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Patient and public involvement in pragmatic trials with older adults: a multi-methods study of researchers' experiences

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Abstract

Background Patient and Public Involvement (PPI) in health research, including clinical trials, enhances research relevance and quality. However, data on PPI prevalence and characteristics in trials involving older adults remain scarce. We aimed to describe the prevalence and nature of PPI in trials with older adults and identify the main benefits and challenges associated with PPI in such trials.

Methods We conducted a multi-methods study, embedded within a survey of 3,163 corresponding authors of pragmatic trials published between 2014 and 2019. We used authors' self-reports and an electronic search filter to identify the subset involving the older adult population (≥65 years). We approached interested respondents who indicated that they had conducted PPI to participate in a semi-structured interview. Survey results were summarized using descriptive statistics, and interview transcripts were analyzed using thematic analysis.

Results One hundred authors met the eligibility criteria, having completed the survey and been involved in a trial involving older adults. Most respondents were women (64.8%). PPI was reported in 46.0% of trials, primarily involving in-person discussions. Most respondents (90.7%) perceived PPI as beneficial, citing improved interventions, increased applicability of findings, higher research quality, and enhanced recruitment/retention. Challenges included communicating trial design, methods, and results (62.5%), identifying or recruiting PPI partners (50%), scheduling meetings (45.8%), and sustaining involvement (45.8%).

Thematic analysis of N=8 interviews revealed five main themes related to challenges, some specific to older adults: recruitment and retention of PPI partners, importance of a good PPI chair, training for PPI partners, workload for researchers and burden for PPI partners, and procedural barriers. PPI partners influenced various research aspects, sometimes described as exceeding expectations, by influencing aims and outcomes to measure, developing interventions, refining patient-facing materials, aiding recruitment and retention, and contributing to analysis and interpretation of results.

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Conclusion Despite being implemented in fewer than half of the trials, PPI had a significant perceived impact. Addressing identified challenges, both general and specific to older adults, could enhance PPI uptake, as well as the quality and relevance of research.

Keywords Patient involvement, Older adult, Senior, Pragmatic trial, Patient and public involvement in research, Stakeholder engagement

Background

In the last decade, involving patients and the public has become an important way to improve the relevance and quality of health research. This practice, in which there is active collaboration between the patients and/or public and researchers, is most often referred to as *patient engagement*, *Patient and Public Involvement (PPI)*, or *participatory research* [1–3]. In this manuscript, the term PPI will be used. The United Kingdom National Institute for Health Research (NIHR) defines PPI as "research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them." [4].

PPI in health research is strongly recommended by different national and international bodies [5–8], institutions [9, 10] and stakeholder groups [11, 12]. For example, the National Institute for Health and Care Research (NIHR) and the Medical Research Council (MRC) in the United Kingdom, the Patient-Centered Outcomes Research Institute (PCORI) in the United States, and the Canadian Institutes of Health Research (CIHR) through its Strategy for Patient-Oriented Research (SPOR) initiative have been particularly influential in advancing PPI. In clinical trials, patient/public partners (referred to as PPI partners in this paper) can contribute across all stages of the research process, from refining the research question and informing study design to supporting data interpretation and dissemination. Incorporating patient perspectives in clinical trials has been shown to enhance trial design and delivery - for example, by improving recruitment strategies or by selecting outcome measures that are more relevant to patients and feasible to collect - ultimately leading to more meaningful and applicable trial results [13]. PPI also aligns closely with the aims of pragmatic trials, which seek to generate evidence directly applicable to real-world practice. This focus on relevance shapes design decisions—such as adopting broad eligibility criteria, ensuring interventions are feasible in routine care, providing accessible study materials, and prioritising outcomes that matter to patients and healthcare providers—all areas in which PPI partners can play an influential role.

Despite the recognised benefits, the prevalence of PPI in clinical trials remains low, with estimates ranging from less than 1% up to 15% [5, 14–16]. PPI with frail or older adults appears to be even less common, with limited evidence regarding its prevalence in this population specifically. A systematic review of PPI with older care-home residents identified only 11 studies between 1990 and 2014 [17]. Similarly, a scoping review on methods for involving long-term care residents living with dementia identified just three studies [18], while a review of qualitative, quantitative, and mixed methods research on partnering with frail or seriously ill patients reported only 30 reports for the period 2005–2019 [19].

While barriers resulting from illness and frailty may hinder the involvement of older adults in PPI activities within health research, data show that older people and their caregivers can be successfully involved in the research process [20, 21]. Involvement strategies for the general population seem relevant to older adults and caregivers, but specific challenges related to this group – such as the practical or emotional needs of PPI partners, the timing and methods of involvement - need to be considered [19, 22–25]. Additionally, there remains a need to better understand the most effective approaches for frail older adults or those facing specific barriers (e.g., dementia, sensory/mobility impairments, or transportation limitations [20].

To address these identified needs, we aimed (a) to describe the prevalence and nature of PPI with older adults within a cohort of pragmatic trials, and (b) to identify the main benefits and challenges related to PPI in trials of older adults. The study examined both the practical aspects of implementing PPI and its impact on research methods and study conduct.

Methods

We undertook a multi-methods study, with an initial survey to capture the reported prevalence and characteristics of PPI which was followed by qualitative interviews to explore in more detail the benefits and challenges experienced when undertaking the reported PPI activities. The Ottawa Health Science Network Research Ethics Board approved the study (20210684–01 H).

Survey

Study design and data collection

The study was embedded within a larger survey of pragmatic trial authors published between 2014 and 2019 [26, 27]. Pragmatic trials are trials explicitly designed to evaluate the effectiveness of interventions under real-world conditions, with the goal of generating evidence directly applicable to clinical practice. Such trials typically use settings and methods similar to usual care and consider

the perspectives and priorities of patients [28]. The detailed methods for the larger survey have been published [27]; in summary, an electronic search filter [26] was used to identify health-focused trials more likely to be pragmatic among RCTs published between January 1, 2014, and April 3, 2019 on MEDLINE. This revealed 4336 primary reports of potentially pragmatic health focused RCTs. The corresponding authors of those reports were the sampling frame of the self-administered online survey. To conduct the survey in English and focus on settings in which the investigators team had experience, only corresponding authors from the following countries were targeted: Canada, United States, United Kingdom, Australia, New Zealand, South Africa, France, Belgium, Denmark, Finland, Germany, Italy, the Netherlands, Norway, Spain, Sweden and Switzerland. Only one report was included per author. For those authors with multiple eligible studies, the most recently published report was selected. All participants were invited to review a participant information sheet at the start of the survey and were notified that the survey was voluntary and continuing implied consent.

