

Democratising patient and public involvement – A case study from the RELAX (Reducing Levels of AnXxiety) randomised clinical trial

Mary Newburn

`mary.1.newburn@kcl.ac.uk`

King's College London

Brittannia Volkmer

King's College London

Nathalie Towner

King's College London

Yogini Sawjani

King's College London

Tannice Hemming

King's College London

Siobhean McCarthy-Perham

King's College London

Abigail Mensah

King's College London

Victoria Ferreira

King's College London

RELAX Public Involvement Writing Group

King's College London

Colette Hirsch

King's College London

Research Article

Keywords: Patient and public involvement (PPI), impact of PPI, GRIPP2, collaboration, PPI lead, realist research

Posted Date: October 22nd, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-11191943/v1>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License. [Read Full License](#)

Additional Declarations: Competing interest reported. MN, the PPI lead, was anticipating a paid consultancy role when a PPI co-applicant. As PPI lead she was paid up to 0.2 WTE. CH has received financial support from National Institute for Health Research Maudsley Biomedical Research Centre; received accommodation costs and honoraria for speaking at conferences and research funding for related research in other populations from Wellcome Trust, MQ Mental Health Research, National Institute for Health Research, Parkinsons' UK. Other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Abstract

Background: Perinatal anxiety is a public health concern, affecting over one fifth of women during a vulnerable life stage. The RELAX randomised clinical trial tested a psychological training designed to prevent escalating anxiety. This paper describes and appraises the patient and public involvement (PPI).

Objective: PPI aims were to: 1) make the trial relevant and acceptable for participants; 2) reduce barriers to engagement among those often underrepresented in research, including Black and Asian women; 3) assist recruitment; and 4) develop and promote PPI good practice.

Methods: We used co-production values, and Guidance for Reporting Involvement of Patients and the Public (GRIPP2-SF) for planning the PPI. We carried out a PPI reflections survey with open and closed questions and drew on research records. Reflexive thematic analysis was used to analyse PPI advisers' reflections. We adopted a realist research perspective, describing the PPI context and processes, reporting PPI outcomes and considering what worked for whom, and why.

Results: Key PPI themes were: (1) feeling valued, gaining confidence; (2) achieving something good from bad experiences; (3) making a difference to the study; (4) supporting equity and inclusivity; and (5) being part of a community. PPI began with extensive consultation (7 meetings). A large, diverse PPI advisory group was active throughout the study (14 meetings, mean attendance: 11 PPI advisers). Innovations: focus on diversity and inclusion; employment of a service-user researcher to facilitate public involvement; a WhatsApp group for communication and support; researchers' responsiveness to PPI ideas, publicity contributions, co-analysis and co-authorship. Limitations: limited PPI input into study methodology; PPI wish for training to be accessed via smartphone was not permitted, and some advisers felt shy in online meetings. PPI enhanced trial recruitment; ethnic diversity and high retention.

Conclusions: PPI contributed to research quality in this trial and empowered PPI advisers. During the study PPI became increasingly democratised, moving from *consultation*, to *collaboration*, and some *co-production* as a result of principal investigator support for PPI; an experienced service-user researcher to lead and promote PPI good practice; and RELAX researchers' flexible responsiveness. A focus on equity and diversity, and relationship-building innovations contributed to overall success.

Plain English summary:

One in five pregnant women experience anxiety disorders during pregnancy and many more distressing anxiety symptoms. The RELAX study aimed to help pregnant women and birthing people have less anxiety. Researchers asked a diverse group of parents with experience of anxiety in pregnancy to help them design and carry out the study. This is called public involvement (PPI).

Researchers and PPI advisers worked together to make the RELAX website and training relevant and accessible. We checked the language was easy to understand and made videos about the study. Public advisers shared information on social media and locally to help with recruitment. This case study is a positive example of PPI in a trial, with useful learning points.

Good practice: a large, diverse public involvement advisory group, advisers always paid for their time, childcare and travel costs, and continuous support.

Innovations: diversity and inclusion; employment of a service-user researcher to facilitate public involvement and advise on good practice; use of WhatsApp for team-building and support; researcher responsiveness to demand for frequent advisory group meetings; and involvement of public advisors in analysis and authorship. Progression during the study from consultation, through collaboration to co-production.

Limitations: limited in-depth involvement prior to funding, advisers' wish for training to be accessed via smartphones was not permitted, and some advisers felt shy to speak in meetings.

Impact: Evaluating public involvement creates useful learning. Advisers felt respected and valued; research quality and learning about co-production increased. The training will soon be offered on a new smartphone app.

Background

Public involvement in RELAX

More than one in five pregnant women and new mothers in the UK experience an anxiety disorder (1), and many more have symptoms of anxiety and worry that impact their day-to-day lives (2). It is therefore a significant public health concern and affects many women and families at a vulnerable and pivotal stage in their lives. Clinical psychologists have developed interventions using cognitive-bias modification for interpretation (CBM-I) to train individuals with clinical anxiety to interpret uncertain or ambiguous information in more positive ways, to reduce anxiety (3–5). The RELAX (Reducing Levels of AnXxiety) randomised clinical trial (RCT) used this approach aiming to reduce repetitive negative thinking (RNT) and prevent escalating anxiety during pregnancy and after birth (6). Patient and Public Involvement (PPI) was part of the RELAX study from the funding application stage. We seek to add to the PPI literature by reporting how PPI was carried out in RELAX, the difference that it made to the study, and the impact for PPI advisers and researchers, using a structured reporting framework created to improve PPI reporting (7).

PPI in research

PPI in healthcare research is promoted and practised in many countries (8, 9), and in the United Kingdom (UK) there is broad institutional support (10). PPI can be seen as a democratic right, associated with the phrase ‘nothing about us, without us’ (11). Another rationale for PPI is the potential to improve the relevance, accessibility and overall quality of research. Despite positive developments, PPI is often poorly reported or absent from clinical journal articles (12, 13).

The National Institute for Health and Care Research (NIHR) defines PPI as the need for research carried out ‘with’ or ‘by’ patients or members of the public, rather than ‘to’, ‘about’ or ‘for’ them (14) and emphasises the importance of partnerships that are diverse, inclusive and impactful (15). In the RELAX study PPI included individuals with lived experience of worry and anxiety during pregnancy, and representatives from community groups, networks, maternity and neonatal voices partnerships (MNVPs) and maternity and perinatal mental health charities. UK Standards for Public Involvement provide a clear framework of expectations on inclusive opportunities, which include removing barriers to involving under-served communities (16, 17).

PPI aims were to: 1) make the RELAX trial relevant and acceptable for participants; 2) reduce barriers to engagement among those often underrepresented in research, including Black and Asian women; 3) assist recruitment; and 4) develop and promote good public involvement practice.

In this paper we refer to RELAX ‘PPI advisers’, emphasising that lived-experience and public expertise was sought, and as recognition of status (18).

Methods

Design

Initially, the RELAX PPI plan was created by the PI (CH) and the PPI lead (MN), a service-user researcher, using Guidance for Reporting Involvement of Patients and the Public, Version 2, in its short form (GRIPP2-SF) (7). The plan was informed by co-production values (19, 20) and aimed to support equity, diversity and inclusion (EDI), overcome barriers to involvement, and ensure reciprocity and fairness.

The results section is structured to address how PPI worked, in what circumstances, for whom, and why (21, 22). These realist research questions, are widely used when evaluating complex social interventions and considering what factors enable positive outcomes to happen (23–25). The approach identifies specific circumstances (context), and the ‘spark’ (mechanism) that enables a desired outcome to come about (22).

We report the findings from the PPI advisers' reflections survey to highlight their perceptions and views, and draw on research records (e.g., meeting agendas and minutes) and RELAX research and PPI outputs (26–29) in reporting how PPI worked.

PPI reflections survey

The PPI advisers' reflections survey was designed with input from PPI advisers and researchers on what they considered important. The online questionnaire, hosted on Qualtrics, contained open-ended (i.e., free-text, written responses) and closed (i.e., pre-defined options) questions. A link was distributed by email to all PPI advisers, four months before the end of the study, with a consent form. A separate, optional, socio-demographic questionnaire was used to protect anonymity and confidentiality. The survey remained open for six weeks and two emailed reminders were sent.

The free-text responses to the reflections survey were analysed by MN, using reflexive thematic analysis (30–32). The codes and themes were reviewed and commented on by NT to enable an additional reading of the data, and shared, reflexive, understandings (31, 32). First the responses were read and re-read, each response was coded, codes were revised and adjusted iteratively, then a smaller number of themes were created to best represent the story of the experiences and views expressed.

GRIPP2-SF

The GRIPP2-SF was completed by MN drawing on research records, meeting minutes, impact meetings, and discussed and revised with researchers and PPI advisers (Supplementary materials 1 – GRIPP2 checklist). The PPI lead also conducted semi-structured PPI reflections interviews with seven RELAX researchers, reported separately (Newburn, submitted 2026).

Results

The findings of PPI in RELAX are reported in four sub-sections: (1) how PPI worked – providing an overview of the specific circumstances, what happened when, the structures, values, degree of power-sharing and support provided; (2) results of the reflections survey; (3) for whom did PPI work? and (4) Asking why PPI worked? – considering the *context*, *outcomes* and possible *mechanism*?

1. How PPI worked

Good practice and PPI innovations

The PPI began early, while the research idea was being developed, including the service-user researcher being recruited as a co-applicant, and as PPI lead subject to funding. The following points map out the *context* of PPI in the study, and some potential *mechanisms*.

