NHS
Health Research Authority

Addressing the barriers to people-centred clinical research

Recommendations for system-wide action

May 2024

Contents

Introduction

Clinical research aims to find out more about an illness, condition, therapy or care by directly involving people in a project.

Lots of people are already included in clinical research, but we know there are lots of people who have not had the opportunity, or who are under-represented in research and the findings it generates. This is demonstrated in **data from the National Institute for Health and Care Research**. We want to change this.

We want to make sure that the priorities and needs of the people who take part in clinical research, and the people who will be affected by the outcomes of the research, are the focus of how clinical research is done. We describe this as being 'people-centred', which means asking what matters most and working together in partnership.

Being people-centred in research is one of the five themes in **Saving and Improving Lives: The Future of UK Clinical Research Delivery**. The policy paper states that improving research to be more people-centred is not a 'nice-to-have', and it aims to help ensure that:

- more people can take part in clinical research because research is done in ways that help people to take part
- it is better for people who take part because it is a better experience for them
- research is more successful, and research waste is reduced because the research is less likely to fail
- research design and delivery is enhanced, because more appropriate questions, methods and outcomes are chosen
- better health and care decisions are made, because research is more relevant to the health care needs and it is more likely to have an impact in the real world

The People-Centred Clinical Research project was set up to answer the question "what are the barriers and enablers to the behaviour change needed to make people-centred clinical research happen more often in the UK?".

The project was established as part of the Department of Health and Social Care (DHSC) Recovery Resilience and Growth Programme, to deliver the UK Vision for Clinical Research Delivery.

This report

The purpose of this report is to share the findings of the People-Centred Clinical Research project, to make recommendations and influence system-wide change.

Together with an explanation of the project, the steering group who led it, our methods and a description of our findings, we present 19 areas for improvement in four categories, to address and create a people-centred clinical research environment for the future. **Nine hallmarks of good People-Centred Clinical Research** have been co-created to show how research and researchers can act and demonstrate their research is people-centred.

Combining evidence in the literature and experiences of both the barriers and facilitators we have been told about during the project, we present these hallmarks and improvement goals from the perspective of the people we hope will take part in research and to support behaviour change.

These are the ingredients required system wide. Individual organisations, researchers and sponsors will need to assess with public partners where their own improvements in these areas should be made. All parts of the research eco-system are asked to review and identify where improvements and interventions can be made to facilitate people-centred research and to remove barriers. This might include providing support, guidance, policy, processes and resources, including funding which may not exist for individual projects or scenarios. Further guidance for researchers will be provided in due course.

When these conditions are met research and researchers should be better placed to show they are meeting the hallmarks of good people-centred clinical research and the conditions we know are important for people taking part.

This report has been prepared by the Health Research Authority (HRA) and the University of Lincoln's Impact Literacy Institute on behalf of, and with support from, members of the **People-Centred Clinical Research steering group**. The University of Lincoln team undertook all data analysis and rapid review of the literature. Members of the steering group (Julie Bayley, PS, Amin Islam, Chris Ward, Sarah Williams and Matthew Burns) directly contributed to writing the report.

Acknowledgements and thanks

Our very many thanks to everyone who has taken part through holding conversations with us or by completing the survey, especially Expert Citizens, the Lawnmowers theatre group, NeurOX YPAG and CRISP.

Particular thanks extends to the members of the **People-Centred Clinical Research steering group**, and co-chairs, without whom this project would have far less impact. The significant contribution of the group on every area of the project, is outlined in further detail on **page 7** of this report. We are extremely grateful to them for their honesty, time, commitment, energy and expertise.

Part 1: The People-Centred Clinical Research Project

About the project

The project had three objectives to answer the question, "what are the barriers and enablers to the behaviour change needed to make people-centred clinical research happen more often in the UK?", these were:

1. **To find out what is known about people-centred clinical research:**
    - to agree what we mean by people-centred clinical research
    - to present a working definition of people-centred clinical research
2. **To find out what matters most for people taking part in research, the barriers and enablers for participants and researchers:**
    - to understand what is important to people about taking part in research
    - to identify what helps people take part and what is in the way
    - to understand good and bad experiences of taking part in research
    - to identify what good people-centred research looks like
    - to identify what helps or prevents research teams doing research in people-centred ways
    - to identify ways to improve and what needs to change
3. **To make recommendations for practice and influence change:**
    - to show clearly what good people-centred clinical research looks like and how it can be done well
    - to provide guidance to researchers
    - to share our findings with the research community and be clear about the action required to support change
    - to make recommendations to improve the way clinical research happens in the UK
    - be clear how the HRA will take action

Public involvement and the project steering group

It was important that a project about people-centred clinical research was led by both members of the public and the clinical research community from the outset. The **People-Centred Clinical Research steering group** was established in June 2022 to take the project forward and to oversee it.

Eight members of the public and eight members of the research community were appointed from over 80 applications to take part, creating a group diverse in personal perspective experience and expertise and in research participation.

Working together to a charter they developed and supported by the University of Lincoln and the HRA, the group has been fundamental to shaping the whole project and its outcomes.

This includes the following and is further depicted in a Figure 1 on page 7 of this report:

- **defining clinical research** in plain language
- instigating a change in language from 'patient-centred' to 'people-centred' (because not all participants in clinical research are patients)
- creating a working definition of **people-centred clinical research**
- reviewing the search terms and results of a rapid review of the literature
- combining these results with personal insights to create **six draft hallmarks** of people-centred clinical research for sharing and for feedback via the survey
- shaping survey questions and survey design, including structure, questions and demographic data to be collected
- suggesting interventions for communicating and ensuring inclusive engagement
- monitoring project participation, demographics and community engagement
- reviewing and commenting on the combined (survey and review) results for synthesis into final hallmarks and improvement goals
- creating the final **three principles and nine hallmarks** of good people-centred clinical research including from the participant voice
- making recommendations for change to make people-centred clinical research to happen
- reviewing and editing resources, documents and information for the website, reports and publications
- supporting communications including blogs, newsletters and presentations

The group was co-chaired by one public partner and one research partner, meeting virtually eight times on pre-agreed meeting dates throughout the year. Additional drop-in sessions, email discussions and feedback sessions were also held.

The group has been critical to this project, results and outputs being people-centred itself. In particular, the development of new hallmark resources to be held by and to amplify the participant voice and experience was a suggestion from the group.

Part 2: Methods

What we asked and how we asked it

We explored people-centred clinical research three ways, as shown in Figure 1.

First, we held discussions with the group to establish an initial working definition of clinical research and to provide early thoughts on what people-centred meant.

Secondly, we ran a rapid review of existing literature. This highlighted a range of issues which can block people-centred research or make it difficult in practice. These included barriers within the research system, practical issues for researchers and participants, and attitudes to the value and appropriateness of people-centred methods.

We used these findings as a basis for discussion with the steering group. This both reinforced the review findings and highlighted a range of further barriers and good practice to be considered until we had created a working definition and draft hallmarks of people-centred clinical research.

Thirdly, we used all these insights to design a survey to explore the barriers and facilitators and to ask about the hallmarks. This included a range of tick box and open response questions, with the steering group helping design not only the content but the format, phrasing, and recruitment plans.

Within the survey, we asked about the barriers for people taking part in research and for researchers doing good people-centred clinical research.

We asked this in three ways (see appendix for examples):

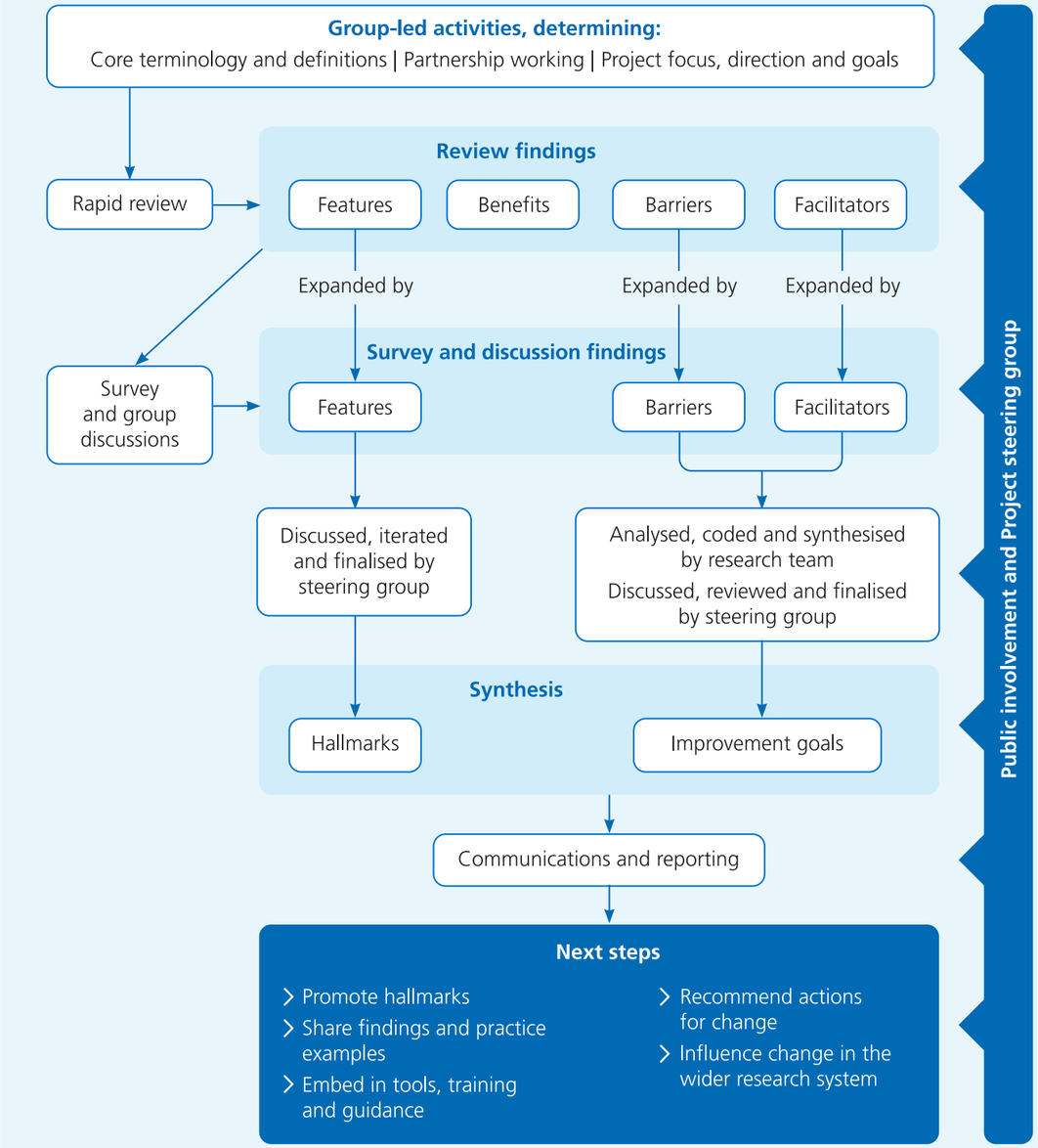
- providing a list of barriers and asking people to tick 'all that apply'
- inviting open (written) comments about the barriers and any poor experiences of research
- inviting comments about the draft hallmarks

The survey was launched on the **HRA website** with support from UK partners in the Recovery Resilience and Growth Programme.

Invitations were sent to 280 community organisations, including charities, faith and support groups from across the UK. Communications were sent by email, added to newsletters and shared on social media to invite public responses. Organisations were approached by emailed letter and asked if they would promote the survey or contact us for further conversations. Translated materials were offered as an option but not requested. A communications pack including newsletter and social media copy, as well as graphics for use on social media were also provided.

We held discussions with four groups who the steering group advised may not be as likely to otherwise engage online. In these instances, the survey was used as the basis for a discussion, with comments recorded and analysed in the same way as for the survey. Some one-to-one conversations were held with individuals as we were exploring who to speak with. The final set of findings and recommendations combines the review, group expertise and survey data.

Figure 1 - diagram to show how people-centred clinical research has been explored



Who we heard from

We heard from **412** people via the online survey. We also held four conversations with groups who were less likely to complete or find the survey online and received one written organisational response from the Association of Medical Research Charities. 'Appendix B – Demographics', shares details of responses to the survey.

The groups conversations were held with:

- **Expert Citizens CIC** - a community interest company led by and supporting people with lived experience of homelessness, mental ill-health, addiction, domestic abuse, poverty, or histories of offending behaviour
- **The Lawnmowers** - a theatre group of individuals with learning disabilities who provide advice and support as public contributors in research
- **NeurOx Young People's Advisory Group** - a group of young people who work with the Neuroscience, Ethics and Society (NEUROSEC) team to help develop methods for working with young people to better understand their views
- **CRISP** - an expert patient group at King's College Hospital NHS Foundation Trust supporting Parkinson's research

Most people who completed the survey (90%) had some experience of taking part in research but 9% did not (1% did not know). The reasons why people did not take part in research and their motivations were explored and incorporated into the analysis.

The demographic data of people who completed the survey showed responses were received from across all groups and categories within them, including gender, sexual orientation, employment status, gender identity, religion, belief or heritage and ethnicity. Responses were received from across all ethnic groups proportionate to the Census except for Asian or Asian British people and people identifying as male, which were lower.