The survey questionnaire was developed based on previous surveys about PPI [29–32], the research team's own experience, and input from two PPI partners with established training and experience in PPI (MS, AH). The survey started with a definition of PPI which respondents had to indicate that they had read and understood prior to completing the survey. Of particular relevance to the present substudy, respondents were asked the following question: "For your randomized controlled trial identified in the email invitation, please indicate if the trial specifically focused on older adults, i.e., recruited participants aged 65 years and older; OR recruited "older adults" using your own preferred definition (e.g., geriatric, senior, elderly) and mean or median age of participants was at least 65 years of age."

In addition, the questionnaire consisted of 27 open- and closed-ended items pertaining to PPI in the published trial, including whether PPI had taken place (yes, no, don't know) as well as reasons for involving or not involving patient/public partners in the study. Respondents who indicated they had involved patients or public partners in their trial were asked how they had been involved, both in terms of the trial aspects and the methods used to involve the patients/public. Respondents were also asked to indicate if there had been benefits and challenges of PPI, and if so, they were presented with a list of options derived from the literature. In addition, open text response options were provided to capture additional benefits or challenges. Finally, the survey contained a series of demographic questions and respondents were also asked to indicate their willingness to participate in a follow-up interview on specific aspects of PPI in their trial. The survey questionnaire is available in Appendix 1.

The survey was administered via SurveyMonkey. After a pilot phase with a random sample of one hundred participants, personalized invitation emails were sent to all remaining eligible corresponding authors on February 8th 2022, followed by two reminders respectively two weeks and three weeks later. The survey was closed on April 5, 2022. Survey participants were given the option to be entered into a draw for one of five $100 CAD Amazon gift cards.

Out of the 3,163 corresponding authors who were invited to complete the parent survey, 2585 invitations were delivered and 710 (27.5%) completed the survey.

Selection of substudy participants

The present work is a secondary analysis focusing on the subgroup of respondents that conducted pragmatic trials within the older adult population (defined as people aged 65 and over). To facilitate estimation of the response rate and for sample size and planning purposes, it was necessary to identify a cohort of 'likely older adult trials' within the sampling frame of 4336 RCTs. This was done using an electronic search filter applied to the 4336 trial manuscripts.

Our initial sample of respondent data was taken from the 116 out of 710 survey respondents (16.3%) who self-identified their trial as a 'trial with older adults'. A manual check was performed by one researcher (PN or AS) for (a) the 55 trials out of the 116 that were not identified as an older adult trial by the search filter: eighteen trials with an average age under 65 were excluded; and (b) the six trials which were screened in by the filter but not reported as older adult trials by authors: two had an average age over 65 and were included. Thus, the total sample was 100 responses that pertained to older adult trials (see appendix 3).

Analysis

We used descriptive statistics to summarize the demographic characteristics of survey respondents and details related to PPI in the included studies, including the characteristics of PPI partners, as well as the rationale, benefits, and challenges reported by study participants. All responses were analyzed regardless of completeness. Some closed-ended questions of the survey allowed respondents to select "Other" and elaborate in a text box. Those responses in the text box were collated and independently reviewed by study team members (SV, PN, SN, MT) to determine if the response could be re-classified into an existing category or required the creation of a new category. Disagreements were resolved through discussion among study team members.

Semi-structured interviews

Interview participants

To further explore our respondents' perceptions about PPI, a voluntary response sampling method was used for the interviews. Participants had to meet the following criteria: survey respondent for a pragmatic trial conducted exclusively with older adults (to ensure that the feedback was relevant to this population); who conducted PPI for this trial; and who had indicated willingness to participate in a follow-up interview. We initially planned on also interviewing survey participants that did not perform PPI, but we instead focused on examining benefits and challenges faced in trials that had PPI. Consenting individuals received an invitation to participate in a single semi-structured interview. A maximum of 2 reminder emails were sent. We planned on recruiting participants for interviews until reaching data saturation (i.e. no emergence of new themes), or until all potential respondents had been invited.

All participants received the consent form via email prior to their interview. They were asked to review, sign electronically if they agree and send it back to the study team prior to the interview. Each participant to the interview was offered the opportunity to receive compensation of $100 CAD in the form of an Amazon gift card, which was transferred electronically to them.

Interviews

The interviews were conducted by two trained researchers (KB, JH) using a semi-structured topic interview guide (Interview guide available in Appendix 2). One PPI partner (MS), who aligns with the older adult category, provided feedback on the interview guide. The questions explored the specific goal for PPI in the trial, strategy for recruitment and involvement of PPI partners, barriers and facilitators for involving PPI partners, impact/outcome of PPI and lessons learned for future research. When needed, answers to the survey were used to introduce a new question or to probe for additional information. All interviewers had previous experience with qualitative research and interview conduct. All interviews took place through Microsoft Teams and were audio-recorded with participants' consent. The verbatim transcription generated by Microsoft Teams was checked and corrected by one researcher (PE). After that, the transcripts were imported into a qualitative data analysis software (NVivo v11) for analysis.

Analysis

Examination of the interview transcripts followed a thematic analysis approach [33] in which textual data are coded and labeled in an inductive manner. This process of coding was iterative with data analysis using the constant comparison method occurring alongside the interviews. This allowed us to modify and adapt both the interview guide and the coding tree, to enable deeper exploration of new themes emerging from our data. All interviews were independently coded by two researchers (PE and SN), who met to discuss the coding tree after each interview analysis, and met twice with another research (AS) to discuss coding. Disagreements were resolved through discussion. They also sought to identify specific considerations or challenges to PPI with older adults and their caregivers.

After the initial phase of open coding, individual codes were grouped into overarching themes or constructs through a process of data reduction; with the themes operating at a higher level than the immediate codes. Themes were then discussed and revised with another researcher (AS), before comments and input from the broader team.

Results

Survey

The total sample was 100 responses that pertained to older adult trials (see appendix 3). Most respondents were women (57, 63.3%), aged 56 and over (52, 57.1%), and had more than 10 years of experience with PPI (51, 56.7%). Table 1 summarises respondents' characteristics.

The proportion of respondents who reported PPI in their study (46/100; 46.0%) was similar to the proportion who reported no PPI (48/100; 48.0%), with 6 respondents (6%) responding that they did not know whether there was PPI in the trial about which they were responding. This split was similar across jurisdictions, with the exception of the UK where more respondents reported PPI than no PPI in their study (Appendix 4). The three main reasons for not involving patient/public partners were insufficient knowledge of how to involve patient/public partners (16/42; 38.1%), because there was no requirement to do so (15/42; 35.7%), and lack of resources or funds (12/42; 28.6%) (Appendix 5).