1. The PI (CH) held multiple engagement meetings to consult with women/people with lived experience of anxiety during pregnancy. She introduced the planned study and asked for feedback at her local Maternity Voices Partnership (MVP); Parent Action, a support project for parents of young children, and an Applied Research Collaboration (ARC) maternity PPI network (asking questions such as 'Would people be interested in taking the training?' 'When would be a good time to offer it?'). Once the study commenced, two online PPI workshops were hosted on Zoom, recruited via social media, and a face-to-face community event was held at Parent Action (see Fig. 1).
1. There was considerable public support for the study. The interest expressed by those with lived experience of perinatal anxiety and MNVP members can be summarised as: what non-stigmatising support can be made available for the many pregnant women/people experiencing upsetting worries and anxiety who are currently below the threshold for access to an NHS service? They wished to see a change in services and welcomed research largely as a means to an end.
2. Three individuals with lived experience of perinatal anxiety joined the Trial Steering Committee.
3. A diverse, lived-experience, Patient and Public Involvement and Engagement Advisory Group (PPIE-AG) was established drawing members from attendees of the earlier meetings, MNVP leads from the southeast, northwest, southwest of England and a senior officer of a maternity charity. From eight PPI advisers initially, PPIE-AG membership was extended to 19 (three

Asian/British Asian/Other Asian, seven Black/African/Caribbean/Black British, and nine White people). These were: mothers, a birthing parent who was transitioning from female to male, and a father who supported dads on perinatal mental health matters. The founder of The Motherhood Group lent support but could not attend regular meetings. Around two-thirds of those active at the start continued to the end of the study, over 3.5 years later.

4. The researchers were committed to PPI; the clinical trial coordinator (CTC), the PI and research assistant (RA) all attended PPIE-AG meetings, planning the agendas with the PPI lead, who chaired and facilitated meetings.
5. There were many online contact hours. Altogether, 28 PPI meetings were held: 14 PPIE-AG meetings (13 online and, finally, a face-to-face results sharing workshop/celebration), plus 14 sub-group meetings for specific research purposes (see Supplementary materials 2).
6. PPIE-AG attendance was consistently high. Peak PPI attendance (n = 17 PPI advisers) was at an open advisory group meeting (October 2024) when support for recruitment was needed; mean PPI attendance was n = 11.
7. The PPI meeting payment (£75), covered paid time for preparation and actions afterwards (33), and was administered so that making claims inconvenienced people as little as possible. All necessary childcare and travel costs were also funded.
8. A PPI WhatsApp group was created in March 2022 to develop relationships, provide informal support, build a sense of community and facilitate communication between meetings. Initially, 17 advisers volunteered to join, consenting to share their mobile phone number. A review in July 2025, showed that 10 were active on the group within the previous month, reflecting its popularity and the extent of continuing engagement. PPI advisers shared information and mutually supported each other by this means, as well as receiving support from the PPI lead. Further support was also offered one-to-one, and via 30-minute 'stay-on-and-chat' sessions with the PPI lead after PPIE-AG meetings.
9. PPI training was offered and signposted, with expenses and PPI time paid.
10. Researchers demonstrated flexible responsiveness – manifested in many ways, such as frequency of PPIE-AG meetings which were doubled in response to demand, recruitment of new PPIE-AG advisers to extend diversity, PPI in-pot becoming central to the communications plan, and commitment to creating connections with additional relevant networks and voluntary organisations in ways that they could accommodate.
11. Five e-newsletters were produced to update, motivate and acknowledge PI advisers and the study's voluntary sector supporters (e.g. celebrating the start of recruitment, requesting social media re-tweets, and profiling advisers' independent community work, information and support achievements and wider interests). Each edition contained a profile of one or two PPI advisers who had been especially active on behalf of the study in recent weeks, including information about their other community and social media work, as relevant.

The public were *consulted* from the start of the study and increasingly had opportunities for *collaboration* as relationships were formed, the study's PPI culture developed, and advisers gained confidence to express their views and preferences (see Fig. 1).

Limitations

Although there was a great deal of initial engagement work, introducing the proposed study to many interested parties and community groups, there was no in-depth collaboration about the trial methodology, the outcome measures, or power-sharing *per se* at the outset. The PPI lead reflects that it did not feel easy to create space and time for reflective discussion about PPI methodology at research team meetings as the trial protocol, statistical analysis plan, ethics and medical device approvals, website creation and scenario development took up considerable researcher time. MN's PPI reflections log entry for February 2022 reads:

[It has been] decided that MN and BV will meet F2F monthly to facilitate closer, clearer communication. Had a good, safe-feeling chat about what is working well or not so well. (MN had been feeling a bit sidelined; left out of key discussions and updates. It's quite difficult in the time available to keep on top of everything.)

1. PPI advisers' perceptions and views – results of the PPI reflections survey

Around half (11/19) of those who had been a PPI adviser at some stage responded to the reflections survey, with eight answering most of the questions about their PPI experiences, motivations and reflections. Ten provided socio-demographic information. All were female and aged between 25 and 49 years old (see Table 1). There was considerable diversity: three were Asian/Asian British, one

Table 1
Socio-demographic characteristics of patient and public Involvement advisors

Sex	<i>n</i>	%
Female	10	100
Age		
25–29	1	10
30–34	3	30
35–39	3	30
40–44	2	20
45–49	1	10
Ethnicity		
White British	4	40
White Other	2	20
Asian/Asian British – Indian, Bangladeshi, Kazakhstani	3	30
Black/ Black British - African	1	10
Religion		
No religion	4	40
Atheist	1	10
Christian	3	30
Muslim	1	10
Sikh	1	10
Age at leaving full-time education		
16 or younger	0	0
18 or younger	1	10
Over 18	9	90
Number of Children		
0	0	0
1	1	10
2	5	50
3	4	40
Years of public involvement in research before RELAX		
None	7	70
0–4 years	3	30

was Black/Black British and six were White/White British. Half were not religious, others were Christian, Muslim and Sikh. Most left full-time education over the age of 18 years and had two or three children (several being born during the study). Two-thirds had no

experience of PPI in research before RELAX (see Table 1). A large percentage had personal experience of anxiety before or after birth and also other experience, such as social contacts with perinatal anxiety (see Table 2).

Table 2
Experience of perinatal anxiety (n = 9)

Experience of anxiety...	n	%
...during pregnancy		
Personal experience	9	100
Other experience	7	78
No experience	0	0
...during the first year after birth		
Personal experience	9	100
Other experience	8	89
No experience	0	0
<i>Note: Responses were permitted for both personal experience and other experience, or no experience, for both questions</i>		

Themes

Five themes were created when the qualitative responses to open questions were analysed (32), articulating why and in what ways RELAX public involvement worked for the PPI advisers. There was a sense of (1) feeling valued, gaining confidence; (2) achieving something good from bad experiences; (3) making a difference to the study; (4) supporting equity and inclusivity; and (5) being part of a community. Responses to the closed questions are consistent with findings from the free-text reflections and are reported under relevant themes. Finally, PPI advisers provided their insights into the impact of PPI and things that they felt could have been improved. All quotes, in italics, are from the survey, with respondent numbers in brackets, PPI3-PPI13, unless otherwise stated.

- Feeling valued, gaining confidence

Respondents described what they had ‘enjoyed the most’ about their involvement in the study, they also commented on whether there were ‘any aspects of the PPI role that they hadn’t expected’. Free text reflections suggested that PPI advisers felt valued and respected as individuals and in their PPI role. They had opportunities to learn, take training, and actively contribute to design of the website, creation of scenarios, and social media content.

I didn’t expect that we would be treated as equal team members, with such a respect and care. It was clear that the RELAX team genuinely valued our input and opinions, and our voices truly shaped the direction of the project/work. ... [I] felt truly comfortable and welcome. Their kindness, professionalism and encouragement created a very positive and supportive environment. ... [It] inspired me to stay engaged. (PPI12)

[I didn’t know] how seriously we would be taken. This was better than expected. (PPI10)

Five of eight PPI advisers responding to a question on training needs, said they had not needed any training, but most were aware that training was available.

There were multiple opportunities given for training for research methods etc, if I wished to go on them (PPI5)

Once the study was established, opportunities for active collaboration were discussed regularly at PPIE-AG meetings. Two PPI advisers were invited to take part in framework analysis of responses to a nested telephone survey of RELAX training acceptability. Both experienced this positively, gaining important new skills (Volkmer et al, submitted). One commented to the PPI lead that they felt valued, trusted to work with confidential study data, and stimulated to think analytically about concepts such as ‘treatment burden’.

The PPI reflections survey asked a closed question about what PPI advisers felt they had gained from their PPI adviser role. The benefits given most weight were gaining confidence and personal satisfaction, having a way to process or make positive use of lived experience of anxiety, opportunities for more research involvement, and gaining new personal relationships and connections. Developing new skills or knowledge was the next most endorsed item regarding what they had gained (see Fig. 2). This is consistent with the theme of feeling valued and gaining confidence.

- Creating something good from bad experiences

Working with researchers on the study enabled public advisers to have a sense of agency by using past, or continuing, difficult personal experiences to produce something constructive for themselves and for the future good of others. They found it rewarding to turn something personal and troubling into a means of change.

Feeling like I'm part of something that might be of help to others who are going through what I went through. I wouldn't wish it [perinatal anxiety] on anyone, and it can be so hard to access help sometimes. (PPI9)

Figure 2: **What do you feel you have gained from involvement in the study? (n = 8)**

It was a great opportunity to share my experience and help improve future services for pregnant people. (PPI12)

The PPI reflections survey also asked advisers to rate the extent to which three pre-defined potential motivators had driven their involvement in PPI for the RELAX study (see Fig. 3). For many there was a lived-experience motivation for taking part, 'to express and make sense of my own experiences' reflecting views expressed frequently at meetings about the need for a service to meet the needs of people in pregnancy whose low-moderate level of worry and anxiety was not currently catered for, including those below the threshold for referral to mental health services.

Everyone was offered the opportunity to try the training method for themselves. The more PPI advisers discovered about the CBM-I approach, the more committed they became.