Recognising the gap, the steering group advised making additional efforts to speak with groups under-represented in our responses. However, despite conversations with community organisations, we ran out of time to hold additional meetings.

Therefore, further exploration of how the hallmarks and the barriers particularly impact on young people under the age of 18, people from Asian or Asian British and Black African, Caribbean and Black British ethnic minority backgrounds, people identifying as male gender, and people who have not taken part in clinical research should be explored further.

How we analysed the data

The findings of the rapid review were analysed to identify key themes, forming the basis of the first version of the survey, which was developed further by the group.

Survey data was analysed in two ways – frequencies were run on tick box questions, and open response ('comments') answers were coded to identify categories of barriers.

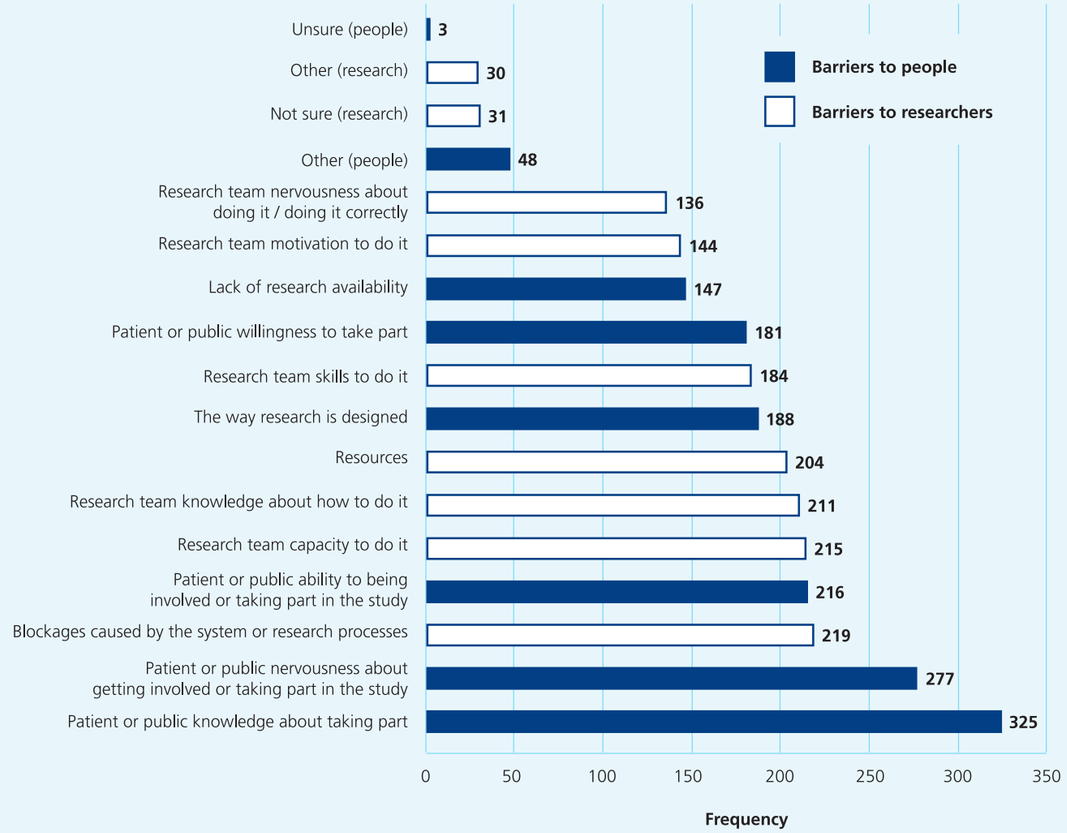
A fuller account of this process will be provided in an upcoming academic paper.

Part 3: Barriers, conditions and towards change

What are the barriers to people-centred research?

We first analysed the tick box questions from the survey to identify which of the barriers listed the respondents felt were the most or least common. The results are shown in the graph in Figure 2 below. The graph also shows which are barriers to people, and which are barriers to researchers.

Figure 2 – barriers to doing good people-centred clinical research



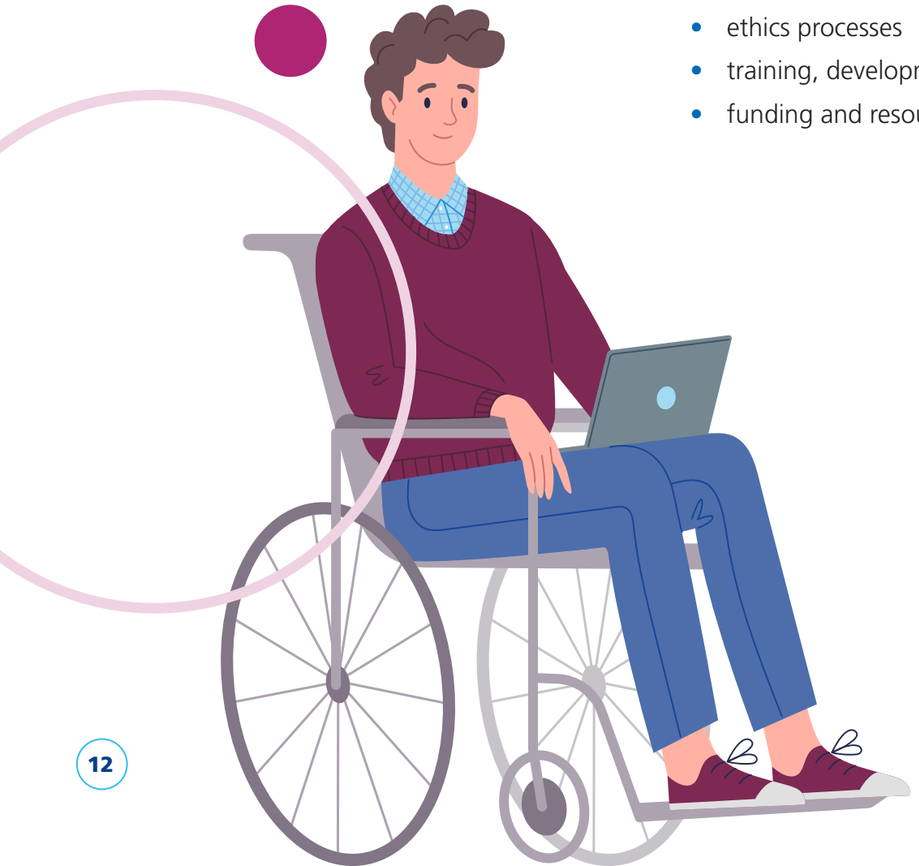
Public knowledge about research was reported the most times to be the barrier to people taking part in research, followed by nervousness about getting involved and people being able to take part.

From the list of barriers affecting researchers, respondents most frequently picked blockages in the system, capacity and knowledge about how to do people-centred research.

This quantitative data provides us with a starting point for understanding the changes required. However, the open responses to the barriers and facilitators share greater insights into the reasons behind the blocks and areas we had not considered in the tick list. We therefore undertook analysis of the full data (survey, conversations, group insights and literature review), coding all the data and combining them to identify nineteen categories of barriers to be looked at:

Categories of barrier to people-centred clinical research

- accessibility
- opportunity
- cost and inconvenience
- exclusion and inequity
- information about research
- fears about safety, confidentiality and disrespect
- communication
- care, value and recognition
- collaboration and co-production
- research design
- impact
- engagement
- capacity
- motivation attitude or approach
- advocacy
- system support and administration
- ethics processes
- training, development and skills
- funding and resources



What conditions are needed?

Our analysis showed three key conditions which must be in place for people to take part in research, and a fourth vital aspect – a people-centred research approach or culture.

Possibility - taking part in research needs to be possible

Research is not always accessible or happening in ways that are best for people taking part. Information about research is not available. People don't know about research; they are excluded from it or it is too hard.

Trust - people need to trust research and researchers

People do not always trust research or researchers. They can be fearful about safety or nervous and suspicious of confidentiality. Concerns are sometimes based upon how people and communities have been treated in the past. There can be a lack of care, respect and good communication. Partnerships with organisations trusted by people and communities, and co-production with members of the public is not yet the norm.

Purpose - people need to understand why the research and their contribution is valuable and worthwhile

People don't always see or value the purpose of research. It does not seem relevant to them or important enough to justify the impact on them. There is limited engagement about research. People may be concerned about their time and contribution being wasted.

A people-centred research culture

In addition, it is also vital to have a people-centred research culture. We heard that our research culture is currently centred (or focussed) on research process, researchers, finance, company drivers or metrics, and we don't have the necessary sector capacity, skills or confidence to do people-centred research well.

To drive real change we need to create the right environment which makes it possible and removes barriers for:

- people taking part in clinical research
- research teams to do good people-centred research
- the public leading and driving research and being part of the research team

What should good practice look like and what helps?

Having identified the barriers to people-centred clinical research, and the conditions which are important to people, we considered how these could be translated into practice.

First, we used the data for each barrier to identify examples of good practice (they help people-centred research) and bad practice (they stop people-centred research).

Secondly, the group discussed how the conditions could be expressed as actions, to help researchers know what to do. The group felt that being **treated well and with respect** was crucial for building **trust**, and that **meaningful** research and engagement was at the heart of **purpose**.

They also felt that there should be clear actions for a **people-focussed culture**, to ensure improvements aren't limited to individual projects. From this we developed a new set of four action-based principles.

Finally, we aligned the barriers, the descriptions of good and bad practice, and the action based principles. Together, these show what researchers need to do to demonstrate good people-centred clinical research, and what the sector needs to do to create an environment in which this can flourish.

Make it possible for people to take part

Offer choices, ensure fair representation and keep it as simple as possible.

What stops people-centred clinical research	What we need to look at	What helps people-centred clinical research
Individual needs are ignored	**Accessibility**	Individual needs are met
People are not approached or made aware of opportunities	**Opportunity**	People are actively made aware of opportunities
Taking part can be expensive and inconvenient	**Cost and inconvenience**	Taking part is convenient and compensated
People are excluded without justification	**Exclusion and inequity**	Research is inclusive by default
Information is institutionalised. It is technical, unclear or inaccessible	**Information about research**	Information is available in different formats and easy to understand

Treat people well and with respect

Show care, respect and appreciation. Ensure people feel safe and that their information is secure. Use great communication throughout.

What stops people-centred clinical research	What we need to look at	What helps people-centred clinical research
People feel unsafe, disrespected or worried	**Fears about safety, confidentiality and disrespect**	People feel respected and safe to contribute
Communication is poor, one-way or limited	**Communications**	There is two-way communication from start to end (and beyond)
People feel they are not genuinely valued, recognised or cared for	**Care, value and recognition**	People feel cared for, and their expertise is valued

Do research that is meaningful

Share a clear purpose and show how taking part will help to make a difference.
Work in partnership.

What stops people-centred clinical research	What we need to look at	What helps people-centred clinical research
People are not actively involved in developing or delivering the research	**Collaboration and co-production**	People are active partners and co-produce the research
Research questions or goals are not appropriate for people because they have been designed without them	**Research design**	Research questions and goals are appropriate because they have been designed with the people the research is for and about
People do not know the difference the research or their contribtuon will make	**Impact**	People know what difference the research, and their contribution to research, will make
People are not actively engaged	**Engagement**	People are actively engaged throughout the research process

Be people-focussed

Make sure people are the focus. Ask what matters most. Work on solutions in partnership.

What stops people-centred clinical research	What we need to look at	What helps people-centred clinical research
Researchers do not always have a people-centred mindset	**Motivation attitude or approach**	Researchers have a people-centred mindset
Researchers have limited capacity to do people-centred clinical research well	**Capacity**	Researchers have capacity to do good people-centred research
Research is only promoted within the research system	**Advocacy**	Research is promoted beyond the research system
The processes for running research make people-centred approaches too complex, difficult or time consuming	**System support, administration and leadership**	Research systems and processes are designed to support people-centred approaches
Ethics processes and system do not encourage, or make it difficult to work collaboratively with people	**Ethics processes**	Ethics processes and systems support people-centred approaches
There is little or no training about people-centred approaches	**Training, development and skills**	Training is available for researchers, people and wider workforce
Research is under-resourced for people-centred approaches	**Funding and resources**	Research is resourced for people-centred approaches

How can we be clear on what people-centred clinical research is and why it is important?

During the project it became clear that people did not always understand what people-centred clinical research is, as distinct from broader activities to involve patients and the public in research.

Being people-centred in research means asking what matters most to the people the research is for and about and working in partnership with them. It also means thinking of those who should have the opportunity to take part and doing research in ways people say are important to them when they take part.

Hallmarks

To address this and communicate how essential improvements for participants are, we further developed the hallmarks to be more easily understandable and shared. We also aligned them to the conditions that are needed and important to people about taking part in research.

These hallmarks combine all that we have learned about what research and research teams should show if it they are being people-centred and what good looks like.

This is in addition to conducting good ethical practice and acting with scientific integrity.

Each hallmark has an action statement for the research team and a corresponding statement from the participant perspective showing how they might expect to feel if the hallmark is met.

We have created a summary infographic in Figure 3 to explain people-centred clinical research and the benefits. A version of this and all the individual hallmarks can be downloaded from the **People-Centred Clinical Research section on the HRA website**.