Table 2 describes reported approaches to PPI partners' identification and involvement by respondents who indicated that there was PPI in the trial about which they were reporting. Identification mainly occurred through previous collaborations (24; 54.5%) and partnering with other organizations (19; 43.2%). PPI partners were mainly older adults themselves (32; 72.7%) and caregivers (17; 38.6%). The researchers attempted to ensure that PPI partners reflected the diversity of the trial population in half of the cases (22; 51.2%). Patients/public partners' contribution covered several aspects including designing or developing interventions (38; 86.4%), developing recruitment or retention strategies (25; 56.8%) and suggesting dissemination strategies (17; 38.6%). PPI partners were mainly involved through face-to-face discussions (41; 93.2%). In most cases, they were not compensated

Table 1 Survey respondent characteristics (N=100) (authors who provided demographic information)

Characteristic	Frequency (%)
Region of residence (N=88)	
USA	28 (31.8)
Non-UK Europe	25 (28.4)
Australia or New Zealand	17 (19.3)
UK	12 (13.6)
Canada	6 (6.8)
Age (years) (N=91)	
36-45	14 (15.4)
46-55	23 (25.3)
56-65	33 (36.3)
>65	19 (20.9)
Prefer not to answer	2 (2.2)
Gender (N=90)	
Man	31 (34.4)
Woman	57 (63.3)
Prefer not to disclose	2 (2.2)
Stage of research career (N=90)	
Early career researcher (within 5 years of first academic appt)	3 (3.3)
Mid-career researcher (6-15 years since first academic appt)	19 (21.1)
Late career researcher (>15 years since first academic appt)	61 (67.8)
Retired researcher or Professor Emeritus	4 (4.4)
Non-academic researcher or other	3 (3.3)
Years of PPI experience (N=90)	
<1 year	5 (5.6)
1-3 years	5 (5.6)
4-10 years	29 (32.2)
>10 years	51 (56.7)
Racial or ethnic group* (N=91)	
White	82 (90.1)
South or Southeast Asian; Pacific Islander; Chinese	5 (5.5)
Latin American/Hispanic	2 (2.2)
Prefer not to answer	4 (4.4)
Mixed (without specifying)	1 (1.1)

*More than one selection possible

(29; 69.0%). The median number of PPI partners involved per study was 10 (IQR 3–24).

Table 3 outlines the reported rationale, benefits, and challenges of conducting PPI. The most frequent reasons for involving patient/public partners were increased relevance of research (41; 93.3%) and increased quality of research (34; 77.3%). Most respondents (39; 90.7%) reported that PPI benefited their study. Benefits were varied and included: improved interventions (26; 66.7%); increased applicability of findings (25; 64.1%); higher quality research (22; 56.4%) and improved recruitment or retention (21; 53.8%). The most frequent challenges were communicating about trial design, methods and results (15; 62.5%), identifying or recruiting patient/public partners (12; 50%), scheduling meetings (11; 45.8%) and sustaining involvement of PPI partners throughout the study (11; 45.8%). Despite these challenges, involving PPI partners was perceived as a positive experience by almost all respondents.

Semi structured interviews

Forty-seven survey respondents out of 100 (47%) consented to be contacted for an interview. Twenty-one had reported conducting PPI in their trial: 15 - who had performed the trial exclusively with older adults - were invited and 9 agreed to participate. We interviewed authors between May and December 2022. Median interview duration was 51 min (range 40 to 90 min). While conducting and checking the transcript of one of the interviews, we realized that PPI activities as described by their author could not be considered as PPI based on the definition given at the beginning of the survey. Therefore, only 8 interviews were retained for analysis. Seven out of the 8 interviewees were women. The interventions evaluated were exercise programs ($n=2$), an integrated care model ($n=1$), simulated family presence in delirium ($n=1$), general practitioner education on dementia diagnosis ($n=1$), church-based marketing of balance classes ($n=1$), social dancing classes ($n=1$), and ophthalmologic treatments ($n=1$). The characteristics of PPI mirrored survey results: patient/public partners were mainly older adults and informal caregivers; involvement of PPI partners was performed through discussion, in group meetings, or in focus groups; and PPI partners were involved in various stages of the trials.

Despite interviewing all available and consenting authors, we did not reach data saturation. Still, interviews provided an insight into current PPI practices, benefits and challenges with older adults.

Below, we first describe and illustrate the challenges and enablers relative to PPI – and whenever possible we highlight aspects that are specific to older adults. We then present examples of benefits and impact of PPI as reported by participants.

Challenges and enablers of PPI

Challenges and enablers of PPI fell into 5 main themes: recruitment and retention of PPI partners, importance of a good PPI chair, training for PPI partners, workload for researchers and burden for PPI partners, and procedural barriers and enablers. Details on these themes are given below. We aimed to highlight when some aspects were particular to older adults (e.g. high turnover in PPI partners), but many aspects were not (e.g. training).

Recruitment and retention of PPI partners Recruiting and building PPI groups was a challenge expressed among interviews. Making sure that the group included relevant

Table 2 Characteristics of identification and involvement of patient/public partners (N=46)

Characteristic	Frequency (%)
How patient/public partners were identified* (N=44)	
Previous collaborations	24 (54.5)
Health system partnering with other organization	19 (43.2)
Word of mouth/recommendation from colleague(s)	16 (36.4)
Community outreach/social media	12 (27.3)
From a directory	9 (20.5)
Other (e.g., matching service)	9 (20.5)
Don't know	1 (2.3)
Characteristics of patient/public partners* (N=44)	
Older adult patients (>65 years of age)	32 (72.7)
Caregivers of adult or older adult patients	17 (38.6)
Patient advocacy group members	14 (31.8)
Adult patients (>18 years of age)	13 (29.5)
Members of the public	13 (29.5)
Other	5 (11.4)
Did researchers attempt to ensure patient/public partners reflected the diversity of the trial's target population? (N=43)	
Yes*	22 (51.2)
Age	19 (86.4)
Race/ethnicity/culture/language	17 (77.3)
Gender	13 (59.1)
Sex	12 (54.5)
Place of residence	10 (45.5)
Socioeconomic status	7 (31.8)
Education	4 (18.2)
Occupation	2 (9.1)
Religion	1 (4.5)
Social capital	1 (4.5)
Not specified	1 (4.5)
No	21 (48.8)
Specific aspects of the study where patient/family partners were involved* (N=44)	
Designing or developing interventions	38 (86.4)
Developing recruitment or retention strategies	25 (56.8)
Designing recruitment materials	25 (56.8)
Suggesting dissemination strategies	17 (38.6)
Participating in the Trial Steering Committee	16 (36.4)
Selecting outcomes	16 (36.4)
Interpreting data or results	15 (34.1)
Developing data collection tools	14 (31.8)
Setting research topics or questions	14 (31.8)
Presenting findings to a lay audience	11 (25.0)
Troubleshooting issues	11 (25.0)
Writing or reviewing lay summaries	9 (20.5)
Writing or reviewing manuscripts	8 (18.2)
Identifying or screening potential participants	7 (15.9)
Collecting data	4 (9.1)
Determining the target difference (4) or developing the statistical analysis plan (1)	4 (9.1)
Analyzing qualitative or quantitative data	3 (6.8)
Participating in the Data Safety Monitoring Board	2 (4.5)
Preparing presentations for scientific conferences	2 (4.5)
Other (e.g., informing missing data handling, delivering intervention)	3 (6.8)
How patient/family partners were prepared* (N=44)	
Written materials about the study	34 (77.3)
Orientation sessions	30 (68.2)
Discussion of mutual expectations for involvement	29 (65.9)
Terms of reference	11 (25.0)
Research (6) or PPI training (5)	8 (18.2)
Other or no preparation	4 (9.1)
How patient/family partners were involved* (N=44)	
Face-to-face (40) or virtual meetings (6)	41 (93.2)
Email (15) or online forums (3)	16 (36.4)
Surveys	4 (9.1)
Telephone calls/interviews	2 (4.5)
Don't know	1 (2.3)
Patient/family partners were compensated (N=42)	
Yes	11 (26.2)
No	29 (69.0)
Don't know or other	2 (4.8)
Patient/family partners were acknowledged* (N=43)	
Named in acknowledgements	16 (37.2)
Patient partners did not wish to be acknowledged	5 (11.6)
Named as individual co-authors	4 (9.3)
Included in group authorship	3 (7.0)
None of the above	14 (32.6)
Other	4 (9.3)

