [3] provides clear, practical recommendations for the development of accessible participant information materials, covering formatting, content, language, style, and readability. Despite its relevance, at the time of writing, these recommendations are not yet fully reflected in the HRA's official guidance, which remains a primary resource for researchers conducting applied health research within the NHS. This gap may contribute to inconsistent implementation and represents a missed opportunity to promote best practice.

Notably, many of the accessibility principles prioritised by our PPI group closely align with those identified in the Coleman consensus paper [3], reinforcing their relevance. While previous literature (e.g., [20, 21]) has highlighted challenges related to language and readability in trial documents, Coleman et al. [3] offer specific, actionable guidance to address these issues. Wider adoption of this guidance, particularly through integration into HRA templates and approval processes, could support more equitable, person-centred informed consent practices.

Our PPI group emphasised the importance of reassuring participants that their data will be handled responsibly and providing clear explanations when there are limits on their control. For example, they highlighted the need to explain why data could only be withdrawn up to the point of analysis, while noting that excessive detail in the original PIL was overwhelming. Coleman et al. [3] acknowledge that GDPR requirements contribute to longer PILs, yet little is known about how the public prefers this information to be communicated. Previous consultations in oncology suggest that patients often treat PILs as "companion documents," expecting verbal explanations to supplement written materials [22]. This highlights the need for PILs to balance regulatory compliance with clarity and accessibility to support informed decision-making.

In recent years, researchers have adopted more creative approaches to presenting trial information, such as layering content through multiple versions of the PIL (e.g., long and short formats), or supplementing a paper-based PIL with additional details hosted on a study website or digital platform [23, 24]. While these alternatives show promise in reducing the cognitive burden associated with lengthy PILs and may enhance recruitment of individuals from minority ethnic backgrounds [25], it is important to recognise that a notable proportion of the UK population remains digitally excluded. Approximately 1.6 million people in the UK are living offline, and around a quarter of the population have the lowest level of digital capability [26]. As such, layered information strategies must be designed to accommodate individuals who lack the access, confidence, or skills to engage with digital resources, to ensure that inclusivity remains central to the design and delivery of trial materials.

We recommend that researchers engage in ongoing dialogue and collaboration with regulatory bodies such as the HRA to develop guidelines that balance legal compliance with person-centred communication principles. Further research exploring innovative and user-friendly ways to present regulatory information—while maintaining necessary legal protections—may help to bridge this gap and further improve the informed consent process. Encouraging researchers to share their experiences, may also help engage the wider community with establishing what works, and what doesn't.

Limitations

While our co-design-informed process generated meaningful improvements to the accessibility and usability of the PIL, we acknowledge limitations. Firstly, although our PPI group comprised only five individuals, we purposefully sought to include contributors with diverse characteristics and experiences relevant to the study population, including varied age, ethnicity, gender identity, disability, and language backgrounds. Nevertheless, a larger group may have yielded broader perspectives and potentially different priorities. Secondly, the work was conducted within the constraints of the study's regulatory and governance timelines, which influenced the number of iterative feedback cycles and opportunities for deeper engagement.

Conclusion

Our experience developing the PIL for the RaCeR2 study highlighted that our patient representatives valued clarity, brevity, and accessibility—priorities that were somewhat difficult to reconcile with current regulatory requirements in the UK. This tension underscored the importance of balancing legal and ethical obligations with person-centred communication. It also reinforced several key principles for creating accessible research materials:

1. **Co-design from the start:** For materials that genuinely meet patient and public needs alongside regulatory requirements, it's vital to involve patient and public representatives early and often. Allowing flexibility in how PPI members engage (e.g., via telephone, email, online, or in-person) is also key; this approach, successfully implemented in the RaCeR2 study, promotes broader inclusion and reduces the burden of participation.
2. **Follow accessibility best practices**: In line with recommendations provided by Coleman et al. [3], use clear fonts, avoid unnecessary formatting elements, and structure content for readability. The British Dyslexia Association Style Guide is a helpful resource for anyone developing written materials [13]. The Home Office guidance on designing accessible services also provides valuable advice for ensuring inclusivity across different disability and neurodivergent communities [14].
3. **Test with assistive technologies**: Ensure compatibility with screen readers and other accessibility tools.
4. **Simplify language and layout**: Plain language benefits all users, not just those with additional accessibility needs [9, 10], and the tone should be engaging and welcoming.
5. **Advocate for patient priorities**: Work with the HRA and ethics committees to explore more user-friendly ways to present required information.

Abbreviations

ADHD	Attention Deficit/Hyperactivity Disorder
ASD	Autism Spectrum Disorder
BDA	British Dyslexia Association
GDPR	General Data Protection Regulation
HRA	Health Research Authority
PIL	Participant Information Leaflet
PPI	Patient and Public Involvement
PPIE	Patient and Public Involvement and Engagement
RCT	Randomised Controlled Trial
REC	Research Ethics Committee

Supplementary information

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Supplementary material 1

Supplementary material 2

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Author contributions

MM led the PPI activity described, supported the development of the final version of the PIL used in the RaCeR 2 trial, and drafted the manuscript. RS participated in online PPI sessions, led revisions in response to PPI group feedback, and commented on manuscript drafts. MF, a PPI group member, took part in the activities described and contributed to drafting the final manuscript. CL, the chief investigator, oversaw all PPI activity and provided feedback on manuscript drafts. BM, AR, LW, TP, and SL contributed iterative feedback and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Consent for publication

Not applicable to this article as no personal details of any specific individuals are included.

Competing interests

The authors declare no competing interests.

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