The steering group played an important role in the development of these new hallmark resources, amplifying the participant voice for the first time. We hope these will be used to support conversations between researchers and participants and to help communicate with people what they might expect to experience in research. Further suggestions for **how the hallmarks can be used** are outlined on the HRA website.

The following examples visually demonstrate two of the hallmarks.

Figure 3 - infographic summarising what people-centred clinical research is and why it is important

Part 4: Recommendations

In this section we present recommendations for change.

First, we have summarised and presented them, grouped by the condition we want to achieve:

- possibility
- trust
- purpose
- a people-centred research culture

Secondly, we present some general recommendations in support of system-wide behaviour change.

Lastly, we describe each barrier in detail, with quotes from the data and recommended actions. These are provided to help people, researchers and groups across the research system identify specific changes they can start to make.

Recommendations are made with a call to action to improve or remove the barriers by providing system-wide support, through guidance, policy, processes and resources, including funding.

Recommendations for change

Below is a list of the 19 improvement goals for action grouped by the condition they want to achieve. They are not presented in order of any priority.

Possibility - make it possible for people to take part

- **accessibility** - improve accessibility. Make research and the information about it more accessible
- **available opportunities** - improve the availability of opportunities for people to take part in research. Make it easier to find research, including how and where research is advertised, and people are approached to take part
- **cost and inconvenience** - reduce the cost and inconvenience to participants taking part in research. This includes the impact on benefits and earnings. Reduce complexity and burden for the participant and improve choice
- **exclusion and inequity** - improve equity, diversity and inclusion in research and research practice
- **information about research** - make all information about research and research opportunities more focussed on the people it is for. Make information more human, effective and prevent jargon

Trust - treat people well and with respect

- **fears about safety, confidentiality and disrespect** - provide information and reassurance about safety and protection of data
- **care and recognition** - remove tokenism. Improve care, value and recognition. Improve how respect is visibly shown throughout research
- **communication** - improve two-way communication and feedback throughout research

Purpose - do research that is meaningful

- **co-production and collaboration** - improve collaboration and co-production in research and make this visible to participants. Work in partnership with members of the public. Remove barriers to public involvement
- **research designs** - improve research designs to be more people-centred.
- **impact** - improve visibility and likelihood of research impact. Ensure research does not waste people's time and effort
- **engagement** - improve methods of engagement for research

Culture

- **mindset and attitude** - improve researcher mindset to be more people-centred. Embed understanding of the hallmarks
- **advocacy** - improve research advocacy beyond the research system. Advocate for people-centred approaches
- **system capacity** - improve capacity across the clinical research ecosystem.
- **system support, administration, and leadership** - make it easier to do people-centred research and provide leadership
- **ethics processes** - support people-centred approaches through the ethics process
- **training development and skills** - include people-centredness in training and skills development. Provide training and development
- **funding and resources** - fund people-centred approaches and infrastructure

General recommendations and observations

Creating a people-centred clinical research environment requires action from across the research eco-system and for this action to be co-ordinated where possible.

This report aims to help prioritise this action and to support answering the question "what are the barriers and enablers to behaviour change that will make people-centred clinical research happen more often?".

The Department of Health and Social Care and the UK Recovery Resilience and Growth programme partners should review and consider their ongoing work and how they should act both individually and collectively with partners. This applies equally to all those across the research sector who can and should bring change, but there are roles to play for everyone.

Support to address the barriers

Each of the barriers and improvement recommendations in this report require further work to unblock the way for research teams and people taking part.

The NHS England and DHSC funded Research Engagement Network (REN) Development Programme is a good example of how this can work.

This programme aims to increase diversity in research participation through the development of research engagement networks with communities who are often underserved by research, and by ensuring diversity in research is considered by integrated care systems (ICS).

The sector should consider how the lessons learned from the REN programme and other work can be co-ordinated, shared and scaled up where appropriate.

At all times there should be public involvement to ensure that the research sector is not deciding for itself what good people-centred research approaches or appropriate action looks like.

As we become more people-centred we may change what becomes important to people in the future and there will be different issues to solve. Members of the steering group felt it important therefore to recommend the sector continues to check what matters most and to re-assess action plans in partnership with the public and research community.

Support for the hallmarks

There should be wide support for research teams to understand and meet the hallmarks of good people-centred research.

We should collectively:

- promote the principles and hallmarks widely
- support and expect researchers to demonstrate them in their practice
- support the public and researchers to find out about the hallmarks and to use them in their communications about research
- support researchers to find out about and share examples of people-centred research and how the hallmarks can be demonstrated well in practice
- continue to adapt research information tools to include the hallmarks so that they are in a media that is more accessible to the public. This includes creating culturally appropriate, easy read and translated versions
- expect the principles and hallmarks to be visible in applications. Make recommendations where they are not
- encourage sponsors and funders to monitor participant experience against the hallmarks and act accordingly
- consider running a future survey and engagement exercise to assess any movement on how people-centred our research is becoming in the UK, and whether the barriers have changed

> "The hallmarks should be referenced and available to participants and the whole team throughout the research cycle and it should be possible to check in on them to make sure they are being met."

Detailed description of the barriers and recommendations

Includes quotes from the data and recommended actions, to help everyone assess what changes they can make.

Possibility

People can find it difficult to take part. Research is not always accessible, or it is not possible in ways that are best for them. Information about research is not available. People don't know about it. It is too hard. People are excluded.

Accessibility

Barriers for people

Research is not always accessible and individual needs are not provided for. Digital, language and comprehension barriers are in the way before, during and after participation for some people. Participant information and research activities can be unclear or inaccessible. Study visits or procedures are not always possible to attend or to maintain at physical locations or in digital format. Those with visual and hearing loss, learning disabilities or who are neurodivergent are not generally well supported to take part in clinical research. Health and other conditions and can prevent people from taking part or continuing in a study.

What people told us

"I wish for more flexibility in the ways to be involved. When I can participate where I am e.g. at my local community centre or GPs. Having access to parking/transport links if need to go to where the research is conducted and knowing this prior."

"In the past, I have reviewed numerous Patient Information Sheets (PIS) relating to stroke research projects. Some have been dense and difficult to read (I am registered severely visually impaired, so read using magnification)."

"Do not rely on digital as there is a significant digital divide due to connectivity, affordability, accessibility and understanding of digital platforms. Make use of all."

Recommendation

Improve accessibility.

Make research and the information about it more accessible.

Ensure that:

- research opportunities are not only made available but accessible to people. This includes being in the formats and environments people can access and digital and non-digital ways where appropriate
- information about research and study activities are available for different languages and levels of literacy and comprehension. There is support for people with learning disabilities, visual and hearing impairments to take part in clinical research, so that individual accessibility needs in research can be met as far as possible
- Participant Information Design and Review Principles and guidance for proportionate consent are met

Barriers for research teams

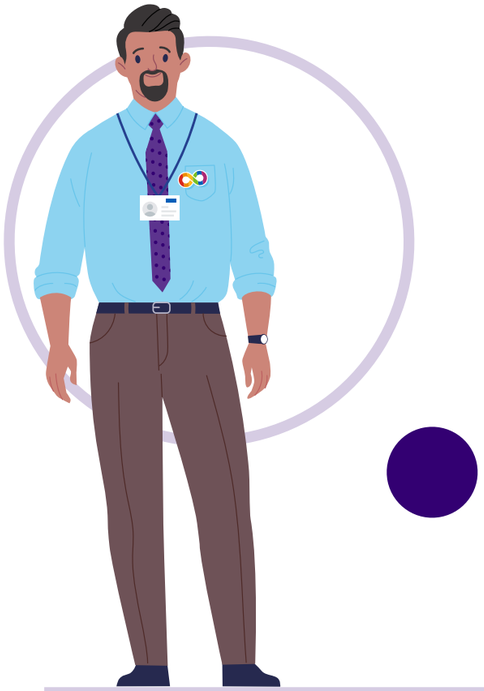
We identified the following barriers to doing this:

- researcher nervousness, caution or difficulty knowing what is required for different population groups and how projects or materials can be best adapted to different settings
- the expense to translate documents is not accounted for and limited availability of resources in hospitals or health settings for translation services
- there is limited language translation support for the duration of the project, including for analysis (not just the participant information sheet or consent process)
- there is a lack of knowledge and confidence about accessibility in research and how to do it properly
- there is limited capacity for researchers to go out to communities or provide non-digital solutions. Teams can find it difficult to do research beyond traditional settings and so it is the exception rather than the norm

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ support sponsors and research teams to judge when their research might be required in different languages, formats and locations at the right times and when this needs to be provided upfront. Provide support through the provision of better services
- ✓ help and expect researchers and sponsors to embed HRA Participant Information Design and Review Principles, proportionate consent and other regulatory guidance that promotes proportionate, simplified or streamlined approaches
- ✓ support global studies to know how to provide suitable materials for the UK
- ✓ support delivery teams to easily adapt study materials to their local communities where needed. This might include improving capacity and diversity within research and research delivery teams



- ✓ make it clearer to researchers when local interpretation and translation of materials is okay without amendment or sponsor intervention at site
- ✓ provide support and encouragement to do research in written and non-written formats, including visual considerations. Encourage easy read and expect other accessible formats for all clinical studies that should include people with learning disabilities
- ✓ improve knowledge and provide guidance and training for researchers on accessibility requirements in relation to research
- ✓ provide support to researchers, participants and communities about conducting research outside of hospital and in non-traditional settings. Identify and remove the blocks to improving access where possible. This might include support for governance, administration and capacity

Available opportunities

Barriers for people

People aren't approached or made aware of opportunities to take part in research. It can be a chore to find opportunities and people don't know about research. Information is disconnected. There can be gate keeping. It is too hard for individuals to find out about research that might be appropriate for them.

Research is still mysterious to people, and it is not widely promoted as it is seen as a burden by staff who aren't in a specific research role. Research websites or platforms can appear inaccessible and unavailable. Research is not available because there is no capacity to do it. Rare conditions or conditions that are complex are under-researched.

What people told us

"I have never been approached nor seen any research relevant to me. As I am nearly 72 and have various health conditions, my not being approached makes me wonder who is."

"Some studies rely heavily on clinician referral for recruitment to studies, clinicians can be a huge barrier sometimes to their patients taking part in research. Sometimes they made the decision not to approach a patient about a study because they don't think the patient will say yes, other times clinicians are just too busy to even consider research as an opportunity for their patients because they have too many other things to think about."

"I do all this work trying to find something that might help me, and in the end, it leads to nothing, and I think what's the point? It feels like they don't want me to know about research, it's a closed shop, it's only a club for the initiated, it's so hard, you really have to search for information."

"Patients are not getting the choice to take part if clinical staff do not provide information (protocol dependent)."

"Most patients don't understand the clinical trials available and often don't get offered the chance to take part."

"People with a rare condition like Multiple System Atrophy are desperate to be involved in research but there is little investment in research for such a 'niche' condition."

Recommendation

Improve the availability of opportunities for people to take part in research.

Make it easier to find research. Including how and where research is advertised, and people are approached.

Ensure that:

- there is clear, connected information for the public about where to find research opportunities
- research opportunities are widely advertised in more engaging ways and are easy to find and understand (taking accessibility into account as above)
- there are improved research options for rare diseases and under-researched areas. This includes older populations and people with co-morbidities
- more people are approached to take part and can choose between a variety of research options
- clinical and non-clinical teams can easily promote research opportunities and people are approached to take part
- people with complex health needs are not overlooked for recruitment into trials when they are eligible to take part
- there are more options for self-referral into clinical research
- clinical staff do not prevent access to research information. There is no gatekeeping
- people who are under-represented in research are provided with research information that is relevant to them, and how they can get involved
- research is available in different places, beyond traditional settings
- capacity to do research is improved

Barriers for research teams

We identified the following barriers to doing this:

- researchers are not always the most appropriate first point of contact to promote research or to involve people
- research teams need a mix of skills and expertise that aren't always available to them, including communications and engagement support
- funding for relationship building, outreach and engagement activities can be limited, particularly outside a specific funded project
- there is a lack of flexibility in working hours limiting the ability to offer choice
- studies are not always opened quickly or deliverable where there is clinical need
- there is limited staff resource and suitable space to hold conversations or to undertake research procedures
- recruitment timescales can be too tight to offer people opportunities to take part
- studies often need one-to-one recruitment efforts, and it can be particularly challenging to recruit people with complex health needs or who researchers and clinicians believe will be difficult to include

What people told us

"We are not good at getting research out to the public; many studies do not allow self-referral, too many eligibility criteria; studies not shared across the country and not opened in areas of disease burden."

"Research presence needs to be maintained in the local communities to normalise research chats, participation and peer support."

"Research and delivery teams go for easy wins over and above where there is a research need."