*More than one selection possible

perspectives and was diverse in these was noted as a particular challenge.

> *"We found it was very easy to get women to serve on the boards. It was a little bit harder to get men, so we had to work a little bit harder for that. We wanted to have some diversity as far as race [...]. And then also socioeconomic status. [...] So, we wanted to make sure that we were weren't just identifying the people, the easy people, to get on the board. But people that might not have volunteered to participate without being asked" (P3).*

Some challenges were specific to the older adult population. For example, some researchers noted that they faced high turnover in PPI partners, mainly because of age and illness. This turnover was particularly recognised for groups that included older adults with dementia.

> *"[The] Project went on for some years. And of course, they went downhill during that time and we had to actually refresh the group towards the end because*

the person with dementia could no longer participate in a meaningful way" (P6).

Transportation was also a reported barrier for older adults. To overcome this, some researchers had to organize taxis to bring PPI partners to meetings. One interviewee explained that in response to the travel challenges they split their group into two boards, with two distinct localisations in the city in order to minimise the burden of travel.

"We really worked hard to make it easy for them to attend the meetings, so we covered a fairly large area, so we ended up splitting our boards into two. One that was more the inner city. And one that was more the suburbs, because the inner city people didn't want to cross the bridges… and vice versa. It was just. You know, nobody wants to drive more than 15–20 minutes." (P3).

In some cases, retention challenges were put down to a lack of perceived salience, with one interviewee noting that they as researchers needed to first identify what the needs are and then select people that are best placed to meet those needs.

"There was some turnover on the board, you know, people come and go. I think we might not have had the best match at the beginning. You know, we weren't really sure. And then they felt like they weren't really contributing. It wasn't really in their wheelhouse, so, you know, they kind of stepped off and then, you know, we're dealing with older adults with health issues. » (P3).

To overcome the challenge of recruitment, a reported practice was to recruit among existing patient groups such as patient support groups (for specific diseases), or public associations. Recruitment was also eased by the intervention of gatekeepers, meaning people that had the links and trust of the community, and could help identify potential PPI partners.

"One thing that we did is asking pastors to help identify people that would give us good opinions. I think that helps. » (P7).

Importance of a good PPI chair Interviewees highlighted the importance of having a good chair who could accommodate the needs of older adults and facilitate PPI discussions during the PPI activities. This chair was felt to be crucial to ensuring that all PPI partners felt comfortable and could express their opinions. When discussing the skills of the chair, interviewees commented on

Table 3 Rationale, benefits and challenges among trial authors who reported PPI (N=46)

Characteristic	Frequency (%)
Reason for involving patients/public partners in study* (N=44)	
Increased applicability/relevance of research	41 (93.2)
Increased quality of research	34 (77.3)
Increased dissemination/uptake of findings	27 (61.4)
Morally or ethically the right thing to do	27 (61.4)
Funding body requirement/recommendation	19 (43.2)
Increased feasibility or quality of intervention	4 (9.1)
Institutional requirement/recommendation	2 (4.5)
Target journal requirement/recommendation	1 (2.3)
Other	3 (6.8)
Benefits of involving patient/public partners* (N=43)	
Yes	39 (90.7)
Improved/more feasible interventions	26 (66.7)
Increased applicability/relevance of findings	25 (64.1)
Higher quality research	22 (56.4)
Improved recruitment or retention	21 (53.8)
Enhanced relationships/networking with partners	20 (51.3)
Enhanced understanding of condition	19 (48.7)
Increased dissemination or uptake of results	18 (46.2)
Increased participant satisfaction	16 (41.0)
Increased satisfaction of research team	13 (33.3)
Increased accountability or public trust in research	12 (30.8)
Led to identifying knowledge gaps or future research topics	12 (30.8)
More ethically acceptable methods	12 (30.8)
More useful evidence for patients	12 (30.8)
More useful evidence for decision-makers	11 (28.2)
Led to collaboration on other studies	8 (20.5)
Improved data quality	7 (17.9)
Increased funding opportunities	5 (12.8)
No	4 (9.3)
Challenges experienced* (N=43)	
Yes	24 (55.8)
Communicating about trial design, methods, results	15 (62.5)
Identifying or recruiting patient partners	12 (50.0)
Scheduling meetings	11 (45.8)
Sustaining involvement of patient partners throughout the study	11 (45.8)
Clarifying roles and expectations	10 (41.7)
Time commitment	10 (41.7)
Building relationships with patient partners	5 (20.8)
Costs	4 (16.7)
Managing conflicts	3 (12.5)
Study timeline extended	3 (12.5)
Compensation	2 (8.3)
Challenges relating to the intervention development	1 (4.2)
Ill health	1 (4.2)
Representation of population of interest	1 (4.2)
No	18 (41.9)
Don't Know	1 (2.3)

Table 3 (continued)

Characteristic	Frequency (%)
Involving patient partners was a positive experience (N=24 who experienced challenges)	
Strongly agree	21 (87.5)
Somewhat agree	2 (8.3)
Neutral	1 (4.2)
Somewhat disagree	0
Strongly disagree	0

*More than one selection possible

the need for strong communication skills to effectively explain study components and researchers' expectations. Interviewees also noted the need for focus; in case of focus groups or groups meetings, the chair should also have the ability to keep meetings on track.