I didn't expect to benefit personally in terms of my anxiety in the way that I have done - I trialled the scenarios as part of the testing process before [the RCT] launched, and just looking through these has helped me to 'reframe' situations and consider how they are affecting me. (PPI6)

[RELAX training] was incredibly helpful for me personally (contributor to PPI impact meeting 2).

So, while the study's main methodology and the type of psychological intervention was chosen by researchers, it was widely endorsed by PPI advisers and was fully consistent with their own priorities and concerns.

Figure 3: **Motivations for patient and public involvement in RELAX (n = 9)**

- Please indicate how much you agree with each of the following statements by picking a number from 0 (not at all) / 1 (only a little) to 5 (a great deal).
- **Research Quality** - I am motivated to be involved in research to contribute to making sure that studies are of the highest quality (e.g. the research is relevant, the methodology is suitable, the study is rigorous and accessible)?
- **Own Experience** - I am motivated to be involved in research to express and make sense of my own experiences?
- **Ethics and Equity** - I am motivated to be involved in research to ensure that particular groups or communities that can be exploited, excluded or discriminated against are included ethically and equitably in research?

- Making a difference to the study

PPI advisers were also motivated to 'contribute to making sure that studies are of the highest quality (e.g. the research is relevant, the methodology is suitable, the study is rigorous and accessible)' (see Fig. 3). PPI advisers felt that they had made a significant difference to the RELAX intervention and the way the trial was conducted.

The amount the researchers took on board from my own experiences and points of view when reading such things as the scenarios and the layout of the platform. (PPI5)

Limit[ing the] time needed for [each online training] session – i.e. not too long. (PPI8)

The RELAX study landing page was made more inviting and easier to navigate, with fewer words, use of plain English, and bullet points.

[The] quality of the resource and application to real life situations. ... [You feel] that you are really making a difference and shaping the study. We are being listened to actively and our advice is taken on board. (PPI10)

PPI advisors collaborated with researchers on the length and content of the pregnancy-related scenarios, asking researchers to 'avoid triggering participants' (PPI6). Overall, it was felt that 'service user experience has been at the heart of all stages [of RELAX]' (PPI6).

- Supporting equity and inclusivity

PPI advisers emphasised the importance of equity and inclusivity in the study, in relation to PPI, the language used in the study, and study participation. They felt that the project took issues of equity and inclusion seriously, that researchers listened well and acted on advice (see Supplementary materials 3).

[I valued] hearing all the different perspectives in the group from different ethnicities. Watching really skilled listening and facilitation from the group leads. ... Awareness of differently educated people, different ethnicities, and different demographics. (PPI3)

[I feel there was] more diverse recruitment [to the study] due to input and support from [the] PPIE group. (PPI12)

As shown in Fig. 3, there was strong support for the survey question on motivations about ensuring 'that particular groups or communities that can be exploited, excluded or discriminated against are included ethically and equitably in research'.

- Being part of a community

A sense was created of the project being a 'community'. This seems to have been to do with responsiveness and authentic relationships. Everyone felt they were appreciated for the contribution they made. There was also a sense of a shared mission: to do everything possible to deliver the research and generate clear evidence which, if results were positive, would help make the case to extend effective services for those suffering anxiety during pregnancy.

The team, the fact everyone valued each other's input and the community [that was] built. (PPI4)

[I enjoyed] the meetings and reconnecting with individuals.... I didn't anticipate for [PPI in the study] to be this long but I am grateful it has. The study has become a part of my household. (PPI13)

Thank you so much for the opportunity to be part of the RELAX family! It's been a truly wonderful and rewarding experience. ... I'm truly proud to have contributed in a small way to something that can make a real difference for generations to come. (PPI12)

The study commitment to PPI reciprocity and being responsive to requests and ideas from everyone, all seem to have contributed. Regular collaboration, relationship-building and PPI-focused communications were highlighted as reasons for the positive impact of PPI in RELAX.

Regular involvement and/or engagement e.g. regular meetings, email and WhatsApp comms and the newsletter (PPI6)

An important element of the PPI work was expression of real regard for each individual, their feelings, strengths and talents. Communication was practised in an empathetic and person-centred way, acknowledging people's life events, their losses, such as illnesses and bereavements, and joyful events such as pregnancies and births.

Their kindness, professionalism and encouragement created a very positive and supportive environment. ... Communication was excellent throughout, and we were always kept up to date with all latest developments and news. (PPI12)

I don't think I could have been made to feel more welcome. Everyone has been so lovely the entire time. It has been incredible. (PPI4)

1. What has made RELAX PPI successful?

These themes are reinforced by responses to a closed question asking 'what do you think has made the public involvement in the study successful?' Eight people selected their top five from a list of 21 phrases generated by MN, plus an 'Other, please explain' option. Of all the listed phrases, 13 were selected by at least one person. The word cloud shows which phrases were selected, and size of letters indicates frequency of selection (see Fig. 4). There was a strong focus on characteristics which are aligned to co-production 'key principles' (20): being listened to and treated with respect, friendly researchers and (the enabling role of) the PPI lead. PPI advisers felt that PPI had improved

Figure 4: **Word cloud – PPI advisers' views on what has made public involvement successful (n = 8)**

the overall quality of the research and highlighted the importance of public involvement from the start. They appreciated the opportunity of meeting new people, a chance to learn, and being paid for their time, demonstrating the importance for them of reciprocity. Other factors which they felt had particularly supported the PPI process were, having online meetings, the PPI WhatsApp group, good admin support and commitment to diversity and inclusion.

PPI impact - what difference did it make?

The survey asked PPI advisers what they felt the impact of PPI had been 'on the way the study has been carried out?' They were provided with a definition: 'an effect or influence on the quality, relevance or ethical considerations in the research'. As positive impact for PPI advisers has been well covered above, points are not rehearsed again here. Suffice to say:

It has given a different perspective to think about, ... We can ask different questions which a researcher may overlook or not consider. (PPI5)

PPI impact - what could have been improved?

The survey asked two questions to encourage feedback about aspects of PPI practice that might be improved. The first, 'Have you had any negative experiences during your involvement?', generated 'no' from all respondents (n = 9). However, further probing, phrased as 'what would have made you feel more welcome or more comfortable?', led to a few suggestions. Two people (PPI5, PPI6) commented that meeting face-to-face early in the project would have been welcomed, but with the caveat of knowing that travelling would be difficult for some individuals. Two different individuals (PPI3, PPI11) explained how they found it difficult to speak during online meetings, or felt others had more knowledge. One suggested more small group work.

'Maybe splitting into small groups sometimes to discuss things. Then I might have had more confidence to speak up. It sometimes felt like all the same voices. And I sometimes felt under confident to speak.' (PPI3)

They also said

'...despite [the group leads] being incredibly kind and inclusive, ...I feel like the group could have tolerated and would have benefitted from a conversation that was more "practical" in its focus and more "analytical / questioning". For me the best contributor was a woman who led a mum's group in Blackpool and when she described just how deprived the context was, I wasn't really convinced that the group leads were fully engaged or responsive to their needs. ... I felt the approaches to research could have been a bit more radical ... and a bit less anodyne / academic'. (PPI3)

This suggests a degree of frustration about conversations not had, research methods not explored collaboratively, and possibly limited knowledge of research methods. Commenting on the first draft, one PPI co-author suggested expanding the limitations discussion, stating, 'experts still lead and drive the project'. This may refer particularly to the initial consultation stage, when the RCT design and the outcome measures were selected by the funder and researchers. So, despite enthusiastic support for the study, and many of the PPI practices, some people made constructive, critical comments on how processes could be further improved.

3.) For whom did PPI work?

A comprehensive assessment of positive PPI impacts: for the research, for PPI advisors, the researchers and the PPI lead has been created (see Supplementary material 2 GRIPP2-SF) and submitted with the main RCT results paper (27). We report these first, then challenges and limitations of PPI, as well as mitigations, and any noted negative effects.

For the research

We identified seven positive impacts of PPI for the research.

1. *Confirming that the research question was important* - The focus of the research was an important priority for those with lived experience of worries and anxiety during pregnancy and organisations working with parents before and after birth.
2. *Improving the design of the study* - Planned features of the RCT were confirmed as appropriate for the intended audience: the CBM-I intervention, and being able to complete the training online, at home, at times of the participant's own choosing. PPI input increased accessibility and acceptability. The study online landing page was made more welcoming and easier to read, using plain English principles.
3. *Improving training scenarios* – Community group discussions and PPI advice helped researchers create pregnancy-related scenarios for the training, reduce the length of scenarios where possible, ensure that all the scenarios were relevant for pregnant women/birthing people, and use clear and sensitive language.
4. *Co-designing marketing and communications* – recruitment videos, testimonials and social media featured ethnically diverse women to support the message of relevance and welcome to groups who are often excluded from research. There was a strong focus on images reflecting 'relatable realism' rather than model-like beauty, and clear, empathetic messaging. PPI advisers created and recorded testimonials about the training and advised on the professional videos created to introduce the study. The intervention was referred to as 'training' to be non-stigmatising, even aspirational. PPI advice on social media usage, resulted in Facebook, Instagram (Meta), and Twitter/X being used.
5. *Aiding rapid recruitment* – After a delayed start for logistical and technical reasons, recruitment of 268 participants occurred over 13 months. This is attributed in part to PPI input into communications planning and marketing, via social media support and display of posters and flyers in local health settings, shops, playgroups etc. PPI advisors (see named contributors below) were innovative in facilitating recruitment. For example, MH took a poster to four supermarkets in two different cities, two community centres, two libraries, a GP surgery, a wellbeing centre, a playgroup, shops, charities, and a church (MH's list). OC and her MNVP hosted an Instagram Live RELAX webinar which received over 700 views. TS and MH encouraged others by posting images of their displayed posters on the RELAX PPI WhatsApp group.
6. *Contributing to high retention rates* – PPI is believed to have contributed to the unusually high retention rates in the trial (93–96% of follow up assessments completed). First, there was a sense that the study was known via social media to have broad community endorsement. Secondly, PPI relationships and activities made researchers feel additionally motivated (Newburn, submitted). Thirdly, PPI advisers successfully advocated for an NIHR-funded extension to allow the usual time for all later-recruited participants to complete the final online assessment, emphasising the importance of equity and how many demands new mothers have on their time.
7. *Facilitating good engagement with the intervention* - For those offered RELAX training, there was very good engagement, with 81% of participants completing a 'full dose', defined as completing at least 10 out of 12 sessions (27). This was partly attributed to PPI input into the training design, including shortening the sessions.