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ support research teams with the skills, tools and mechanisms to better communicate research opportunities. Encourage them to develop and share communication packs
- ✓ support and expect research teams to include people in delivery who are well-placed to communicate or engage with the people the research is for and about
- ✓ help and encourage researchers to create studies and develop research opportunities for those currently underserved by research
- ✓ help research teams to involve and enable non-clinical staff to support research
- ✓ encourage research and delivery teams to recruit people with complex health needs where appropriate
- ✓ make it easier to do research, particularly across boundaries and beyond traditional settings
- ✓ build support for research and presence in local communities. Being careful not to add burden, this should be alongside support within existing research infrastructure
- ✓ help and encourage researchers to design research that allows more self-referrals where appropriate
- ✓ speed up the whole research process so it is easier to create and offer clinical research opportunities
- ✓ encourage researchers and sponsors to design in longer recruitment periods if appropriate

Cost and inconvenience

Barriers for people

Procedures and schedules of events can be difficult for people to do and are a commitment over time. Taking part in a research study can be costly and inconvenient, despite expenses being provided. There is a lack of choice about how to take part. Payments can impact on benefits. Complex projects can be complicated for participants. The burden is often on the participant to travel or get to the research at a time suited to the research team that are usually in working hours. There can be car parking and other costs to pay upfront. Protocols can be written for the collection of data and what the research team want to know, not for the convenience of the participant taking part.

What people told us

"It is rare for patient participation to be adequately budgeted for in proposals."

"Some methodologies like questionnaires or interviews still seem to place too high a burden on the patients e.g no. of meetings or questions."

"Are all the visits necessary? Are we offering visits close enough to home? We should be covering travel expenses in every trial. Focus on what matters to children and young people, is it online, could it be an app? Could it be remote consent? Avoid missing school, education or work as much as possible."

"Sometimes research can be so burdensome it is off-putting to potential participants."

"Having taken part in research myself and supported my husband through research participation, even when you are committed and you see the benefit, it's an additional activity that requires your time when you could be doing other things (i.e. it's an inconvenience) - need to minimise this as much as possible."

Recommendation

Reduce the cost and inconvenience to participants taking part in research.

This includes the impact on benefits and earnings. Reduce complexity and burden for the participant and improve choice.

Ensure that:

- the financial costs of taking part are recognised, reimbursed or otherwise compensated
- taking part in research does not have a negative impact on tax, benefits or earnings
- people in receipt of benefits are supported to take part in research
- people are not required to pay for costs upfront and then reclaim
- research is more convenient for the people taking part
- research protocols and requirements are less burdensome on participants and research teams. The research commitment for participants is manageable
- complex studies are as easy as possible to take part in
- improve choice for how people can take part

Barriers for research teams

We identified the following barriers to doing this:

- researchers and sponsors may not be aware of the financial costs and burdens to participants, and this can be difficult to understand in large projects or across countries
- researchers and delivery teams often work standard office hours
- researchers must balance providing payment for costs without coercing people to take part or breaching commercial standards
- complicated systems for supporting expenses

What people told us

"There is lack of understanding of challenges faced by participants and insufficient resources are allowed to reimburse and compensate participants for taking part in research."

"Making sure that expenses are paid promptly. We currently have to wait at least six weeks. This must discourage people who are less well-off and skew the sample."

"Take time to understand who your participants are. Relationships matter."

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ support research teams to invest time to better understand the participant experience through public involvement
- ✓ support sponsors and funders to understand more generally the costs of participation in different settings and to plan for them
- ✓ make it easier for sites and sponsors to make payments to participants
- ✓ build up research and research delivery teams that deliver research outside of office hours so that it doesn't cost participants to lose work time
- ✓ streamline reimbursement of costs offered to participants for taking part
- ✓ support researchers to focus on costs to participants, as well as costs to organisations
- ✓ help researchers to be clear about when incentivisation is coercion, whilst better enabling schemes for rewarding and recognising participation

- ✓ encourage researchers to create simpler protocols. Share examples of flexible protocols that offer choice to reduce the burden of taking part
- ✓ explore the implications of UK tax and benefits on research participation and people-centred ways of working
- ✓ support sponsors and researchers to understand the implications of payments for research on tax and benefits. Support them to make it clearer to people
- ✓ encourage researchers to create protocols that are simple and flexible whilst ensuring data quality
- ✓ ensure mechanisms for payment of expenses are easy

Exclusion and inequity

Barriers for people

People are excluded without justification. Different groups are poorly represented in research data. There are groups of people who are underserved by research and are often overlooked for example by age, sex, gender, ethnicity, race, socio-economic status, co-morbidities and geographic locations. Research practices are not always inclusive or help people to take part. Research teams, public involvement and research systems are not always as diverse as they could be. People with poor health are often excluded from study protocols by default.

What people told us

"Exclusion criteria of 'must be proficient or fluent in English' is very often seen in protocols when there is no need for this. Excluding huge populations of underserved communities unnecessarily. All health and social care departments have access to interpretation services."

"Too many barriers put in place by researchers only looking for a perfect fit to their criteria. Single mindedness, they seem to look for reasons not to."

"Diversity should include everyone who isn't part of the research conversation; single mothers, shift workers, single fathers, agricultural workers and 9 to 5 employees (research favours those available between 9am and 5pm)."

Recommendation

Improve equity, diversity and inclusion in research and research practice.

To improve equity, diversity and inclusion in research and research practice ensure that:

- it is an expectation that groups traditionally underserved by research have a fair opportunity to take part in clinical research where it is relevant to them. This includes age, sex, gender, ethnicity, race, socio-economic status, co-morbidities and geographic locations
- research teams and those in the research system are more representative
- public involvement is more representative
- diversity in research is monitored using robust data (at study and system level)
- research engagement methods are more inclusive and appropriate for diverse population groups
- research protocols, information and activities are culturally appropriate and inclusive
- there is no discrimination in research or research settings

Barriers for research teams

We identified the following barriers to doing this:

- there can be nervousness to approach communities. Fear of offence and a tick box mentality. Researchers can be fearful of offending people who are of a different culture or background to their own
- researchers can be unsure of when inclusion is okay for safety reasons. For example, they can be nervous of age, comorbidities or pregnancy
- inclusion is time consuming and can be challenging particularly around language support and relationship building
- costs for involvement and engagement activities can be high and unpredictable
- researchers lack confidence and awareness around the appropriate language to use
- there can be a lack of knowledge, diversity and bias
- demographic data is not collected consistently in the health records

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ support researchers to think inclusion first
- ✓ make it clear when exclusion criteria are reasonable and justified, for example for good safety or scientific reasons
- ✓ build confidence and competence in areas where there is uncertainty and nervousness around inclusion
- ✓ support researchers to reduce their exclusion criteria where appropriate
- ✓ help researchers to develop and report against inclusion recruitment goals
- ✓ help researchers to monitor inclusion and exclusion in their studies
- ✓ improve consistency of reporting and access to demographic data
- ✓ create more awareness of bias and discrimination and how exclusion from research can foster health inequalities
- ✓ help research teams and clinical teams invest in and build better relationships with communities without over burdening those communities
- ✓ help researchers to build diverse and inclusive teams, including with members of the public and delivery teams

Information about research

Barriers for participants

Jargon is a barrier. Information about research and research opportunities are institutionalised and in ‘research speak’, on institutional websites or behind paywalls. There is information overload. Information about research and research opportunities can be long and impenetrable. Information given about research can be complex, complicated and of poor quality. Corporate branding from research or clinical institutions can feel unfriendly and may not be adaptable.

What people told us

“I suggest the quality of information provided is fundamental to engaging the interest of patients.”

“The terminology and vocabulary is often pitched at under-graduate levels of understanding, when they should be pitched for the non-academic with limited reading skills. For convenience, Participant Information Sheets are often replicas of ones used in earlier studies and adapted to fit the new study. Commercial studies and those from America may have been drafted by lawyers and therefore run to many pages, people with poor reading skills are not able to engage with such missives.”

Recommendation

Make all information about research and research opportunities more focussed on the people it is for.

Make information more human and effective. Prevent jargon.

Ensure that:

- information about research is written in ways that people speak with a focus on how they will receive it
- information about research and research findings are free, accessible and in non-scientific formats
- paywalls are removed wherever possible
- communication is with the right people in mind and in personable ways
- personalised communications are used where possible and not just blanket communications
- information overload is reduced

Barriers for research teams

We identified the following barriers to doing this:

- lack of expertise and capacity to communicate in accessible and engaging ways
- researchers are trained to write in the third person and in scientific ways
- research communications and engagement expertise and capacity for research teams is limited
- there can be the perception that ethics committees will prevent information sharing in engaging ways

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ improve, share and develop skills to make participant information accessible, engaging and easy to read
- ✓ ensure research teams co-develop and test public-facing materials with patients and the public
- ✓ find out effective means of communicating information about research and tell researchers
- ✓ help researchers communicate more effectively between teams, organisations and with clinicians and other key groups and bodies
- ✓ remove the perception that ethics committees require information in a format that is not engaging
- ✓ ensure organisational branding is flexible to enable adaption

Trust

People don't always trust research or researchers. There can be fear about safety with nervousness and suspicion about confidentiality. Concerns are sometimes based upon the treatment people have received in the past. There can be a lack of care, respect and good communication. Partnerships with organisations trusted by people and communities, and co-production with members of the public is not yet the norm.

Fears about safety, confidentiality and disrespect

Barriers for people

People can feel unsafe or are worried about being harmed. There are concerns about treatment of data and how people have been treated in the past. There is broken trust. People may not believe the researchers are telling the truth or trust their reasons for doing the research. There can be misinformation.

There can be worries about the impact of research on treatment and care or the research is felt to be intrusive. People can be concerned they need to be academic to take part. Doctors and organisations of 'authority' can be a source of anxiety for some, there is a power imbalance. There can be some uncertainty about post-research care.

What people told us

"When I discussed my participation to friends and family I received some negative responses such as 'you don't know what they'll inject you with'."

"Historical abuse in research involving ethnic minority groups and lack of notable changes when studies are conducted with ethnic minority groups."

"Patient and public are being nervous - stigmatisation of being the 'guinea pig'."

"I think a lot of people fear interventional research, in particular, that offers no guarantee of care as good as standard care, or worse, that is dangerous. A close family member, for example, has made their wishes clear that if I have to take a decision on their care while they are incapacitated, under no circumstances should they be included in research."

"What are they doing with this information? Who is going to see it? Where is it stored? Are they selling it on?"

Recommendation

Provide reassurance about safety and protection of data and change the image of research and researchers.

Make it clearer how taking part in research and personal data are safeguarded.

Ensure that:

- there is greater transparency and openness in research practice. Our research and research systems are more open to scrutiny
- there is enhanced communication for transparency on safety measures and confidentiality of data
- power in the research system is shared with the public. Members of the public can influence the system
- there is investment in partnerships with organisations across the research ecosystem that are trusted by people and communities
- concerns about historical research practices are recognised, acknowledged and fears are discussed and addressed
- there is an investment in time and resources to build relationships with those who have been previously harmed or who are disenfranchised by research
- any emotional cost of taking part in research is acknowledged and addressed
- people's concerns about the research process are taken seriously and acted upon
- mechanisms for support and complaints are communicated well, with respect and transparency
- information about our ethical, legal and integrity systems are clearer and more available to the public. They are communicated in ways that are meaningful to them
- the way we care for people and their data and confidential information is clear and easy to understand
- awareness of research and research practices is created in the wider public
- consent processes are simple, informative and easy to understand
- mis-information about research is addressed and widely communicated
- re-think the image of research and researchers and how they are promoted to the public

Barriers for research teams

We identified the following barriers to doing this:

- researchers are external to the people they are asking to take part and cannot easily influence how they are perceived by them
- a lack of ability to influence or reassure because of historical practice
- concerns and nervousness about working with communities as part of the research team
- perceptions of research

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ improve systems to ensure transparency and trust in research
- ✓ support researchers to communicate about the systems we have that protect people taking part ensuring ethical practice, safety and information governance
- ✓ support researchers to partner with organisations that are trusted by people and communities and to make this visible. Encourage partnerships with community organisations for trust-building
- ✓ develop partnerships with organisations outside of the research system who may be trusted by research participants
- ✓ support researchers to understand what good looks like and to express this
- ✓ support researchers to understand public perception of research and researchers and to act on it
- ✓ provide support and training for building trust and effective communication

What people told us

"There needs to be trust, enthusiasm and a culture change about taking part in research, built at staff level. More information shared by the HRA to help potential participants understand that there are gateways and legislation to protect them when taking part in a study via the NHS, rather than just associating research with stealing data, 'big pharma', Big Brother or poorly conducted research."

"The patient often does not feel confident enough to come forward. When trying to recruit, I start with a slide saying, 'I am not a scientist'. We need to gain their confidence and provide enough support and training for participants."

"Things require a really nuanced approach, the fine line to coercion is difficult. If your experience of health care is not great, then being asked by your clinician is the worst thing you can do."

Care, value and recognition

Barriers for people

People feel there is tokenism and that they are treated as a commodity. There is a lack of thanks and appreciation for taking part. There is sometimes a lack of care in helping people to attend or kindness in the way people are treated.

What people told us

"They didn't check if I was ok to talk."

"Then they said to me 'and by the way as part of a clinical trial we would like to take samples from you to keep them' and I said 'well will that mean that you would be able to treat me' and they said 'oh no, no this is just for a trial we just need to take your blood and will keep it and do research on it but and there's no benefit for you and will just take a few hours' I was really disappointed because I just been told that I couldn't be treated at (city location A) and then they were asking me to participate in a trial that was based in the same (city location A) but I wouldn't get any treatment or support from them so it didn't feel very kind."

"We are often seen as just a resource for their research."

Recommendation

Remove tokenism, improve care, value and recognition.

Improve how respect is visibly shown throughout research.