> *"Crafting focus groups and having facilitators who understand, you know, physical and cognitive needs of older adults. Sometimes, you know, just takes you a little longer to process something. [...] so think of communication skills with older adults is really critical and maybe more personal interviews might be better in some cases." (P7).*
> *«I found the biggest challenge to keep them on track ... But you know, sometimes they would just coming, going completely in their own story. And that is sometimes difficult, but on the other hand it's also understandable because some of them were really very old and not very mobile. So they don't get out very often and they have a whole life behind them. So, they are full of stories. So yeah, you just have to take your time. (P1)*

Indeed, some interviewees described how they had employed professional facilitators for this role. Having another person in the room to observe people's expressions was also described as an enabler and as a "*connector*" (P9) between academics and PPI partners. Additionally, having a patient serve as the chair was suggested to remove barriers and to help minimize power dynamics.

Training PPI partners Some researchers reported the need for PPI partners to receive some kind of training to be able to understand research concepts and methodology. The development of training materials adapted for older adults was also suggested.

> *"It [accessible training materials for older adults] would have been very helpful. So we basically train them on the go. When you ask them, for example, way before, to come in to discuss the design. We had to explain them the implications of why we are doing things a certain way, and explain in lay terms some changes that they would discuss how it would introduce bias and so those types of things, it would be helpful if it was readily available for them and we didn't have to spend so much time. » (P4).*

Workload for researchers and burden for PPI partners Interviewees reported that including PPI in their trial was very time consuming and required additional efforts and sometimes adjustments. Organization and coordination of PPI meetings were also a time burden. Despite this additional workload, researchers believed that PPI was worth the additional efforts.

> *"Well, I mean, just from the logistics of it, it's just time consuming. If you didn't have to do focus groups and public involvement, obviously you'd have more time to do something else. But you know that's not an effective program » (P7).*
> *« Yeah, everything, took more time. So, you know, we had to wait for feedback...When you have something —instead of just creating it and running with it, we always, we take it to the board, wait for their feedback and incorporate it. So that just takes time. » (P3).*

While some researchers reported that time commitment was not an issue for PPI partners, others reported the need to cut back on the number of meetings, or difficulties for partners to read materials they were asked to review.

> *"Burden was not an issue for this group of folks. » (P4).*
> *« It was supposed to meet four times a year but they thought that was too cumbersome and they asked that we cut it back. So, we ended up meeting, I think three times a year » (P3).*
> *« And I think the carers got very stressed too towards the end. The carers... They're not academics and asking them to review written material was probably not reasonable and some of them spat the dummy [reacted in a bad-tempered way] about that and said I can't read anymore, what you sent me. And that's understandable. They're not academics. So you know, it was a learning curve, yeah. [...] now I wouldn't even ask people to review a 5 pages document if they're consumer or carer, unless they expressed a particular interest in doing that. I'd pull out some of the issues out of that document, maybe some paragraphs or something and say how does this sound? » (P6).*

Procedural barriers and enablers Several participants indicated that PPI was a component of the funding call. This enabled compensation for PPI partners for their time and involvement, which researchers deemed important. However, researchers highlighted the need to have preliminary results and relatively precise project ideas to request funding. This may act as a barrier to including PPI in the early project phases, reducing opportunities for PPI partners to impact the project.

> *"What's really hard, of course is when you apply for funding for anything, you had to have done at least some of that research ahead of time. […] So, we had to beforehand sort of pick churches and pick the area where we wanted to work. So that's the, you know, disadvantage of the funding system. We couldn't go to the public and do a lot of research on." (P7).*

Similarly, the termination of funding at the end of a project, coupled with the need to move on to subsequent projects, made it difficult to maintain PPI relationships and activities.

> *"I remember we put a paragraph together for them to disseminate the findings, but then at that time, we did not have time to keep up with that because again, funding came to an end. And as researchers, we have to go out to the next, and the engagement basically had to stop there for lack of resources and lack of time. » (P4).*

One interviewee reported some difficulties related to ethics process because of the need to make some study data available to PPI partners.

> *"Yes, we had to go through ethics to do the PPI because they were going to be data from our study made available to them. Not that we gave them huge tranches of data, but still any data. They were a little unfamiliar back then, […]with the PPI process themselves (ethics) and they were concerned that, even though we were talking about deidentified data, … some of the qualitative data might be identified because these were people living in the community and we were collecting data from people being in the community and then . there was smaller numbers and could they be identified. » (P6).*

On the other hand, PPI partners were also reported to facilitate acceptance of research protocols by ethical committees.

Benefit and impact

Across the interviews seven key aspects of research were identified on the impact that PPI partners had on various stages of the research: influencing aims and outcomes to measure; development of interventions; refining patient-facing materials; recruitment and retention; analysis of findings, and interpretation of results. Below we summarise and provide exemplar quotes.

First, PPI partners influenced decisions around study aims and outcomes to measure.

> *"They said, well, this is really a great question, but once the research is done and your staff leaves, we're left with nothing. Can we modify the study to include a secondary aim, they didn't say aim, they said: Could we also look at you training someone at our facility to do the program? And so when… I don't think it was published in that article, but it was part of the main study part of the grant, where our secondary aim was looking at the outcomes of the intervention delivered by someone we trained at the facility. That research question, which was important to these sites came out of discussions with the sites" (P3).*
>
> *"We also ask them to look at what outcomes are collected, if those, especially the performance-based battery, if those are important for them. I will give you a very cute example. Participant said: oh, you know what, these are all good. These [outcomes] are all very good, but I have a hard time to sit on the floor and come up to play with my grandkids. And that's ugly. […] So it forces us to think a little bit outside the box and find other tests and measures that would be more applicable to reflect the complaints [sitting on the floor to play with grandkids] that patients had about their functional limitation." (P4).*

Second, PPI partners impacted the development of the interventions tested. This occurred through intervention development, pilot-testing, and refinement.

> *"So, for example, Tai Chi programs, while in some places would be very appropriate, in churches, we did have push back if when the pastor said is this like an eastern religion program? Because we were going to bring classes in a lot of cases into the church building, and they, sort of unexpected for us, had questions about feeling, you know, yoga, Tai chi, like that might be against how they felt there are there. It might be a religious program to them. […] I think if we had not had that participation with that part of the public, we could have picked a, you know Tai Chi as our program and then found that we couldn't get it into a lot of the churches, and that would have*

meant that we weren't getting a random sampling of churches that way." (P7).