For public advisers

We identified five positive impacts for PPI advisers.

1. *Empowerment and representation* – a diverse group of people advocating from lived-experience and community perspectives, for groups often under-represented in research (women, transgender parents, diverse ethnicities, people who suffer anxiety). They felt empowered to use past struggles with perinatal anxiety as an opportunity for representation and empowerment, feeling that this could improve support services offered in the future.
2. *A sense of agency* – PPI advisers felt listened to, valued and invested in. For example, marketing collateral such as posters, RELAX-branded pens and mugs meant PPI advisers felt part of the team and confident to introduce the study.
3. *Enhanced PPI roles* – Some PPI advisers were invited to have a role involving *doing* research rather than *advising* on design. DP and TS worked with researchers using framework analysis, to code participants' views and experiences of using RELAX training and its acceptability (Volkmer et al, submitted). SM-P and MH spoke about PPI in the study at a conference or online event, creating ideas and opportunities themselves. TH, in particular, helped to shape this paper. These were personal and professional development opportunities.

4. *Experiencing co-production values* – the study's commitment to reciprocal benefits (e.g., funded training, remuneration for PPI time and expenses, development opportunities), EDI, creation of co-design and co-writing opportunities (28, 29), and ensuring acknowledgement and authorship for PPI advisers, were all positive.
5. *An opportunity to lead training on EDI* – the expertise of PPI advisers in issues of EDI was acknowledged when they were invited to lead a university training session for researchers. AM shared her expertise from a Black, London, service-user perspective (see Supplementary materials 3), a Blackpool-based adviser (SM-P) shared insights from an area of high deprivation, and the PPI lead reported from a co-production project to enhance reach and inclusion (34).

For researchers

We identified two impacts as specific to researchers.

1. *A realist PPI view of anxiety and the study intervention* – PPI enabled researchers to develop a close connection with individuals affected by lived experiences of perinatal anxiety. They gained important insights into EDI and processes of PPI in research, and had their study endorsed and supported.
2. *PPI leadership from the independent PPI lead* – the PPI lead advocated for and advised on PPI good practice throughout the study, e.g. co-production values, relationship-building, social and emotional support, researcher feedback to PPI advisers, and clear expectations for co-writing, and co-authorship (35, 36).

For the PPI lead

Being offered the role of PPI lead created had an opportunity to use and develop practical and theoretical PPI learning and writing for publication.

Challenges and limitations of PPI, and mitigations

GRIPP2-SF suggests reporting any negative impacts. We felt a more nuanced approach had a better fit, so have chosen to report challenges and limitations of PPI, and mitigations.

PI advisers wanted participation in the study to be accessible via smartphone, as well as laptops and tablets. This was carefully considered by the researchers but, because the intervention had not been studied using a smartphone app before and it was possible that this might reduce efficacy due to less focus and greater distraction, they decided not to use smartphones. This was disappointing and may have reduced uptake in some social groups as smartphone use is widespread but access to tablets and laptops may be more limited. Had PPI advisers had more in-depth involvement at an early stage, this might possibly have influenced the study's design. Issues of access were discussed openly throughout the study. At a community event with Parent Action – convened to feedback study findings (October 2025) – a strong appetite for access to RELAX via community organisations and smartphones was expressed. The PI is now developing an app that will enable access to RELAX training via smartphone.

Some PI advisers were disappointed that there was no access for non-English speakers. This was listened to actively and sympathetically, so managed well. The challenges of creating ambiguous scenarios accurately in translation were explained by researchers. In addition, plans were shared for a follow-on study using CBM-I training to reduce anxiety in two languages, in a middle-income country, subject to funding.

It proved challenging to involve a range of third sector organisations consistently in the PPIE-AG throughout the study. One charity providing PPI advice had a high turnover of staff, so additional work was needed to introduce the study and the value of their support, and to build relationships. Others approached were unable to provide continuous support for resource reasons. In mitigation, the researchers responded flexibly, working in ways that charities could manage, and were grateful for all support provided. Successful examples include (a) engaging 10 perinatal mental health charities/social networks to use social media to promote recruitment to RELAX, and two held live awareness-raising events; (b) taking a stand at the Motherhood Group' Black Mental Health conference where a RELAX study researcher was shortlisted for a Black maternal health research award; and (c) attending a FiveXMore All-Party Parliamentary Group meeting during Black Maternal Health Awareness Week where RELAX links were shared. These connections created stronger two-way communication, greater understanding of health and inequity, additional support for the study and for research in general. Much of this kind of work is often 'hidden' as unreported (37).

There were no serious challenges or unresolved conflicts between the PPI advisers and researchers, or with the PPI lead, during the study. However, there was a significant underestimation of the time that researchers and the PPI lead would commit to PPI work (negative effects). Time, unplanned at budget setting, was invested in co-developing the marketing and communications messaging, and engaging charities to support recruitment. Additional PPIE-AG meetings, creating newsletters, a PPI blog (28) and report (29), exploring possible peer researcher roles, and the PPI reflections survey, all added considerably to workload.

4.) Asking why PPI worked? What was the mechanism?

Literature suggests that the impact of public involvement in research is 'highly dependent on the specific context and precise nature of the mechanism of involvement' (22). Yet, a common problem in evaluation is that the precise mechanisms of the intervention are not directly observable (25). Being able to identify the 'missing links' that actually make a fundamental difference and bring the greatest benefits (22), would inform learning (38). In PPI, understanding mechanisms could inform strategic developments, and enable better assessment of the costs and benefits of different approaches. In this descriptive case study, we cannot *demonstrate* unequivocally what enabled the involvement to work well, however, we can provide informed insider insights into what seemed to make a difference, which may be helpful in generating hypotheses for future testing.

Possible mechanisms

1) Democratising PPI in research

One suggestion is that the PPI in RELAX trial was successful because of a commitment, which grew as the study progressed, to democratising PPI. We started the study adopting the co-production values of EDI, reciprocity, respect and empathy, and fair rewards. This involved listening with purpose and feeding back to the PPI advisers what had changed as a result of their in-put (39, 40). Gradually over time, there was greater shared decision-making and power sharing (19, 20). Once the study was funded, and as relationships formed, with researchers listening and PPI advisers gaining confidence, processes become increasingly collaborative, and a greater range of co-design and co-production opportunities were created, leading to more inclusive research, with greater reach. Figure 5 is a

Figure 5: **Democratising patient and public involvement (PPI): PPI values, processes and outcomes in RELAX**

graphic representation of the values we agreed and practiced, processes that made a difference, and how this led to positive outcomes. We reflected on the degree of power-sharing that the PPI represented and how it was evolving.

For PPI advisers the process increased a sense of self-efficacy and created social capital (41). Connections sustained over the years of the study could have a lasting impact with communities, resulting in less suspicion, more trust and greater understanding of research. A Black adviser said, *'It's opened new doors for me ... and I can tell people within my community "You won't be taken advantage of"'* (PPI impact meeting). Disrupting power hierarchies is not an easy thing to achieve (42), but it is necessary for a democratic model of PPI to flourish (43). The process requires an awareness of positionality (44), something we also began to explore together, particularly during our later reflections and co-writing work.

1. *Flexible responsiveness*

The researchers and the PPI lead aimed to be flexible and responsive and open to learning and adapting throughout the study. This may have been an important mechanism for success. The PPI in the study was developed substantially, using everyone's skills and ideas, and making the collaboration more rewarding. Being creative and not excessively rules-bound enabled public advisers to feel they had a real stake in the process.

The PPI lead role

The independent PPI lead in RELAX, played a central role in facilitating processes and maintaining relationships over time. It may have been that role, long-experience of advocacy, and/or the co-production values that the PPI lead aimed to weave through the processes and interactions, that were a key mechanism. Co-production values are increasingly recognised as central to the strengthening of public involvement (19, 20, 45, 46).

DISCUSSION

Strengths of PPI in RELAX

This observational evaluation of PPI in an RCT has several noteworthy aspects. The PPI was active throughout the trial and is reported in detail, which is unusual (13, 47, 48). We present a democratic model of PPI, which evolved over time, with researchers demonstrating flexible responsiveness and the PPI lead playing a facilitative role. We consider what is best regarded as *context* and what the possible *mechanisms* of PPI success might be (22, 25).

We achieved our PPI aims to make the trial more relevant and accessible for pregnant women/people; to reduce barriers to engagement among those often underrepresented in research, including Black and Asian women; and assist in recruitment in multiple creative ways.

A commitment to the co-production values of EDI, reciprocity, and nurturing of interpersonal relationships and consistent informal support (48, 49), played a part. Also our large diverse PPIE-AG included people with multiple protected characteristics, who are often under-represented in research: including women of different ethnicities, a trans parent and those experiencing pregnancy and perinatal anxiety (50).

There was a strong commitment to address low-moderate levels of anxiety, which affect large numbers of pregnant women and birthing people who do not meet the threshold for referral to mental health services, and often lack support. PPI advisers, said that interventions should be tailored to make Black and Asian people, and other minoritised parents feel welcomed, and address barriers to access, including lack of cultural relevance. This would help to address the poorer maternal (51) and mental health outcomes of minoritised ethnic groups (52).