Ensure that:

- people taking part are treated as equals
- people's needs and experience are the focus of the research and delivery teams
- researchers don't ask people hard questions when they are just diagnosed, or in crisis, where possible
- participants are listened to, and their time is respected
- it is not a transactional relationship. People receive something meaningful to them in return
- participants can see that their contribution, the costs and sacrifice of taking part are recognised and appreciated
- people are thanked
- researchers listen and act with kindness

Barriers for research teams

We identified the following barriers to doing this:

- researchers may be unclear what they are able to do ethically to thank people for their participation and are wary of coercion
- time, capacity and ability to spend time with people
- large cohorts of participants, spread across multiple locations and countries
- a belief that their good intentions translate into a good experience for participants
- unforeseen issues about taking part in research (for example COVID-19 vaccines and travel)

What people told us

"Less 'othering'. Anyone working in the field of research should also take part to see both sides."

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ make it clearer what researchers can practically and ethically do to thank people for taking part. This might include at least time or knowledge exchange
- ✓ support researchers to offer meaningful thanks for participation
- ✓ share examples of good practice in providing feedback to participants. Especially where there is nervousness that contact may cause distress
- ✓ share examples when things go wrong and learn from them
- ✓ build researcher understanding and capacity to do research with care, respect and kindness
- ✓ support researchers and research delivery teams to fund time for relationship building interventions and to help them to build rapport with participants
- ✓ ensure participant facing roles have the right space and time to spend with them
- ✓ support researchers to have difficult and open conversations, which might be around a complaint
- ✓ work to remove any 'them and us' divide between researchers and participants

Communication

Barriers for participants

Communication can be poor, one-way and limited. There may often be no feedback given to the participant during or after the study. The findings of the study are not provided back to the people who took part, or in ways that are meaningful to them. Communication and information sharing between teams and organisations can be limited.

What people told us

"Keep communication flowing. Do not leave the research participant without a contact".

"Give a telephone number so you can contact the team with queries."

"As an unpaid carer with limits on my time, good, clear communication and planning is what I cherish in a research project. I need to know what I need to do and when (or by when) and with preferably with long lead times for meetings or appointments. Being provided with this information assures me that I, and my caring role, are respected. It helps engender a feeling of partnership.

So much time is wasted, and stress caused, by informing participants that something is to happen, say, in the coming months, and that a date will be forthcoming, but then is not. Communication is not difficult these days. Participants having to make enquiries themselves due to non-existent project communication is not people-centred research!"

"I wish that it was routine that researchers provided access to research results."

Recommendation

Improve two-way communication and feedback throughout.

Improve two-way communication and feedback throughout the research process.

Ensure that:

- there is direct, regular and proportionate communication with participants throughout
- the outcomes of the research are always shared with the people who took part
- communication is two-way. Participants know they can contact the research team and how to do it
- communication is timely, reliable and responsive
- communication is clear and accessible and in ways that are best for the people taking part
- plans for how the research teams will communicate with participants throughout and after the research are in place. This is co-designed and tested with public contributors and participants
- communication and information sharing between teams and organisations is maximised

Barriers for research teams

We identified the following barriers to doing this:

- nervousness about appropriateness of contacting people
- concerns about causing distress contacting participants with research outcomes, particularly if there is a risk the person may be deceased
- time and capacity to spend with people taking part and to respond to them
- no mechanisms in place for feeding back on studies that are large cohorts or long-term follow-up

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ share examples of good practice in providing feedback to participants
- ✓ improve research delivery time and capacity to spend with people taking part
- ✓ support researchers with how to communicate findings to participants where they show the intervention is not beneficial
- ✓ support research teams to communicate with participants and to develop good communication plans, co-designing them with public contributors and the people taking part

Purpose

People don't always see or value the purpose of research. It does not seem relevant to them or important enough to justify the time to take part.

"If people don't understand the purpose, then they are less likely to want to respond."

Collaboration and co-production

Barriers for people

There is still limited collaboration with the public. Researchers work 'on' but not always 'with' members of the public in research. It can be challenging for members of the public to become co-applicants or members of the research team. There can be power dynamics and hierarchy.

What people told us

"Historically patients have not been included in research design and delivery, and those of us who have been around for a while have had to rethink and learn how to do it. These are not skills I have ever been taught. Time and resource needs to be included in research design and delivery to achieve this."

"Involving patients and the public is fundamental to well-designed people-centred research. There are many people out there who want to be involved, but researchers seem to lack the time, knowledge and skills and resource to do this."

"Researchers need training in working with the public."

Recommendation

Improve collaboration and co-production in research and make this visible to participants.

Work in partnership with members of the public. Remove barriers to public involvement.

Ensure that:

- public involvement in clinical research is expected, funded and insisted upon
- members of the public can be public contributors, co-applicants and part of a research team
- the UK standards of good public involvement can be met by research organisations
- research starts with communities and people who will benefit from or be affected by the findings
- capacity and capability for public involvement is improved
- public contributors are more diverse and included

Barriers for research teams

We identified the following barriers to doing this:

- there can be a 'them and us' mentality
- funding, time and capacity
- researchers are nervous of tokenism
- researchers are not always the best people to involve members of the public or know how to do it well
- there is inexperience and nervousness
- there is not enough training or awareness of what good public involvement practice means
- a lack of expertise and confidence to remove the barriers to inclusion for diverse public involvement so that public contributors include people who are marginalised or underserved by research and health care
- lack of value or belief

What people told us

"I don't think there has been enough live support for academics - guidance on websites and PPI 'training' (usually delivered by PPI researchers) simply hasn't drawn a critical mass of researchers towards making it part of how they work. I think we need to bring more researchers into all the discussions and decisions about PPI, otherwise we're being as un-inclusive as we accuse them of being."

"During five years of REC attendance, there are very few researchers who appear to want to engage with the public (and RECs). Few researchers build PPI into their research from the bottom up - the ones that do are notable and the research is all the stronger for it. I don't know if this is because they don't know how to 'talk to' the public or potential participants, cost or because they just want to get on with their research."

Suggestions

We suggest the following steps to remove barriers for research teams:

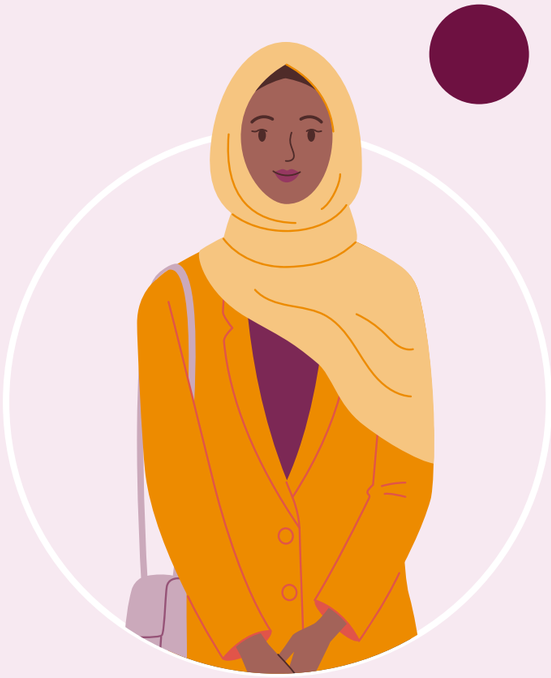
- ✓ provide more support and guidance on how to do good public involvement well and to ensure the UK standards of public involvement are met
- ✓ support and train researchers to use effective ways to involve people and to benefit from their contributions
- ✓ support researchers to make the case for funding public involvement, including the uncertainties that may result from good public involvement in research
- ✓ remove the barriers to good inclusive and accessible diverse public involvement
- ✓ support researchers to partner with organisations and members of the public
- ✓ support researchers to understand the value in public involvement and share good practice
- ✓ ensure funding models for public involvement are flexible enough to allow for uncertainty in the research development process

Research designs

Barriers for people

Research is not always focussed on what is important to the people affected or the people taking part. The research question, activities or outcomes can be inappropriate. Methods chosen can be inappropriate for age or situation. Protocols can be too long and inflexible. The delivery can be impractical.

Designs do not always take a lifecycle approach or focus on the participant journey. Management and delivery can be poor. Methods can be unnecessarily repetitive. Global studies that are designed outside of the UK are not always adapted or optimised for the UK or for non-traditional delivery settings. Stipulating the approach must be undertaken via a particular team or professional group unnecessarily. Timelines are too tight.



What people told us

"The research methods that allow for the messy real world and flexibility should be promoted more as high-level effective methodology."

"More action and participatory research with communities."

"There also seems to be little consideration of where research might be widened to apply to other similar conditions when developing proposals."

"Unnecessary barriers to recruitment for example studies that stipulate that the approach must come from the patient's clinical team, when they themselves don't make that distinction."

Recommendation

Improve research designs to be more people-centred.

For research designs to be more people-centred we must ensure that:

- research protocols are more flexible
- research is designed so that it can run in non-traditional settings outside of secondary care
- research outcomes, questions and objectives are developed with those who will be affected. This happens early enough in the process to make a difference
- participatory methods of research and research delivery are more common
- research aligns with clinical or patient care pathways
- activities are appropriate and relevant for participants including age and circumstance
- practical measures and approaches are trialled or piloted for example as Studies Within A Trial (SWAT)
- people-centred approaches are built into the full research lifecycle of a study
- the people who are going to deliver the study and the people who might become research participants are part of the design team and can input into it
- global studies are supported to adapt to the UK and non-traditional delivery settings
- timelines are realistic

Barriers for research teams

We identified the following barriers to doing this:

- there can be a big gap between where the research is generated and where the research is taking place (it could be developed in a different country) so it is difficult for researchers to design them for local settings
- reliance on traditional methodological approaches
- use of 'cookie cutter' protocols - protocols that are used automatically by research teams and not adapted appropriately for a specific study
- unclear how to integrate people-centredness into traditional designs
- not confident about appropriate engagement methods for certain research designs and methods
- difficult to build necessary flexibility to engage people into rigid methods
- not confident with public involvement in research design
- tight timelines to deliver preventing people-centred approaches

What people told us

"We rarely involve those conducting the trial in the design team."

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ share protocols and approaches for people-centred research
- ✓ help researchers collaborate and improve how they can develop more flexible research projects and protocols
- ✓ support researchers to help global studies adapt to non-traditional or acute settings in the UK
- ✓ address concerns researchers may have around participatory methods, public involvement and real-world research
- ✓ promote research delivery input into research design, include in research training
- ✓ encourage research teams to think more carefully about the needs of the population the research is for and about when using traditional or template protocols
- ✓ encourage more Studies within a Trial (SWAT)s and piloting of practical measures within a study
- ✓ promote methods of self-referral into studies where appropriate
- ✓ challenge traditional concepts of who should be part of a research team
- ✓ support realistic timelines

Impact

Barriers for people

People who take part, cannot see the difference the research could make in the real word. Their contribution to the research is not visible or communicated. Research findings may not be published or make a difference beyond the study. It is not always obvious how research will help.

What people told us

"Some surveys require a lot of time and are often a complete waste of time. They employ a lot of people doing goodness knows what and end up gathering dust (metaphorically)."

"It should be demonstrated how the research can benefit patients now and in the future."

"Studies must be worthwhile and for participants to clearly see the benefits for patients or the NHS."

"What difference is deemed important, tension here between hard outcomes (hospitalisations and deaths) and the 'softer' outcomes (e.g quality of life) that can make a real difference to people."

"Sometimes it is not obvious how research helps."

Recommendation

Visibility and likelihood of research impact.

Research should not waste people's time and effort.

Ensure that:

- the purpose and benefits of research is clearly communicated and that the difference the research could make is communicated to participants
- the difference taking part in research makes as a participant is communicated and participants understand their own impact
- there is an explicit commitment to supporting the translation of research into practice
- research is developed to add value and to increase the likelihood of impact beyond the study

Barriers for research teams

We identified the following barriers to doing this:

- communicating the difference research might make even if it is a negative outcome for the intervention being tested
- lack of consideration of impact
- a lack of knowledge and understanding about how to take steps towards translation and implementation as the research team

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ help researchers to think about impact at the outset
- ✓ help researchers to realise how important 'making a difference' is to participants and to communicate it to them
- ✓ help researchers to fund activities that support communication and translation of research findings into practice
- ✓ help researchers to involve the public in the selection of their research outcomes
- ✓ help researchers to see their role in improving the likelihood of research impact

Engagement

Barriers for people

There is passive engagement. Communication and engagement about research is not designed with people in mind or in ways that are best for them. Methods of engagement and mechanisms for it are limited.

What people told us

"People are often only asked about research at the point they are needed. If there was more general awareness people might be more likely to say yes."

"Greater development of tools to involve people with different learning styles and preferred methods of communication."

"Allow different options for feedback and evaluation - people need flexibility on how to communicate - especially if they have been marginalised."