Third, they impacted language, terminology and design across various documents, such as flyers for recruitment, intervention materials, questionnaires used for outcome measures or study information and consent forms. This was important to identify information and strategies that otherwise may not have been known to the researchers but likely made significant impacts on the success of recruitment approaches.

"So, when we created our recruitment flyers, we took it to the board and said does this make sense, would you do this and the older adults were like: we don't like the word older adults. Don't say that this is a program for an older adult. Say that you're looking for people 65 years of age and older. They're like, describe it. Don't label us. Yeah, and ohh we don't like this artwork or this print is too hard for us to read." (P3).

"So in medicine we have diagnosis management, and management. That's two main headaches, right, that everybody knows, don't they? So then I had these people on the other end of the phone. We don't want to be managed. Well, have you got management in there? We're not trying to be managed. You know nothing about us without us, we're not going to be managed. Don't you go telling us what to do. And that was really awkward because I had to kind of revisit my whole way of looking at the world, having done medicine quite a long time ago and always used that word without even thinking twice." (P6).

Fourth, in a more advanced PPI practice, one interviewee reported that PPI partners were sometimes involved in the analysis plan through selection of covariates for their analyses and of risk threshold.

"They needed to decide what risk factors would go into a model. So we presented them with ten that we thought were candidate once from the literature, and then we asked them to talk freely about what they thought was important. And we actually captured several that we haven't thought of. And we added them to our model. They actually helped select the candidate covariates of a clinical risk prediction model. And that took three sessions, probably to cover that. They also had to determine the risk of progression threshold and that was really quite challenging. Because they had to choose, we had to get them to talk about risk." (P9).

Fifth, PPI partners sometimes contributed to recruitment and retention strategies of study participants or study sites.

"At times they acted as kind of champions for the program, So they helped us recruit at the sites. They would spread the word. Some of them even identified additional sites that we could go to, so they were a real wealth of information and knowledge." (P3).

Sixth, researchers reported that PPI partners were sometimes involved in interpreting the results of the study to maximize impact on older adult patients who may benefit from the research findings.

"And I think with the interpretation of the results as well. That was an important aspect to hear their understanding of the results and their perspective." (P4).

Seventh, PPI partners contributed to the dissemination of the results, in particular to lay audiences, and in the selection of results to present that may be especially relevant to older adults.

"Also for implementing the results it's very important that you know what elements the older adults find important. So you can put an emphasis on that if you want to disseminate the results. So I have found it very pleasant to do it in that way. » (P1).

Some researchers reported that PPI partners input went beyond their expectations, and that unexpected input was sometimes even more valuable than input on what they asked for. Interestingly, life experience of participants beyond their experience of the health condition was valued in PPI activities and sometimes provided unexpected benefits.

"We developed a training manual that could be used to train future instructors of the [PROGRAM NAME], as a result of the trial and as we were putting the manual together, I had never done anything like that, one of our older adult stakeholders, one of the few men on the board, he said to me: I spent my life developing training manuals for my company. Do you want me to take a look at your manual? He goes. I'll read through it and give you suggestions and you know… Like I would have, I would never have thought to ask them to do that, but here is a gentleman who's spent probably the last 40 years of his life doing just that. And so we printed off a copy, sent it to him… So those are things that we weren't looking for but were pleasant surprises." (P3).

Discussion

In the present study, we found that PPI was reported in less than half of the trials involving older adults. Both survey and interview data revealed that PPI offers significant perceived benefits, particularly in developing interventions, as well as in other areas of trial design and implementation. These findings align with those of a previous survey of 64 researchers in aging and health, where 58% of researchers reported experience involving users in diverse research activities, primarily to optimise research relevance [34]. Most respondents (86%) acknowledged benefits of user involvement, though 59% also cited challenges.

Although our study was not designed for formal comparisons with other trial populations, our findings on why, when, and how PPI was conducted—and on researchers' perceptions of its challenges, benefits, and impact in older adult trials—closely aligned with the full survey results published elsewhere [27] Across both samples, the main reasons for involvement, forms of involvement, perceived benefits, and challenges showed similar top categories and comparable frequencies, suggesting that PPI in trials involving older adults is not fundamentally different from PPI in other populations. This is consistent with the literature [24] and with similar work conducted in paediatric trials [35].

More than half of survey respondents reported challenges in involving older adults in PPI, many of which align with barriers documented in the PPI literature in both general and older populations [36–38]. For example, a survey of researchers and older adults involved in ageing and health research found that 59% identified challenges; these included resource demands, recruitment and sustaining participation, representativeness, and the meaningful involvement of older adults [34]. These findings are consistent with our survey and interview results. Importantly, some perceived challenges may be more pronounced or particular within older populations and therefore warrant targeted consideration. In our survey, a higher proportion of respondents reported difficulties communicating aspects of trial design, methods, and outcomes when engaging older adults (62.5%) compared with respondents in the parent survey (40.4%). Kylen et al. also identified fatigue and short-term memory loss among older adults with advanced chronic conditions as perceived barriers to effective involvement [34]. Multimorbidity and the increased complexity associated with cumulative health conditions—both more prevalent in older adults—may contribute to these difficulties [23, 34].

One prominent challenge noted was the difficulty in recruiting and retaining PPI partners. Lessons from our research and other recent studies suggest that a flexible approach is needed [25]. For instance, working with the same group of patients throughout an entire project may not be realistic, especially if the study is prolonged and demands high levels of commitment, or if the study involves PPI partners with dementia [39]. This may also apply to other groups where the eligibility is based on transient characteristics, such as children and youth. Arranging groups so as to minimise burden related to transportation is also valuable. In their framework, which promotes meaningful engagement of older adults and their caregivers, McNeil et al. recommend that accessibility issues need to be addressed in early stages for engagement opportunities to be successful [24].

Another key perceived challenge was the need for skilled facilitation, which more broadly refers to the method used by researchers to involve PPI partners. According to our survey data, group discussions were the primary method of involvement. Such groups require effective facilitation to ensure productive outcomes. They may not be ideal activities for people with communication impairments for example, and recent literature highlights the pressing need for a wider repertoire of methods to choose from when involving older people in research [18, 40, 41]. Interestingly, a recent study employed activity providers—staff already working in care homes—as facilitators, rather than trained researchers [42]. This approach has several advantages: activity providers can leverage their in-depth knowledge of residents, and being onsite, they are familiar with the care home routine. This familiarity allows them to integrate sessions into pre-existing schedules and offer flexibility in session timing. As a result, activity providers were able to involve a larger number of residents in the research process.