There has been considerable public involvement in the analysis and reporting of the research, and authorship of papers (27) (Volkmer et al, submitted). This paper is a collaborative enterprise involving PPI advisers and researchers in co-design of the reflections survey, impact meetings, the analysis and writing, with a service user researcher as first author. PPI co-authors are unusual (37), and non-academic first authors seem rare. Collecting reflections and sociodemographic information from PPI advisers, separately via two independent surveys, enabled much positive and some more critical feedback to be voiced anonymously. All reporting activities have been well supported; 11 advisers attended one of two online meetings to discuss PPI 'impact' (see Supplementary materials 3), 12 contributed ideas and comments on this this paper, once or more, and TH wrote the initial draft of the plain English summary. Our fourth PPI aim, to develop and promote good public involvement practice, is therefore also met.

The RELAX researchers and PPI lead were able to collaborate with communications professionals from NIHR Biomedical Research Centre at the Maudsley and ARC South London whose skills and knowledge contributed to developing social marketing campaigns, artwork, videos, blogs and the PPI report, which made an important contribution to this study, and to PPI experiences. The role of professional marketing and communications professionals seems to be rarely discussed in detail but may be another potential mechanism that plays a huge part in realising positive PPI/research outcomes.

Evaluating PPI

We have found it helpful to draw on a combination of approaches to evaluate and report PPI in RELAX. GRIPP2-SF had been selected for *planning* the PPI (7), however, we found it limited. We support the view that reporting guidance should include how EDI was addressed, who reported the PPI activities and their impact, and PPI authorship (37). We also feel it is valuable to plan for the degree of power-sharing anticipated prior to a study, and to reflect on whether relationships and decision-making processes amount to consultation, collaboration, co-production or user-led research (14, 20, 53, 54).

Reflective thematic analysis was valuable for analysing the responses to open questions in the PPI reflections survey. We found that using realist research categories of context and mechanism (22, 25) helped us to think critically about the complexity of our mixed methods data and how different factors were related.

Areas for learning and improvement

While the study addressed a health question with strong community backing and clear evidence of clinical importance, the PPI work did not include shared decision-making about the study's main methodology (RCT) and outcome measures. Towards the end of the study, there was some more critical feedback about the research and PPI processes, as well as confidence in the study and praise for the CBM-I training. This suggests that there could usefully have been more explicit discussion about the proposed methodology in the early stages of research design. There may also have been value in involving PPI advisers with research experience for their additional confidence and skills, alongside those who are new to research involvement, as it takes time for newly formed groups to function optimally (55).

Furthermore, some lessons have been learned in relation to achieving our PPI aims. While participants in the study specified which NHS site they had been recruited via, where relevant, they were not asked about awareness of the study via social media, word of mouth, community-displayed posters or NHS services that were not full recruitment sites, or what influenced their decision to take the initial screening. Questions could usefully have been included asking how individuals heard about the study (e.g. speaking to a midwife, seeing social media or a poster) and what motivated them to make contact. It would be useful to explore further during implementation whether there are significant barriers preventing those leaving full-time education at 16 or 18 from taking the training as, despite ethnic representation in the trial being broadly in keeping with the UK population, the study lacked participants with lower education levels (27). As access becomes available via a smartphone app, this may extend reach.

Despite working to make the study accessible, the RELAX landing page and Patient Information Sheet had a readability score of 63.5, considered suitable for an English-speaking 14-15-year-old. As half of adults in England have literacy skills at or below primary school leaver levels, a reading age of 9–11 years is recommended for health information (56). This highlights one challenge of democratising access to clinical trials. Another is spoken language barriers. At our Parent Action community meetings, we had Spanish-speaking groups with interpreters, and one of the PPI advisers (T) was keen for RELAX to be available in Bangla, the language spoken by people of Bengali heritage. In these respects, neither the PPI input nor the commitment of researchers was sufficient to remove barriers to participation completely. However, the PI has outline plans for further related research using translated materials, subject to funding.

We significantly underestimated the real costs of public involvement, in terms of PPI lead and researcher time (48), for the degree of investment that we decided to make, e.g. the extent of the marketing, making videos, recording testimonials, co-writing and creating newsletters. Some time was saved by holding online meetings, which was popular due to convenience. On reflection, after a final in-person workshop was held, PPI advisers felt an early in-person event would have facilitated relationship-building and communication.

Researchers sometimes struggle to identify ways to engage patient representatives (17, 57), which matters for democratising research, and to boost participation rates (57). MN's and CH's involvement with pre-existing perinatal and mental health networks, and community connections were important for the study. Nurturing these connections took time, but was probably an important factor in the successful fostering of substantial community engagement. Previously hidden costs of PPI are becoming more visible and recognised (14, 40, 58, 59), and despite having secured what was assumed to be adequate funding for the PPI lead and PPI-AG, it is notable that further resources needed to be allocated to support the PPI in RELAX as the project continued. Strategic work to address gaps in PPI, and PPI workforce, infrastructure, culture and training are welcomed (60).

Conclusion

PPI played a significant part in this RCT, contributing to research quality and empowering PPI advisers. During the course of the study PPI became increasingly democratised in that more power was shared as time passed. The PPI developed from *consultation* prior to funding, to *collaboration*, with some examples of full *co-production*. There was PI support for PPI; an experienced service-user researcher to lead, facilitate and promote PPI good practice; and flexible responsiveness on behalf of all RELAX researchers, who were committed to PPI learning and development. There were also PPI limitations in that researchers and funders determined the trial methodology and outcome measures. PPI advisers would have liked the intervention to be accessible via smartphone; some felt the online PPIE-AG meetings had limitations as well as offering convenience. A focus on EDI and relationship-building innovations contributed to overall success of PPI in the RELAX study, and to development opportunities for the PPI advisors and for researchers.

Abbreviations

CTC

Clinical trial coordinator

MNVP

Maternity and Neonatal Voices Partnership

NIHR

National Institute for Health and Care Research

NIHR ARC

National Institute for Health and Care Research Applied Research Collaborations

PA

Parent Action (formerly known as Parents and Communities Together (PACT))

PI

Principal investigator

PPI

Patient and public involvement

PPIE

AG–Patient and Public Involvement and Engagement Advisory Group

RA

Research assistant

RCT

Randomised clinical trial

Declarations

Ethics approval and consent to participate

Ethical approval for the RCT was granted by the West Midlands—South Birmingham Research Ethics Committee (Reference Number: 22/WM/0273) on 28th February 2023. The Medicines and Healthcare products Regulatory Agency has also provided a notice of no objection on 27th February 2023 (Reference Number: CI/2022/0082/GB). The PPI reflections survey was approved by King's College London (LRS/RGO-24/25-48583).

Consent to Participate

All participants in the trial and PPI advisers taking the Reflections Survey provided written consent to participate.

Consent for publication

Consent was provided for use of anonymised quotes.

Availability of data and materials

Further information is available on request.

Competing interests

MN, the PPI lead, was anticipating a paid consultancy role when a PPI co-applicant. As PPI lead she was paid up to 0.2 WTE. CH has received financial support from National Institute for Health Research Maudsley Biomedical Research Centre; received accommodation costs and honoraria for speaking at conferences and research funding for related research in other populations from Wellcome Trust, MQ Mental Health Research, National Institute for Health Research, Parkinsons' UK. Other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Funding

The study was funded by the Efficacy and Mechanism Award from the National Institute for Health and Care Research (NIHR) Grant Number NIHR131161. It was also supported by the NIHR Maudsley Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King's College London. Further support was provided by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration South London (NIHR ARC South London) at King's College Hospital NHS Foundation Trust. The views expressed are those of the author(s) and not necessarily those of NIHR or the Department of Health and Social Care.

Authors' contributions

MN and CH originally conceptualised the PPI in the study during the grant application process, and this was subsequently expanded once the study was funded with BV, YS, NT, the PPI advisers and the Trial Management Group all playing a significant part. MN drafted the PPI reflections questionnaire, NT applied for ethics approval, NT and VF created the online surveys, and VF created graphs and bar charts. MN wrote the first draft of this paper and the supplementary materials. All members of the RELAX Public Involvement Writing Group, especially TH, SM-P, AM, and researchers BV, CH, NT, VF and YS contributed substantial comments and revisions.

The RELAX Public Involvement Writing Group, consortium members and their affiliations are as follows: Abi Gay¹, Abigail Mensah¹, Dylan Perry¹, Lola Alimzhanova¹, Michele Misgalla¹, Michelle Howard¹, Omar Campbell¹, Siobhean McCarthy-Perham¹, Tania Sutedja¹, Tannice Hemming¹ and Vanessa Weibel¹ who attended a meeting to discuss PPI impact and/or gave written feedback on the first draft, having contributed substantially to the RELAX study. All authors read and approved the final manuscript. A wider group of individuals with relevant lived experience, and voluntary sector representatives, are listed in the Acknowledgements.

¹ All members of the RELAX Public Involvement Writing Group are affiliated to King's College London, Institute of Psychiatry, Psychology & Neuroscience (IoPPN), 16 De Crespigny Park, London SE5 8AB.

Acknowledgements

Huge thanks are due to other active members of the Patient and Public Involvement and Engagement Advisory Group, PPI contributors, and voluntary sector supporters: Caroline Dollar, Catherine Bartlett (NCT), Christina Brownand Ophilia,^[1] Daniella Abraham (NCT) Elizabeth Duff (NCT), Hayley James (NCT), Jennifer, Lorissa Addai, Rachael Leonard (NCT), Sam Newton, Sandra Igwe, Scott Mair, Simi Bansal and Tanjida. We are most grateful to the organisations and networks that have supported the study, Best Beginnings, Blackpool and Fylde MNVP, King's MNVP, Ladies in Waiting community interest company, Make Birth Better, Maternal Mental Health Alliance, Motivational Mums Club, National Maternity Voices, NCT, PANDAS Foundation, Parent Action), Parent-Infant Foundation, The Motherhood Group. We are grateful to the marketing and communications teams at the NIHR Maudsley Biomedical Research Centre and at NIHR ARC South London. Thank you to Dr Carol Kingdon, The University of Liverpool, who read an early draft, made helpful structuring suggestions and gave encouragement.