Recommendation

Improve methods of engagement for research

To improve methods of engagement for research we must ensure that:

- engagement can happen in different ways
- engagement methods are thoughtful, creative, relevant and culturally appropriate
- methods to engage people are throughout the research process
- methods of engagement and communication about research are presented in ways that are important and to the people taking part
- there is more capacity for communicating and engaging with people in people-centred ways
- engagement methods and outputs are co-designed by members of the public and the people they are for
- engagement about research and its impact is increased

Barriers for research teams

We identified the following barriers to doing this:

- time, funding and resources for good engagement
- researchers can lack engagement expertise and confidence in good methods of engagement
- a lack of systems, mechanisms or infrastructure to engage well
- uncertainty about what they are allowed to do

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ ensure time and resources for engagement are built into research and research funding
- ✓ increase engagement strategies to convey the significance of research
- ✓ support researchers to develop clear communication plans to articulate the value of participants' contributions
- ✓ improve engagement expertise and capacity
- ✓ provide support for research teams to identify good engagement methods that can be easily adopted by the NHS or other public sector bodies
- ✓ provide infrastructure that supports great engagement
- ✓ ensure that information governance, IT systems and infrastructure enable and do not hinder good engagement unnecessarily

Research culture and capacity

We don't yet have a people-centred research culture.

We have research or researcher centred, finance, company-centred or metrics-centred culture. There is limited capacity to do people-centred research well.

Mindset and attitude

Barriers for people

Researchers do not always have a people-centred mindset. Researchers may think they do research in people-centred ways already.

What people told us

> "I believe that some researchers don't even think about people-centred research. They are focused on their objective (getting data or trial outcomes) and do not connect at all with participants as people."

Recommendation

Improve researcher mindset to be more people-centred.

Embed understanding in the hallmarks to ensure that:

- researchers think in people-centred ways
- research and researchers show the hallmarks
- researchers ask what matters most and find out how best to work in partnership with people
- researchers reflect on lessons learned and participant experience during the research process
- researchers can adapt to the needs of different people where possible
- people-centred, ethical practice is the end goal

Barriers for research teams

We identified the following barriers to doing this:

- traditional training, guidelines and standards of good practice that are focussed on research outcomes or process
- research careers can be driven by short-term funding, metrics and publication
- participant considerations have been largely focussed on safety, risk and protection to date
- nervousness and knowledge
- language around being people, person or patient-centred encourages traditionally attitudes of doing 'to' participants
- pressure to recruit rather than spend time or do the right thing

What people told us

"The pressure to recruit (recruitment volume and meeting targets) or threat to lose funding can cause research staff to look over people-centred research - and focus more on metrics."

"People-centred research involves ethics training, cultural competency, public participation in research design and specific community participation when looking at research that affects this community."

"Looking to research metrics as less as the end goal and looking at ethical practice as the end goal."

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ promote the hallmarks of people-centred research. Build the principles into other frameworks and guidelines for good research practice (for example ICH-GCP, WHO guidelines, Good Trials and UK policy framework)
- ✓ promote and require people-centred approaches
- ✓ have examples of good people-centred research and the reasons why it is important
- ✓ ensure researchers understand what being people-centred means. Articulate what it is and what it is not
- ✓ ensure researchers understand that public contributors and participants should be the judge of when research is people-centred from their perspective
- ✓ ensure research experience is not adversely affected by research metrics and the pressure to recruit
- ✓ make sure quality metrics are people-centred

Advocacy

Barriers for people

Research advocacy relies on the research system alone.

What people told us

"In the UK we do not explain clinical trials properly to the public at large. We need to start this at school level and continue that with appropriate materials in GP and hospital waiting areas."

"Staff in the NHS need to understand the link and their responsibilities to research as part of their role and the future of the NHS, rather than as an add on. Seeing the big picture, rather than something that is detrimental to their already stretched time and resource pressures - although they may need help or resource to do this."

Barriers for research teams

We identified the following barriers to doing this:

- time for research advocacy is often not funded
- requires system-level advocacy to access mainstream platforms

Recommendation

Improve research advocacy beyond the research system and advocate for people-centred approaches.

We must ensure that:

- systems, processes and cultural norms for clinical research are well advocated for within and beyond clinical settings
- ambassadors for research and for people taking part are embedded within the sector
- relationships are built for research outside of the established research sector
- communities are encouraged, funded, supported and trained to advocate for research
- there are networks and communities of practice for people involved in research
- support for research in the community and primary care is enhanced

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ fund research advocacy as a legitimate activity joining up research teams with communities, clinical and non-clinical settings including with staff who are not usually research active. Fund communities and research teams
- ✓ provide national support to advocate for research via channels and platforms that are more mainstream for the public

System capacity

Barriers for people

Both the research system and the NHS are under pressure and have limited capacity or infrastructure to do clinical research or in people-centred ways and to support people to take part in it.

What people told us

"Limited staff resource and suitable space. Inflexible research staff working hours or staff unwilling to change hours. Lack of engagement from clinical staff, not interested in supporting research or embracing it as part of care."

"We are too overcome and overburdened with service provision."

Recommendation

Improve capacity across the clinical research ecosystem.

To improve capacity across the clinical research ecosystem we must ensure that:

- the pressure on NHS delivery is reduced by finding ways to deliver research outside of a clinical setting wherever possible
- there is an environment in which people-centred clinical research can exist and thrive
- clinical research has more infrastructure and mechanisms in place to deliver it
- people-centred approaches are supported with infrastructure and the mechanisms to do them
- there is a research workforce to support clinical research, that is valued and sustained

Barriers for research teams

We identified the following barriers to doing this:

- pressures on the NHS and NHS staff
- lack of clinical spaces, services and general infrastructure
- time pressures
- workload
- resources
- low capacity to do a good job
- too many different systems at play to improve efficiency
- short-term research contracts for researchers and research delivery staff
- unable to connect and operate across the system

What people told us

"We do not have enough staff to cover all sites which means some women will never be offered the opportunity to participate in research."

"Most research staff are on short-term contracts, there is never enough time and money to support researchers and allow for development."

"More recognition of capacity constraints."

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ fund and create more spaces, the time and the infrastructure (including information technology) that supports staff to spend time with people and for people-centred approaches
- ✓ provide ways to reduce gaps between the different systems that support and inform research. Create a connected picture wherever possible
- ✓ support the research workforce with secure employment contracts
- ✓ improve the ability and confidence of research teams to run research across multiple settings and in different ways
- ✓ recognise capacity as barrier to be addressed

System support, administration and leadership

Barriers for people

Support and leadership for people-centred approaches is still in its infancy. Systems for setting up and running studies can be slow and inefficient.

What people told us

"With staff that have been working in research for decades there can be a reluctance to change working practices. Also, for new staff, if this way of working isn't embedded in research team leaders then they will also not know the importance of this."

"Strong leadership in this area is important in ensuring a whole team approach to people-centred research."

"There is an increasing number of organisational barriers to undertaking large, multicentre research."

"Less reliance on the 'red tape' of research delivery which stifles innovation and makes it harder to include people outside normal channels."

Recommendation

Make it easier to do people-centred research and provide leadership.

To make it easier to do people-centred research and provide the leadership needed we must ensure that:

- there is strong support and leadership to drive people-centred research
- any unnecessary administrative or governance barriers to doing research in people-centred ways are removed

Barriers for research teams

We identified the following barriers to doing this:

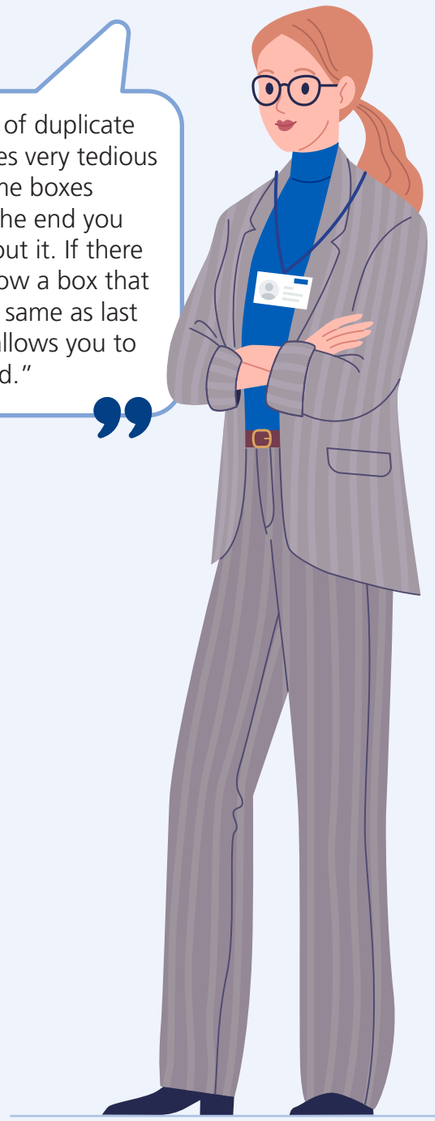
- concern and nervousness about legal compliance, risk and reputation
- metrics that drive action away from people-centred outcomes
- systems are focussed on evidencing compliance

What people told us

"I think there is a lot of fear caused by the systems and approvals process - people want to do a good job and worry about doing things wrong."

"Cutting down the time it takes to get good research through funding and implementation."

"Reduce the amount of duplicate paperwork, it becomes very tedious having to tick the same boxes week after week, in the end you just stop thinking about it. If there is monitoring, just allow a box that says everything is the same as last time and a box that allows you to put what has changed."



Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ support confidence and competence particularly around information governance for people-centred research approaches. This includes ways to engage and communicate, approaches to consent, data collection and data sharing
- ✓ support a research leadership model that is grounded in collaborative teams to drive people-centred approaches
- ✓ reduce bureaucracy and duplicate paperwork for doing research and for evidencing compliance wherever possible

Ethics processes

Barriers for people

Traditional models of research (or research that is not people-focused) are submitted to research ethics committees and approved. Issues specific to people in research cannot be known by ethics committees. Public involvement in research is not ensured.

What people told us

"RECs need to ensure that the public involvement in trial design, endpoint selection and wording in documents has been appropriate and this needs to be spelt out in applications."

"A major way to shift thinking on people-centred research is to see both participants and public contributors as 'citizen ethicists'. In other words, start to value the wisdom of ordinary people in making the ongoing ethical judgements that should shape every step of the research."

"Getting ethical approval for a study doesn't necessarily make it ethical, because often ethics committee members aren't specialists in the disease being studied. I think there needs to be some mechanism to ensure that ethics applications are reviewed by trusted patient representatives to ensure that ethical issues which may be overlooked by non-specialists or non-patients can be raised and addressed before a study is approved."

"Please adjust and tailor ethical processes and procedures to promote inclusion in research."

Recommendation

Support people-centred approaches through the ethics process.

To do this we must ensure that:

- researchers and those supporting research design are signposted to the UK Public Involvement Standards
- expectations of early involvement of people in the design of the research is highlighted
- researchers are aware that people-centred approaches and inclusion are a consideration of the research ethics review process. Diversity of participants is considered in relation to the study aims, within the context of the disease or condition being researched
- good public involvement occurs, supported by the ethics review process, where Research Ethics Committees can challenge shortcomings when they review the study as part of the approvals process (which occurs later down the line)
- researchers are encouraged to provide more detail in planning their studies to evidence that people-centred approaches have been undertaken and adhered to. This might include for example, participant experience or feedback. This could be reported on in the annual reports that are provided to the Research Ethics Committees

What people told us

"Ethical approval systems for communications can prevent sensible communication with participants."

Barriers for research teams

We identified the following barriers to doing this:

- researchers are concerned that the research ethics process won't support their people-centred approaches

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ work with research ethics committees and research applicants to support and promote people-centred approaches
- ✓ work to improve the diversity of ethics committee members and promote recruitment of diverse public involvement in research
- ✓ work to remove unnecessary concerns about people-centred approaches and ethical opinion. Identify the areas of uncertainty and provide guidance
- ✓ provide more samples and examples for researchers to understand what good people-centred approaches look like
- ✓ support researchers and sponsors to develop mechanisms to monitor participant experience in a study
- ✓ support ethics committees to promote people-centred approaches and to balance protection against unethical research with promotion of research opportunities

Training development and skills

Barriers for people

Training for research follows an academic or research-centric model. It is not always people-focussed. Few examples of good practice are shared. There can be insufficient researcher training on how to include the public in their work or to be a co-applicant.

What people told us

"Patient-centred medicine is still quite a new idea, so it would be surprising if most researchers were adequately trained, capable, keen, confident about doing 'people-centred' research, or that research systems were designed from 'people' outwards."

"People working in research should receive training delivered by communities. Staff have been through a lot of training to be clinical and efficient which may create barriers in engaging with people. Help staff to connect to their own lived experience."

Recommendation

Include people-centredness in training and skills development, and provide training and development.

To do this we must ensure that:

- share examples of good practice and support for innovative delivery judged by participants and not just the research community
- build people-centred approaches, public involvement and research delivery methods into current research training and curriculum
- ensure there is training for all people involved in research including public contributors and non-research staff
- disrupt traditional thinking around how clinical research happens so that the focus is on people and teams

Barriers for research teams

We identified the following barriers to doing this:

- researcher training misses out people-centredness. It can be focussed mainly on research methods

What people told us

"Research methods training is not people-centred, it's too technical and lacks the human aspects that it needs."

Suggestions

We suggest the following steps to remove barriers for research teams:

- ✓ improve researcher confidence, competence and understanding of people-centred approaches
- ✓ embed training into career pathways and early or trainee researcher courses
- ✓ improve researcher knowledge of different groups of people and how they might be affected by research. Particularly those who are currently underserved by research now
- ✓ support different people and communities to deliver training to researchers

Funding and resources

Barriers for people and researchers

Research is under-resourced for people-centred approaches. Funding for public involvement is limited.