Approximately half of the trials surveyed reported no PPI, a proportion potentially underestimated due to non-response bias. The most commonly cited reason was a lack of knowledge about PPI—what it entails, why it is important, and how to implement it. This knowledge gap was evident in both survey responses and interviews. The second most commonly reported reason was the lack of formal requirements to involve PPI partners. While PPI expectations have been established for some time in the UK, Canada and US, they are more recent in other countries. These findings suggest that increasing researchers' awareness, knowledge and skills related to PPI, as well as encouraging funding agencies to mandate and support PPI, could enhance its implementation in research - although direct evidence for this remains limited.

In both survey and interview data, we found that reasons for involving patients reflected both what Concannon has described as "instrumental" and "ethical/intrinsic" motivations [43]. While many researchers emphasized practical benefits, such as improving research quality and relevance, a substantial proportion (over 60% in the present survey) explicitly highlighted the ethical imperative of involving patients to ensure

that research addresses what matters to them or treats them fairly. This dual perspective highlights the complex nature of PPI, which integrates both practical and ethical considerations [40]. It also underscores the need for a comprehensive approach when evaluating PPI. Assessments cannot be limited to empirical impact alone, as this focuses solely on instrumental aspects, nor can they rely exclusively on perceptions of inclusion, which may overlook contributions to research outcomes.

Our findings on perceived benefits should be interpreted with the understanding that they reflect the views of respondents who had conducted PPI; nevertheless, they illustrate the valuable contributions that older adults and caregivers can make to the design, implementation, and dissemination of clinical research. Notably, and as a novel finding, older age—through accumulated life experience—was identified as a factor that can shape and enrich impact. While the literature describing PPI with older adults is growing [44–46], and recent trials have begun to report such involvement [47, 48], evidence assessing the impact of PPI specifically within older adult trials remains limited. Further research is needed to better quantify these benefits and to advance best practices and tools that support active and meaningful involvement of older adults in clinical trials [49, 50].

The present study has several strengths and limitations. It is one of the first studies that employs a multimethods approach to offer in-depth insights into the practices, perceived benefits, and challenges of PPI in the context of older adults, which is a relatively underresearched area. The qualitative themes provided valuable supplemental detail regarding specifics of PPI older adult health research. This study focused on trials published between 2014 and 2019, which may not fully capture recent developments in PPI practices, though the interviews captured contemporary reflections of trialists on their past work. The response rate, while reasonable, may still introduce bias, as those who chose to respond might have different experiences with or views on PPI compared to non-respondents. Also, though definitions of PPI and "older adult" were provided to survey respondents, responses were occasionally incongruent with these definitions. While 'older adult' was defined by age for this study, we acknowledge the significant heterogeneity within this group—spanning differences in health, mobility, and engagement capacity. Additionally, surveying and interviewing PPI partners could have provided valuable complementary perspectives, as their experiences may differ from those of researchers. Finally, the number of interviews was small and new themes continued to emerge in the final interviews, indicating that data saturation was not reached and that additional themes or insights might have been missed. Interviewing authors of trials not exclusively involving older adults might have yielded additional data, though potentially at the expense of specificity.

Conclusion

In conclusion, this study highlights the significant yet underutilized role of PPI in pragmatic trials involving older adults. While PPI offers numerous perceived benefits, such as improved intervention design and recruitment of trial participants, several challenges remain, both general and specific to older adults. Overcoming these challenges may require flexible or even innovative strategies, ultimately enhancing PPI uptake and improving the quality and relevance of research.

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

Supplementary Material 5

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Authors' contributions

Study concept and design: AS, MT, SV, SN • Data collection, survey: MT, PN • Data collection, interviews: KB, JH, AS • Data curation and analysis, survey: PN, MT, AS • Data transcription and analysis, interviews: PE, SN, AS • Data interpretation: all authors • Drafting of the manuscript: AS, PE, TA • Critical revision of the manuscript for important intellectual content: all authors• Approval of manuscript: all authors.

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Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study adhered with the Declaration of Helsinki and was approved by The Ottawa Health Science Network Research Ethics Board (20210684-01H). For all participants, informed consent was obtained to participate in the study.

Consent for publication

Not applicable

Competing interests

The authors declare no competing interests.