^[1] Ophilia, Jennifer and Tanjida chose to be referred to by their first names only.

References

1. Fawcett EJ, Fairbrother N, Cox ML, White IR, Fawcett JM. The Prevalence of Anxiety Disorders During Pregnancy and the Postpartum Period: A Multivariate Bayesian Meta-Analysis. *J Clin Psychiatry*. 2019;80(4). 10.4088/JCP.18r12527.
2. Fairbrother N, Young AH, Zhang A, Janssen P, Antony MM. The prevalence and incidence of perinatal anxiety disorders among women experiencing a medically complicated pregnancy. *Arch Womens Ment Health*. 2017;20(2):311–9. 10.1007/s00737-016-0704-7.
3. Hirsch CR, Meeten F, Gordon C, Newby JM, Bick D, Moulds ML. Repetitive negative thinking and interpretation bias in pregnancy. *Clin Psychol Eur*. 2020;2(4):e3615. 10.32872/cpe.v2i4.3615.
4. Hirsch CR, Krahé C, Whyte J, Krzyzanowski H, Meeten F, Norton S, et al. Internet-delivered interpretation training reduces worry and anxiety in individuals with generalized anxiety disorder: A randomized controlled experiment. *J Consult Clin Psychol*. 2021;89(7):575–89. 10.1037/ccp0000660.

5. Hirsch CR, Krahé C, Whyte J, Bridge L, Loizou S, Norton S, et al. Effects of modifying interpretation bias on transdiagnostic repetitive negative thinking. *J Consult Clin Psychol*. 2020;88(3):226–39. 10.1037/ccp0000455.
6. Volkmer B, Sawjani Y, Newburn M, Bennett J, McGovern M, Bridle L, et al. RELAX (REducing Levels of AnXxiety): a study protocol for a parallel two-arm randomised controlled trial evaluating a web-based early intervention for pregnant women with high levels of repetitive negative thinking to prevent escalating anxiety during pregnancy and after birth. *Trials*. 2024;25(1):709. 10.1186/s13063-024-08516-9.
7. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *BMJ*. 2017;j3453. 10.1136/bmj.j3453.
8. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al. Mapping the impact of patient and public involvement on health and social care research: a systematic review. *Health Expect*. 2014;17(5):637–50. 10.1111/j.1369-7625.2012.00795.x.
9. Biddle MSY, Gibson A, Evans D. Attitudes and approaches to patient and public involvement across Europe: A systematic review. *Health Soc Care Community*. 2021;29(1):18–27. 10.1111/hsc.13111.
10. NIHR, Health Research Authority. Shared Commitment to Public Involvement [Internet]. Available from: <https://www.nihr.ac.uk/get-involved/shared-commitment-public-involvement>
11. Jackson D, Moorley C. *Nothing about us without us*': embedding participation in peer review processes. *J Adv Nurs*. 2022;78(5). 10.1111/jan.15122.
12. Lang I, King A, Jenkins G, Boddy K, Khan Z, Liabo K. How common is patient and public involvement (PPI)? Cross-sectional analysis of frequency of PPI reporting in health research papers and associations with methods, funding sources and other factors. *BMJ open*. 2022;12(5):e063356. 10.1136/bmjopen-2022-063356.
13. Vanneste A, Wens I, Sinnaeve P, Louati C, Huys I, Ioannidis JPA, et al. Evolution of reported patient and public involvement over time in randomised controlled trials in major medical journals and in their protocols: meta-epidemiological evaluation. *BMJ*. 2025;389:e082697. 10.1136/bmj-2024-082697.
14. NIHR. Briefing notes for researchers - public involvement in NHS, health and social care research. [Internet]. 2024. Report Version 2.0. Available from: <https://www.nihr.ac.uk/briefing-notes-researchers-public-involvement-nhs-health-and-social-care-research#tab-briefing-note-two-what-is-public-involvement-in-research>
15. NIHR. Improving how we partner with patients, carers and the public. [Internet]. 2025. Available from: <https://www.nihr.ac.uk/about-us/what-we-do/improving-partner-patients-carers-public>
16. NIHR. UK Standards for Public Involvement [Internet]. 2019. Available from: <https://sites.google.com/nihr.ac.uk/pi-standards/home>
17. Butt A, Vaid A, Taylor R, Darbyshire JL. What approaches are used to facilitate people from under-served communities getting involved with health research? A public contributor led review. *Res Involv Engagem*. 2025;11(1):141–15. 10.1186/s40900-025-00803-2.
18. Ward F, Popay J, Porroche-Escudero A, Akeju D, Ahmed S, Cloke J, et al. Mainstreaming public involvement in a complex research collaboration: A theory-informed evaluation. *Health Expect*. 2020;23(4):910–8. 10.1111/hex.13070.
19. NIHR. Guidance on co-producing a research project. [Internet]. 2024 Apr. Available from: <https://www.learningforinvolvement.org.uk/content/resource/nihr-guidance-on-co-producing-a-research-project/>
20. NIHR ARCKSS. A Guide to Co-production for Researchers, Services and Commissioners. NIHR Applied Research Collaboration Kent, Surrey and Sussex. [Internet]. 2025. Available from: <https://arc-kss.nihr.ac.uk/document-download/77-what-is-co-production-april-2021/file>
21. Staniszewska S, Adebajo A, Barber R, Beresford P, Brady LM, Brett J, et al. Developing the evidence base of patient and public involvement in health and social care research: the case for measuring impact: Patient and public involvement in health and social care research. *Int J Consumer Stud*. 2011;35(6):628–32. 10.1111/j.1470-6431.2011.01020.x.
22. Staley K, Buckland SA, Hayes H, Tarpey M. The missing links': understanding how context and mechanism influence the impact of public involvement in research. *Health Expect*. 2014;17(6):755–64. 10.1111/hex.12017.
23. Pawson R, Tilley N. *Realistic Evaluation*. London, UK: SAGE; 1997.
24. Pawson R. *The Science of Evaluation*. London, UK: SAGE; 2013.

25. HM Treasury. Supplementary Guide: Realist evaluation (HTML) [Internet]. 2026 May. Available from: <https://www.gov.uk/government/publications/the-magenta-book/supplementary-guide-realist-evaluation-html>
26. Volkmer B, Sawjani Y, Newburn M, Bennett J, McGovern M, Bridle L, et al. RELAX (REducing Levels of AnXxiety): a study protocol for a parallel two-arm randomised controlled trial evaluating a web-based early intervention for pregnant women with high levels of repetitive negative thinking to prevent escalating anxiety during pregnancy and after birth. *Curr controlled trials Cardiovasc Med*. 2024;25(1):709–19. 10.1186/s13063-024-08516-9.
27. Hirsch C, Volkmer B, Sawjani Y, Towner N, Newburn M, Bennett J et al. RELAX a perinatal digital therapeutic to prevent increasing anxiety: A Randomized Clinical Trial. *JAMA Network Open*. in press.
28. Newburn M, Volkmer B, Abi, Bansal S, McCarthy-Perham S, Leonard R. 'I was a bit sceptical': The RELAX study's public involvement – what we've done and how it feels to be involved [Internet]. 2023 Nov 10. Available from: <https://www.maudsleybrc.nihr.ac.uk/news/i-was-a-bit-sceptical-the-relax-studys-public-involvement-what-weve-done-and-how-it-feels-to-be-involved/>
29. A RELAX study writing group. Diversity, relationships and community leaders – Public involvement tips and reflections from the RELAX (Reducing Levels of AnXxiety in pregnancy and after birth) research project [Internet]. 2025 Dec. p. 11. Available from: <https://www.maudsleybrc.nihr.ac.uk/wp/wp-content/uploads/2026/01/RELAX-study-report-Final.pdf>
30. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Res Psychol*. 2006;3(2):77–101. 10.1191/1478088706qp063oa.
31. Braun V, Clarke V. Reflecting on reflexive thematic analysis. *Qualitative Res Sport Exerc Health*. 2019;11(4):589–97. 10.1080/2159676X.2019.1628806.
32. Braun V, Clarke V. Supporting best practice in reflexive thematic analysis reporting in Palliative Medicine: A review of published research and introduction to the Reflexive Thematic Analysis Reporting Guidelines (RTARG). *Palliat Med*. 2024;38(6):608–16. 10.1177/02692163241234800.
33. NIHR. Payment guidance for researchers and professionals involving people in research. [Internet]. 2025 Dec. Report Version 1.9. Available from: <https://www.nihr.ac.uk/about-us/who-we-are/policies-and-guidelines/payment-guidance-researchers-and-professionals>
34. Ahmed E, Newburn M, Moltedo V, Umutoni K, Agyepong A, Silverio S, et al. Involving diverse communities in maternity and perinatal mental health research – insights and learning from a co-production training event. London, UK: King's College London /NIHR Applied Research Collaboration South London; 2021.
35. Woolley KL, Stones SR, Stephens R, Bharadia T, Yamamoto B, Geissler J, et al. Patient authorship of medical research publications: An evolution, revolution, and solution? *Learn Publish*. 2024;37(3):e1607. 10.1002/leap.1607.
36. Woolley KL, Woolley J, Woolley MJ. Seek and Ye Shall Not Find (Yet): Searching Clinical Trial Registries for Trials Designed With Patients—A Call to Action. *J Particip Med*. 2025;17:e72015–72015. 10.2196/72015.
37. Jones J, Cowe M, Marks S, McAllister T, Mendoza A, Ponniah C, et al. Reporting on patient and public involvement (PPI) in research publications: using the GRIPP2 checklists with lay co-researchers. *Res Involv Engagem*. 2021;7(1):52. 10.1186/s40900-021-00295-w.
38. Staley K, Barron D. Learning as an outcome of involvement in research: what are the implications for practice, reporting and evaluation? *Res Involv Engagem*. 2019;5(1):14. 10.1186/s40900-019-0147-1.
39. Mathie E, Wythe H, Munday D, Millac P, Rhodes G, Roberts N, et al. Reciprocal relationships and the importance of feedback in patient and public involvement: A mixed methods study. *Health Expect*. 2018;21(5):899–908. 10.1111/hex.12684.
40. Mathie E, Smeeton N, Munday D, Rhodes G, Wythe H, Jones J. The role of patient and public involvement leads in facilitating feedback: invisible work. *Res Involv Engagem*. 2020;6(1):40. 10.1186/s40900-020-00209-2.
41. Harper R. The measurement of Social Capital in the United Kingdom. [Internet]. Office for National Statistics.; 2002. Available from: https://old.adapt.it/adapt-indice-a-z/wp-content/uploads/2014/05/rosalyn_harper.pdf
42. Brown CL, Thille P, Ganann R, Allison T, Moorhouse S, Pelletier GC, et al. Disrupting power hierarchies: applying a trauma-informed, intersectional, reflexive engagement strategy. *Res Involv Engagem*. 2026;12(1):104. 10.1186/s40900-026-00930-4.
43. Worsley JD, McKeown M, Wilson T, Corcoran R. A qualitative evaluation of coproduction of research: 'If you do it properly, you will get turbulence'. *Health Expect*. 2022;25(5):2034–42. 10.1111/hex.13261.