What people told us

"Especially in the non-commercial research area - funding, resources and timelines are so tight that there is insufficient resource to support comprehensive participant engagement at all stages."

"Timing and having dedicated funds for grant development allowing more thorough public involvement earlier in the design process."

"My focus is children and young people and their families. This provision needs to be properly resourced with trained staff and ample time - things take longer with children and families."

Recommendation

Fund people-centred approaches and infrastructure.

To fund people-centred approaches and infrastructure we must ensure that:

- people-centred approaches are supported with infrastructure and the mechanisms to do them well
- both commercial and non-commercial funders properly fund research to be people-centred. This includes funding for engagement, inclusion, communication, recognition and time
- both commercial and non-commercial funders and research organisations properly fund public involvement for research
- the time and capacity for community relationships and research team building is properly resourced
- funding is flexible to allow for changes that come with co-creating research

Appendix A:
Steering group members

The People-Centred Clinical Research project was steered by eight members of the public and eight members of the research community who worked alongside a small project team from the HRA and the University of Lincoln.

The group was co-chaired by Ruby Bhatti, OBE (public contributor) and Sarah Williams (research community).

The University of Lincoln project team conducted the literature review, provided project design support and oversight, conducted the data analysis, contributed to the presentation of the data and the hallmarks and co-wrote the report.

Steering group members

- **Aminul Islam** (public contributor)
- **Anne W Ongley** (public contributor)
- **Catherine Pointer** (public contributor)
- **Chris Ward** (South London Clinical Research Network)
- **Dolapo Ogunleye** (public contributor)
- **Emma Collins** (Wye Valley NHS Trust)
- **Lucy Campbell** (King's College London)
- **Matthew Burns** (Liverpool Clinical Trials Centre)
- **Michael Molete** (public contributor)
- **PS** (public contributor)
- **Rubina Reza** (Derbyshire Healthcare NHS Foundation Trust)
- **Ruby Bhatti OBE** (public contributor and co-chair)
- **Sarah Markham** (public contributor)
- **Sarah Williams** (Solent NHS Trust and co-chair)
- **Julie Bayley** (University of Lincoln)
- **Hannah Henderson** (University of Lincoln)

University of Lincoln project team

- **Julie Bayley**
- **Georgia Clay** (qualitative data analysis support)
- **Hannah Henderson**

HRA project team

- **Kate Greenwood**
- **Eve Hart**
- **Janet Messer**
- **Barbara Molony-Oates**
- **Becky Purvis**
- **Ben Solly**

With thanks to Kat Evans, Jane Martin and Nikki Watts.

Appendix B:
Survey barrier questions

Respondents were asked about barriers to people-centred research, including their own negative experiences.

This was asked in two ways:

Ticking 'all that apply' to lists of barriers for people and researchers:

14. Which of the following if any do you think are the main barriers to people taking part in research? Please tick all that apply

- ☐ Patient or public knowledge about taking part
- ☐ Patient or public willingness to take part
- ☐ Patient or public ability to being involved or taking part in the study
- ☐ The way the research is designed
- ☐ Lack of research availability
- ☐ Not sure
- ☐ Other

Please explain and provide comments:

15. Which of the following, if any, do you think are the main barriers to researchers doing good people-centred research and including people? Please tick all that apply

- ☐ Research team knowledge about how to do it
- ☐ Research team motivation to do it
- ☐ Research team skills to do it
- ☐ Research team nervousness about doing it/doing it correctly
- ☐ Research team capacity to do it
- ☐ Blockages caused by the system or research processes
- ☐ Resources
- ☐ Not sure
- ☐ Other

Please explain and provide comments:

By offering, via open comments, barriers and poor experiences of research:

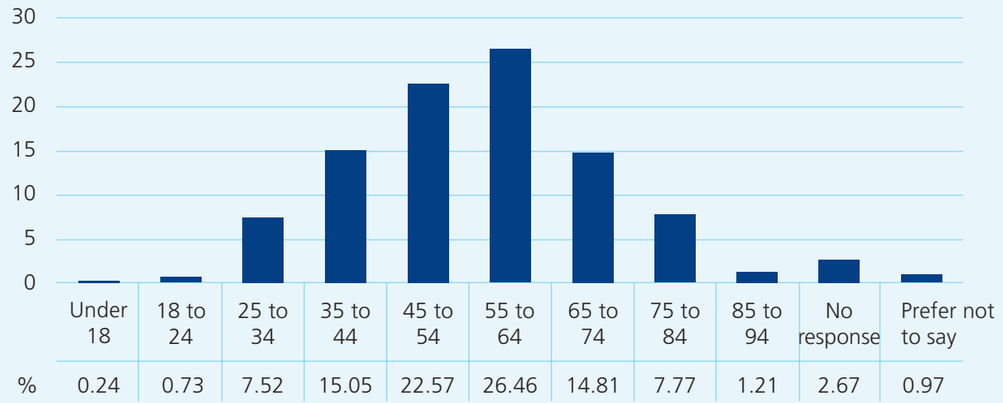
> Please give any negative experiences (big or small) you have had in clinical research, in relation to the way people were included. What made the research feel not people-centred? How did you feel people weren't at the centre of the research?

Appendix C: Demographic data

Pie and bar charts summarising survey respondent demographics (percentages):

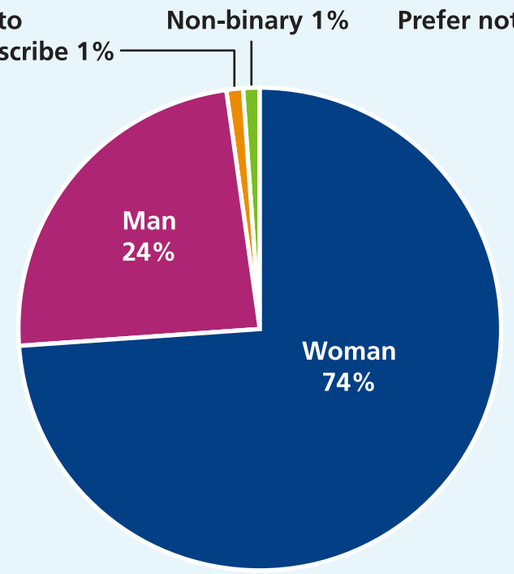
1. Age
2. Gender
3. Ethnicity
4. Employment
5. Religion
6. Disability
7. Daily barriers
8. Sexuality
9. Trans
10. Caring responsibilities
11. Experience of research
12. Survey format (choice and choice by age)

1. Age

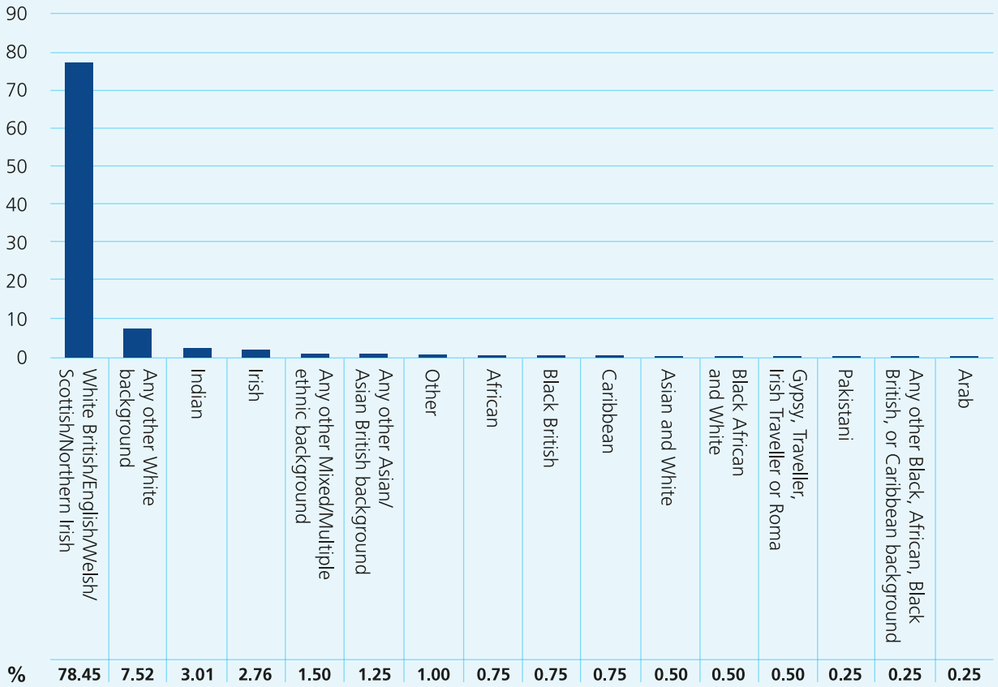


	Under 18	18 to 24	25 to 34	35 to 44	45 to 54	55 to 64	65 to 74	75 to 84	85 to 94	No response	Prefer not to say
%	0.24	0.73	7.52	15.05	22.57	26.46	14.81	7.77	1.21	2.67	0.97

2. Gender

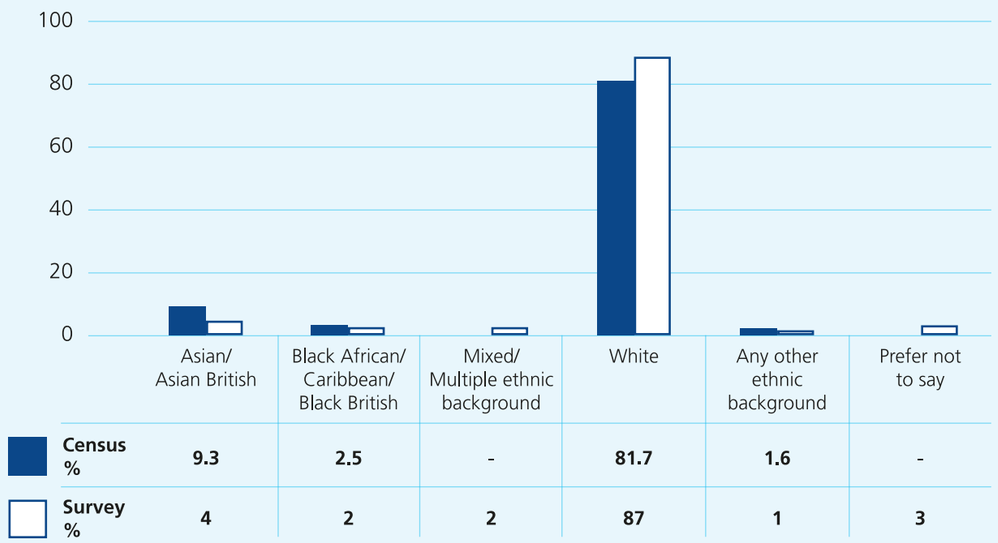


3. Ethnicity



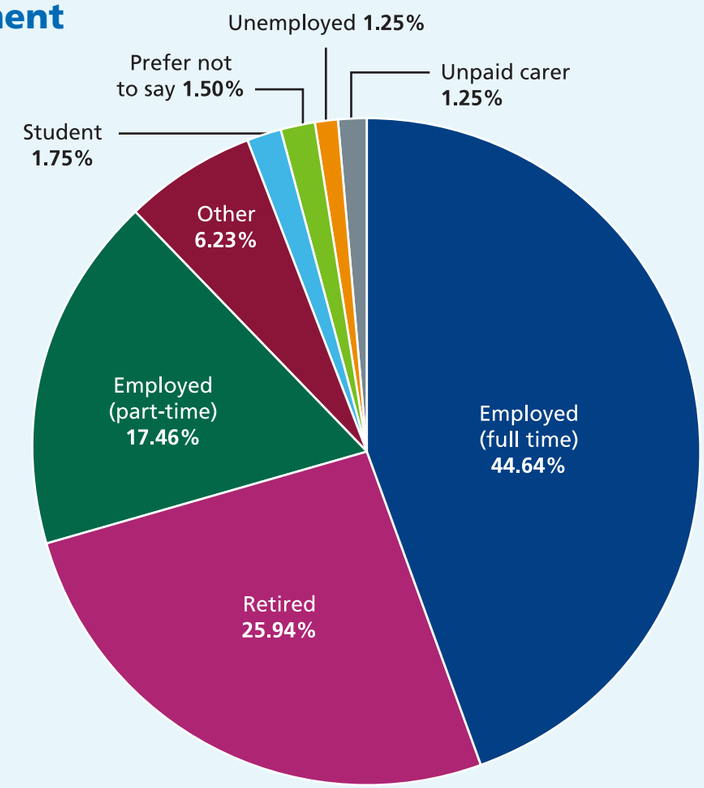
	White British/English/Welsh/ Scottish/Northern Irish	Any other White background	Indian	Irish	Any other Mixed/Multiple ethnic background	Any other Asian/ Asian British background	Other	African	Black British	Caribbean	Asian and White	Black African and White	Gypsy, Traveller, Irish Traveller or Roma	Pakistani	Any other Black, African, Black British, or Caribbean background	Arab
%	78.45	7.52	3.01	2.76	1.50	1.25	1.00	0.75	0.75	0.75	0.50	0.50	0.50	0.25	0.25	0.25

Comparison with Census for England and Wales (2021)

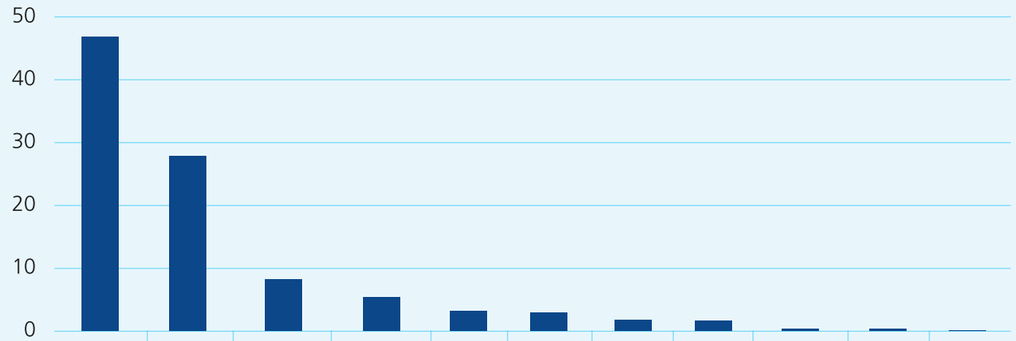


	Asian/ Asian British	Black African/ Caribbean/ Black British	Mixed/ Multiple ethnic background	White	Any other ethnic background	Prefer not to say
Census %	9.3	2.5	-	81.7	1.6	-
Survey %	4	2	2	87	1	3

4. Employment

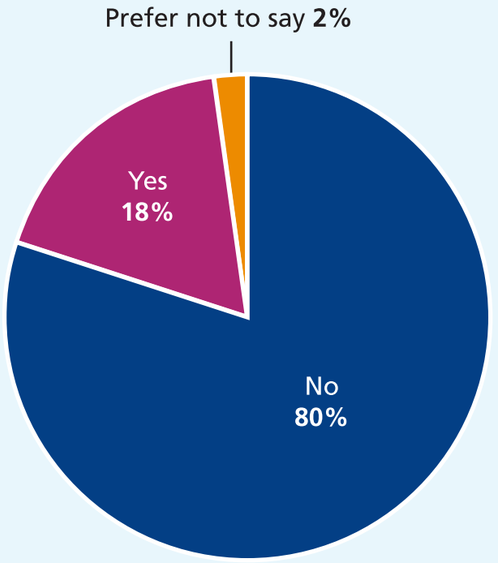


5. Religion

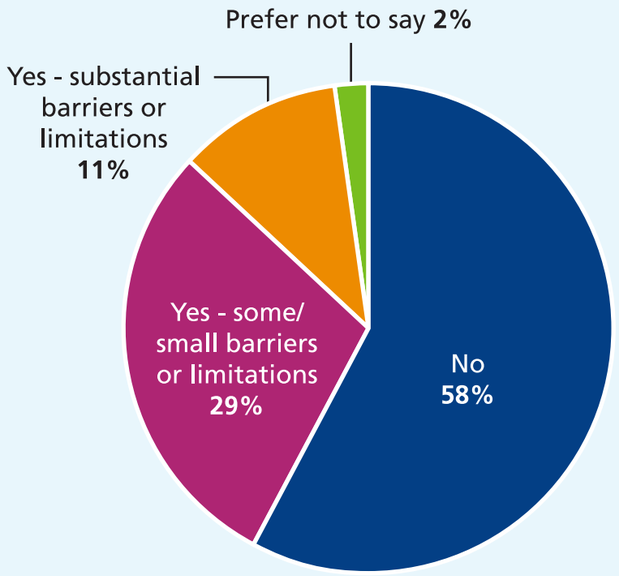


	Christian	No religion	Agnostic	Prefer not to say	Other	Spiritual	Hindu	Muslim	Buddhist	Jewish	Sikh
%	46.84	27.85	8.35	5.57	3.29	3.04	2.03	1.77	0.51	0.51	0.25

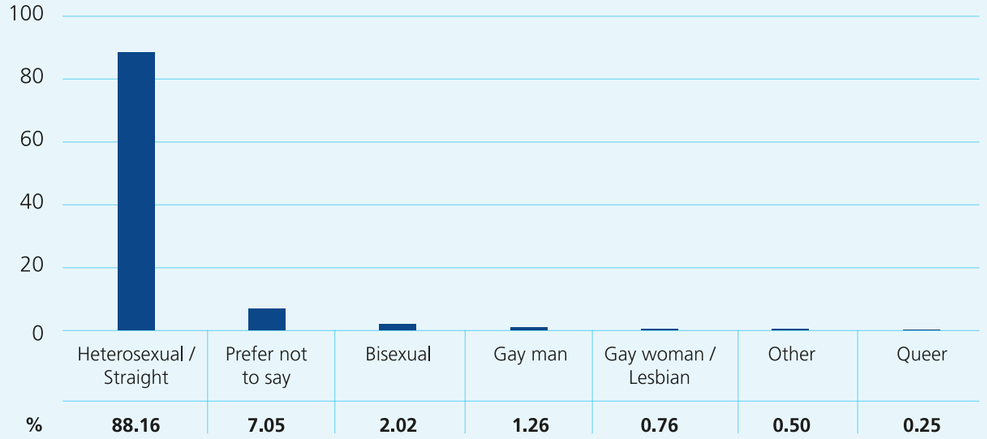
6. Disability



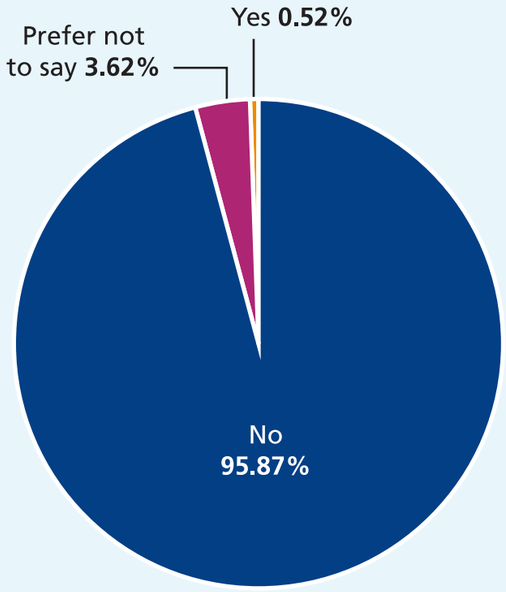
7. Daily barriers



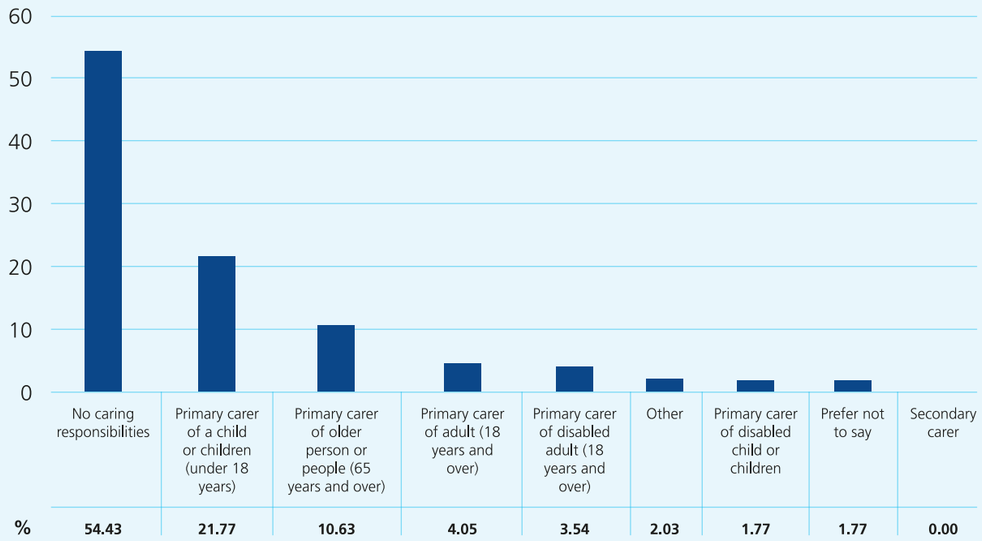
8. Sexuality



9. Trans

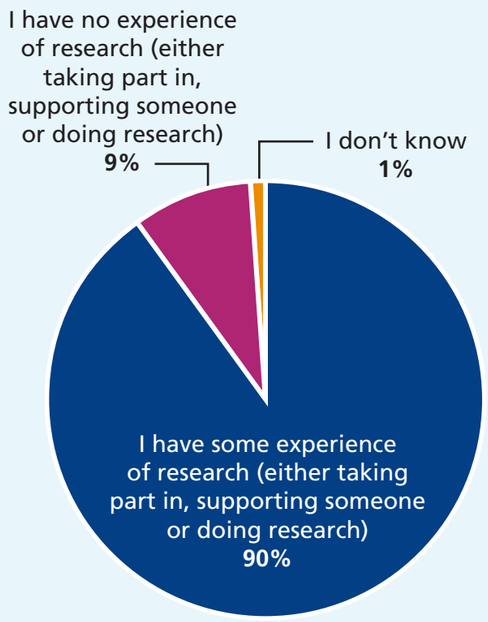


10. Caring responsibilities

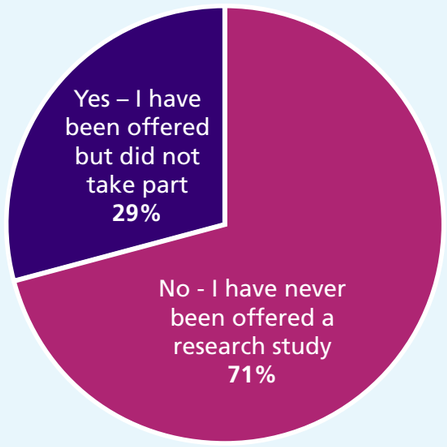


	No caring responsibilities	Primary carer of a child or children (under 18 years)	Primary carer of older person or people (65 years and over)	Primary carer of adult (18 years and over)	Primary carer of disabled adult (18 years and over)	Other	Primary carer of disabled child or children	Prefer not to say	Secondary carer
%	54.43	21.77	10.63	4.05	3.54	2.03	1.77	1.77	0.00

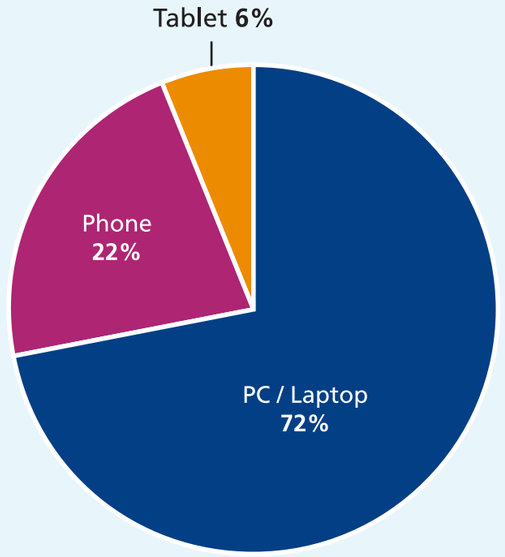
11. Respondents previous experience with research



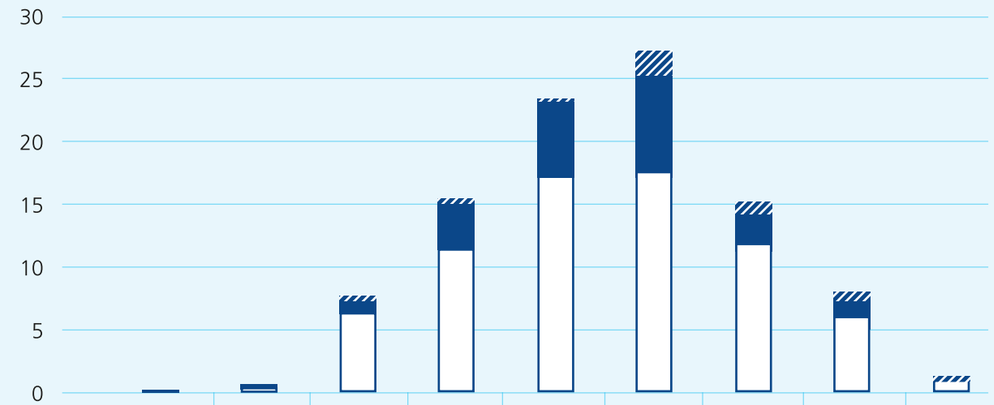
Of those who had no experience of research, how many had been offered the chance?



12. Survey format (choice and choice by age)



How did survey response format vary by age?



	Under 18	18 to 24	25 to 34	35 to 44	45 to 54	55 to 64	65 to 74	75 to 84	85 to 94
Tablet %	0.00	0.00	0.50	0.50	0.25	2.27	1.01	0.76	0.25
Phone %	0.25	0.50	1.01	3.78	6.05	7.56	2.52	1.26	0.00
PC/Laptop %	0.00	0.25	6.30	11.34	17.13	17.63	11.84	6.05	1.01

If you would like to share any feedback on the People-Centred Clinical Research project or anything in this report we would love to hear from you.

We would especially like to hear about any use of the hallmarks, solutions or improvements in people-centred research practice.

Please send any comments to **communications@hra.nhs.uk**

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