44. Cadman R, Syliboy A, Saunders M, Denny S, Denniston M, Barry E, et al. Using positionality and reflexivity to support equity in partnership-driven research. *Conserv Biol*. 2024;38(6):e14396. 10.1111/cobi.14396.
45. Staniszewska S, Denegri S, Matthews R, Minogue V. Reviewing progress in public involvement in NIHR research: developing and implementing a new vision for the future. *BMJ Open*. 2018;8(7):e017124. 10.1136/bmjopen-2017-017124.
46. MacLachlan A, Pemmasani P, Jamieson-Mackenzie I, McMellon C, Cunningham E, Lewis R, et al. Applying co-production principles in research: Reflections from young people and academics. *Childhood*. 2024;31(3):309–28. 10.1177/09075682241269692.
47. Mann C, Chilcott S, Plumb K, Brooks E, Man MS. Reporting and appraising the context, process and impact of PPI on contributors, researchers and the trial during a randomised controlled trial - the 3D study. *Res Involv Engagem*. 2018;4(1):15. 10.1186/s40900-018-0098-y.
48. Evans D, Coad J, Cottrell K, Dalrymple J, Davies R, Donald C, et al. Public involvement in research: assessing impact through a realist evaluation. *Health Serv Delivery Res*. 2014;2(36):1–128. 10.3310/hsdr02360.
49. Howe A, Mathie E, Munday D, Cowe M, Goodman C, Keenan J, et al. Learning to work together – lessons from a reflective analysis of a research project on public involvement. *Res Involv Engagem*. 2017;3(1):1. 10.1186/s40900-016-0051-x.
50. Shimmin C, Wittmeier KDM, Lavoie JG, Wicklund ED, Sibley KM. Moving towards a More Inclusive Patient and Public Involvement in Health Research Paradigm: The Incorporation of a Trauma-Informed Intersectional Analysis. *BMC Health Serv Res*. 2017;17(1):539–10.
51. Vousden N, Bunch K, Kenyon S, Kurinczuk JJ, Knight M. Impact of maternal risk factors on ethnic disparities in maternal mortality: a national population-based cohort study. *Lancet Reg health Europe*. 2024;40:100893–100893. 10.1016/j.lanepe.2024.100893.
52. Bansal N, Karlsen S, Sashidharan SP, Cohen R, Chew-Graham CA, Malpass A. Understanding ethnic inequalities in mental healthcare in the UK: A meta-ethnography. *PLoS Med*. 2022;19(12):e1004139. 10.1371/journal.pmed.1004139.
53. Hayes H, Buckland S, Tarpey M. Briefing notes for researchers: public involvement in NHS, public health and social care research. Eastleigh: INVOLVE.
54. Ocloo J, Matthews R. From tokenism to empowerment: progressing patient and public involvement in healthcare improvement. *BMJ Qual Saf*. 2016;25(8):626–32. 10.1136/bmjqs-2015-004839.
55. Tuckman BW, Jensen MAC, Stages of Small-Group Development Revisited. *Group Organ Stud*. 1977;2(4):419–27. 10.1177/105960117700200404.
56. Reading age position statement. [Internet]. Patient Information Forum. 2025. Available from: <https://pifonline.org.uk/download/file/b1BGNIJIUEtxRFhInnhzb3NZMHo2UT09/reading-age-position-statement-2025/#:~:text=PIF%20guidance%20on%20a%20reading,position%20and%20highlights%20useful%20tools>
57. Domecq JP, Prutsky G, Elraiyah T, Wang Z, Nabhan M, Shippee N, et al. Patient engagement in research: a systematic review. *BMC Health Serv Res*. 2014;14(1):89. 10.1186/1472-6963-14-89.
58. NIHR. The hidden costs of patient and public involvement: a necessary conversation. 2024 Apr. Report Version: 1.
59. NIHR. Going the Extra Mile [Internet]. 2024 Sep. Report Version 1.1. Available from: <https://www.nihr.ac.uk/going-the-extra-mile>
60. NIHR. PPI workforce career recognition and training. [Internet]. 2024 Jan. Available from: https://www.learningforinvolvement.org.uk/wp-content/uploads/gravity_forms/6-341881053f9095fe395a1f986cd7085c/2024/07/Final-report-PPI-workforce-career-recognition-and-training.pdf

Footnotes

1. MVPs became Maternity and Neonatal Voices Partnerships (MNVPs) during the lifetime of the study.
2. NCT charity is counted as one adviser, though the personnel changed over time.
3. Some respondents did not answer every question. The number responding is indicated on tables/figures.

Figures

Figure 1: Timeline of the RELAX study and patient and public involvement (PPI) activities

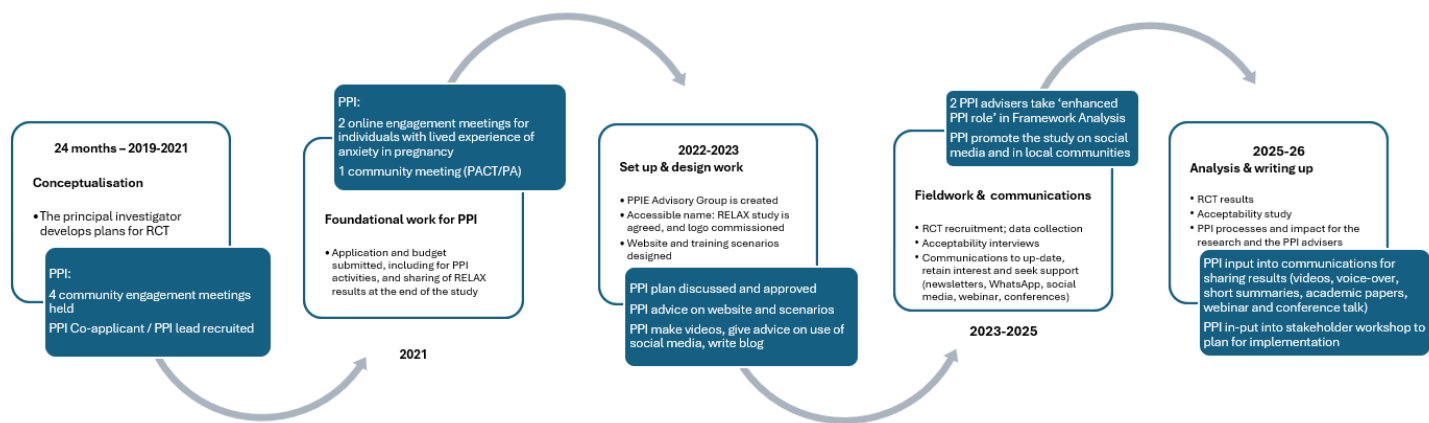


Figure 1

See image above for figure legend.

Figure 2: What do you feel you have you gained from involvement in the study? (n=8)

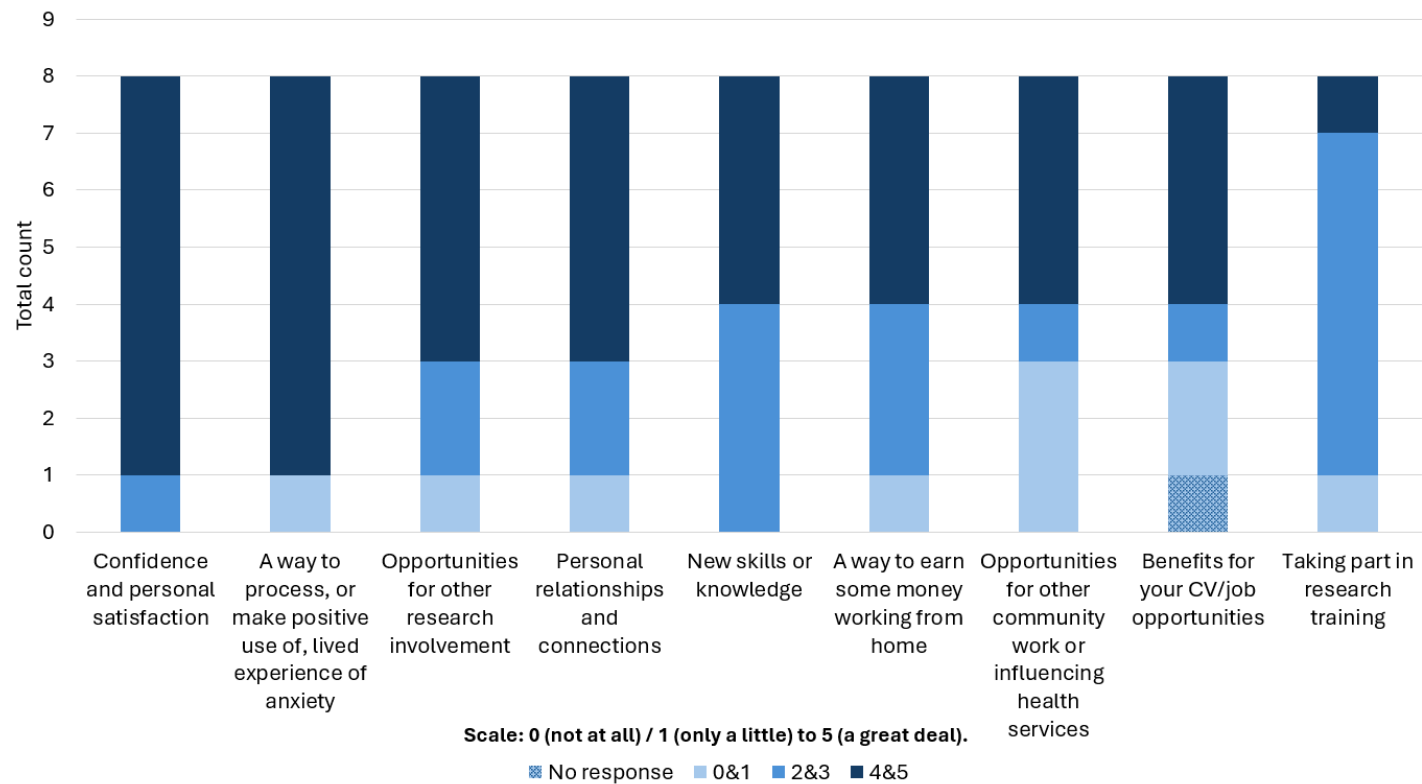
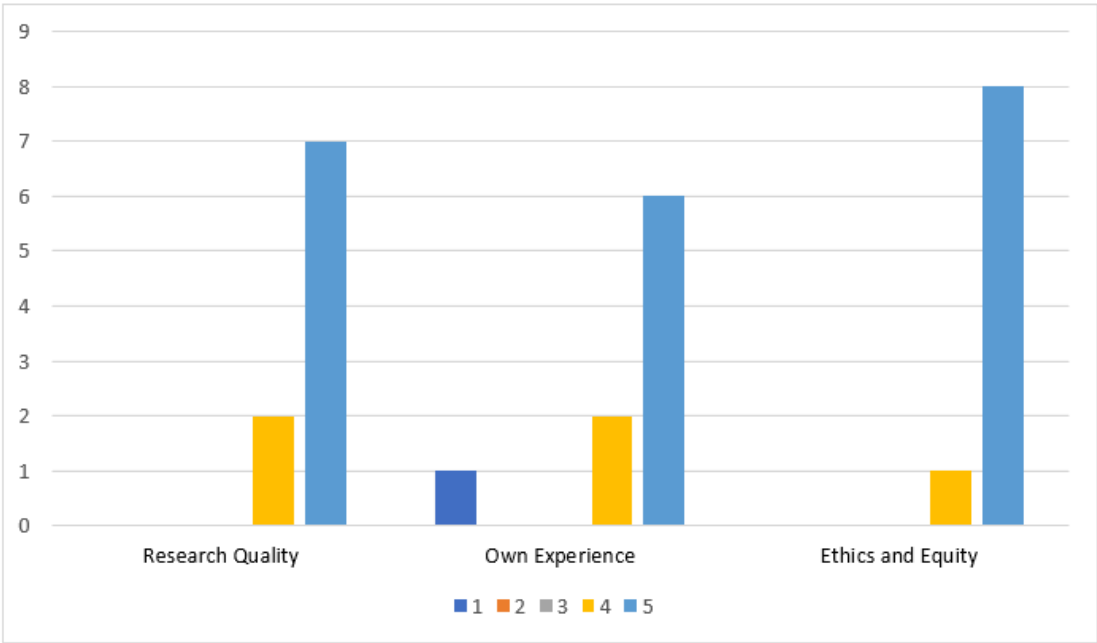


Figure 2

See image above for figure legend.

Figure 3: Motivations for patient and public involvement in RELAX (n=9)



Please indicate how much you agree with each of the following statements by picking a number from 0 (not at all) / 1 (only a little) to 5 (a great deal).

Research Quality - I am motivated to be involved in research to contribute to making sure that studies are of the highest quality (e.g. the research is relevant, the methodology is suitable, the study is rigorous and accessible)?

Own Experience - I am motivated to be involved in research to express and make sense of my own experiences?

Ethics and Equity - I am motivated to be involved in research to ensure that particular groups or communities that can be exploited, excluded or discriminated against are included ethically and equitably in research?

Figure 3

See image above for figure legend.

Figure 4: Word cloud - PPI advisors' views on what has made public involvement successful (n=8)



Note: Word size reflects how frequently advisors endorsed each word, larger words were endorsed more frequently.

Figure 4

See image above for figure legend.

Figure 5. Democratising patient and public involvement (PPI): PPI values, processes and outcomes in RELAX

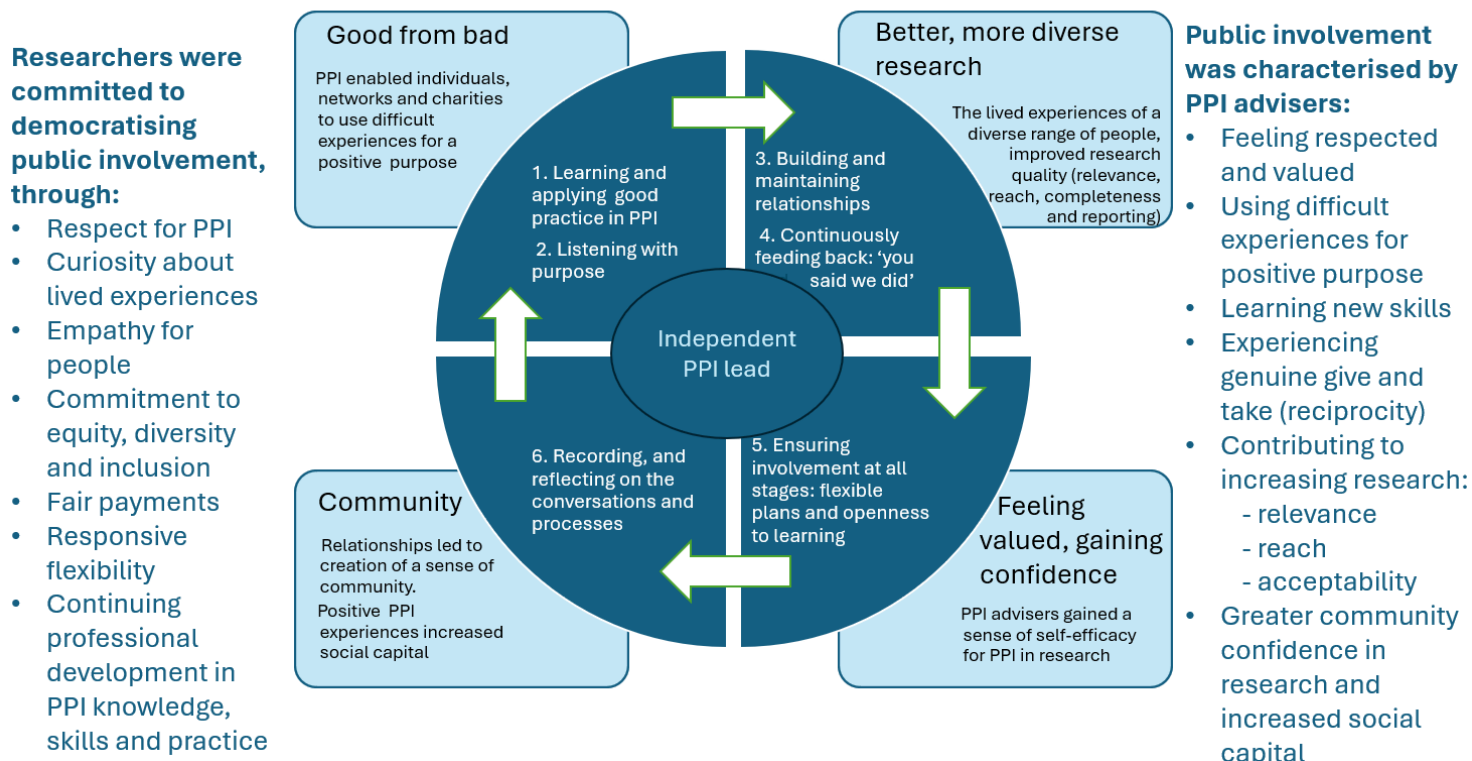


Figure 5

See image above for figure legend.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Supplementarymaterials1GRIPP2shortformchecklistofpublicinvolvementintheRELAXstudy.docx](#)
- [Supplementarymaterials2RELAXPatientandPublicInvolvementandEngagementAdvisoryGroupmeetingsandrelatedactivities.docx](#)
- [Supplementarymaterials3AsummaryofPPImeetingstodiscussPPIadvisersviewsofPPIimpact.docx](#)