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References

1. (CIHR) CIoHR. Patient engagement 2019 [Available from: https://cihr-irsc.gc.ca/e/45851.html
2. Cornwall A, Jewkes R. What is participatory research? Soc Sci Med. 1995;41(12):1667–76.
3. National Insitute for Health and Care Research (NIHR). Briefing notes for researchers - public involvement in NHS, health and social care research 2021 [updated May 2024. Available from: https://www.nihr.ac.uk/briefing-notes-researchers-public-involvement-nhs-health-and-social-care-research
4. The INVOLVE Advisory Group - National Institute for Health Research (NIHR). What is public involvement in research? [Available from: https://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/
5. Fergusson D, Monfaredi Z, Pussegoda K, Garritty C, Lyddiatt A, Shea B, et al. The prevalence of patient engagement in published trials: a systematic review. Res Involv Engagem. 2018;4:17.
6. Hoddinott P, Pollock A, O'Cathain A, Boyer I, Taylor J, MacDonald C, et al. How to incorporate patient and public perspectives into the design and conduct of research. F1000Res. 2018;7:752.
7. The Patient-Centered Outcomes Research Institute (PCORI). The PCORI Strategic Plan 2022 [cited 2023. Available from: https://www.pcori.org/about/about-pcori/pcori-strategic-plan
8. The Canadian Institutes of Health Research (CIHR). Strategy for Patient Oriented Research 2019 [Available from: https://cihr-irsc.gc.ca/e/48413.html
9. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ (Clinical Res ed). 2021;374:n2061.
10. National Insitute for Health and Care Research (NIHR). Involve patients 2025 [Available from: https://www.nihr.ac.uk/health-and-care-professionals/engagement-and-participation-in-research/involve-patients.htm
11. Holland Bloorview. Research Family Engagement Committee [Available from: https://hollandbloorview.ca/get-involved-give/family-leadership-program/research-family-engagement-committee
12. CHILD-BRIGHT Network. What is Patient-Oriented Research? [Available from: https://www.child-bright.ca/what-is-patient-oriented-research
13. Nicholls SG, Campbell MK. Embedding Patient and Health Care Professional Voices in Clinical Trials. JAMA. 2024;332(5):365–6.
14. Benizri N, Hallot S, Burns K, Goldfarb M. Patient and Family Representation in Randomized Clinical Trials Published in 3 Medical and Surgical Journals: A Systematic Review. JAMA Netw Open. 2022;5(9):e2230858.
15. Musbahi A, Clyde D, Small P, Courtney M, Mahawar K, Lamb PJ, et al. A Systematic Review of Patient and Public Involvement (PPI) in Bariatric Research Trials: The Need for More Work. Obes Surg. 2022;32(11):3740–51.
16. Estrup S, Barot E, Mortensen CB, Anthon CT, Crescioli E, Kjaer MN, et al. Patient and public involvement in contemporary large intensive care trials: A meta-epidemiological study. Acta Anaesthesiol Scand. 2023;67(3):256–63.
17. Backhouse T, Kenkmann A, Lane K, Penhale B, Poland F, Killett A. Older care-home residents as collaborators or advisors in research: a systematic review. Age Ageing. 2016;45(3):337–45.
18. McArthur C, Alizadehsaravi N, Quigley A, Affoo R, Earl M, Moody E. Scoping review of methods for engaging long-term care residents living with dementia in research and guideline development. BMJ Open. 2023;13(4):e067984.
19. Ludwig C, Graham ID, Gifford W, Lavoie J, Stacey D. Partnering with frail or seriously ill patients in research: a systematic review. Res Involv Engagem. 2020;6:52.
20. Puts MTE, Sattar S, Ghodraty-Jabloo V, Hsu T, Fitch M, Szumacher E, et al. Patient engagement in research with older adults with cancer. J Geriatr Oncol. 2017;8(6):391–6.
21. McIsaac DI, Fergusson DA, Khadaroo R, Meliambro A, Muscedere J, Gillis C, et al. PREPARE trial: a protocol for a multicentre randomised trial of frailty-focused preoperative exercise to decrease postoperative complication rates and disability scores. BMJ Open. 2022;12(8):e064165.
22. Bethell J, Commisso E, Rostad HM, Puts M, Babineau J, Grinbergs-Saull A, et al. Patient engagement in research related to dementia: A scoping review. Dement (London). 2018;17(8):944–75.
23. Holroyd-Leduc J, Resin J, Ashley L, Barwich D, Elliott J, Huras P, et al. Giving voice to older adults living with frailty and their family caregivers: engagement of older adults living with frailty in research, health care decision making, and in health policy. Res Involv Engagem. 2016;2:23.
24. McNeil H, Elliott J, Huson K, Ashbourne J, Heckman G, Walker J, et al. Engaging older adults in healthcare research and planning: a realist synthesis. Res Involv Engagem. 2016;2:10.
25. Burgher T, Shepherd V, Nollett C. Effective approaches to public involvement in care home research: a systematic review and narrative synthesis. Res Involv Engagem. 2023;9(1):38.
26. Taljaard M, Weijer C, Grimshaw JM, Ali A, Brehaut JC, Campbell MK, et al. Developing a framework for the ethical design and conduct of pragmatic trials in healthcare: a mixed methods research protocol. Trials. 2018;19(1):525.
27. Vanderhout S, Nevins P, Nicholls SG, Macarthur C, Brehaut JC, Potter BK, et al. Patient and public involvement in pragmatic trials: online survey of corresponding authors of published trials. CMAJ Open. 2023;11(5):E826–37.
28. Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in therapeutical trials. J Chronic Dis. 1967;20(8):637–48.
29. Nicholls SG, Carroll K, Hey SP, Zwarenstein M, Zhang JZ, Nix HP, et al. A review of pragmatic trials found a high degree of diversity in design and scope, deficiencies in reporting and trial registry data, and poor indexing. J Clin Epidemiol. 2021;137:45–57.
30. Gamble C, Dudley L, Allam A, Bell P, Goodare H, Hanley B, et al. Patient and public involvement in the early stages of clinical trial development: a systematic cohort investigation. BMJ Open. 2014;4(7):e005234.
31. Crocker JC, Pratt-Boyden K, Hislop J, Rees S, Locock L, Olszowski S, et al. Patient and public involvement (PPI) in UK surgical trials: a survey and focus groups with stakeholders to identify practices, views, and experiences. Trials. 2019;20(1):119.
32. Wilson P, Mathie E, Keenan J, McNeilly E, Goodman C, Howe A, et al. Health Services and Delivery Research. ReseArch with Patient and Public invOlvement: a RealisT evaluation – the RAPPORT study. Southampton (UK): NIHR Journals Library; 2015.
33. McAllister M, Payne K, MacLeod R, Nicholls S, Donnai D, Davies L. Patient Empowerment in Clinical Genetics Services. J Health Psychol. 2008;13(7):895–905.
34. Kylén M, Slaug B, Jonsson O, Iwarsson S, Schmidt SM. User involvement in ageing and health research: a survey of researchers' and older adults' perspectives. Health Res Policy Syst. 2022;20(1):93.
35. Vanderhout S, Taneja S, Nevins P, Nicholls SG, Potter BK, Smith M, et al. Patient and Public Involvement in Paediatric Pragmatic Randomized Controlled Trials: A Mixed Methods Study. Children. 2025;12(12):1638.
36. Agyei-Manu E, Atkins N, Lee B, Rostron J, Dozier M, Smith M, et al. The benefits, challenges, and best practice for patient and public involvement in evidence synthesis: A systematic review and thematic synthesis. Health Expect. 2023;26(4):1436–52.
37. Easley J, Wassersug R, Matthias S, Tompson M, Schneider ND, O'Brien MA, et al. Patient Engagement in Health Research: Perspectives from Patient Participants. Curr Oncol. 2023;30(3):2770–80.
38. Selman LE, Clement C, Douglas M, Douglas K, Taylor J, Metcalfe C, et al. Patient and public involvement in randomised clinical trials: a mixed-methods study of a clinical trials unit to identify good practice, barriers and facilitators. Trials. 2021;22(1):735.
39. Cowdell F, Dyson J, Sykes M, Dam R, Pendleton R. How and how well have older people been engaged in healthcare intervention design, development or delivery using co-methodologies: A scoping review with narrative summary. Health Soc Care Commun. 2022;30(2):776–98.
40. Hultqvist S, Hanson E, Jönson H, Slaug B, Iwarsson S. Why involve older people in research? Revisiting Alan Walker's earlier editorial based on recent

experiences from the UserAge research programme. Res Involv Engagem. 2023;9(1):81.
41. Conway E, MacEachen E, Middleton L, McAiney C. Use of adapted or modified methods with people with dementia in research: A scoping review. Dement (London). 2023;22(8):1994–2023.
42. Micklewright K, Killett A, Akdur G, Biswas P, Blades P, Irvine L, et al. Activity provider-facilitated patient and public involvement with care home residents. Res Involv Engagem. 2024;10(1):7.
43. Zimmerman E, Concannon TW. Evaluating Engagement: Does the Involvement of Stakeholders Improve Research? 2021. Thousand Oaks, California: SAGE Publications, Inc. Available from: https://methods.sagepub.com/book/edvol/researching-health-together/toc
44. Doucette L, Kiely BT, Gierisch JM, Marion E, Nadler L, Heflin MT, et al. Participatory research to improve medication reconciliation for older adults in the community. J Am Geriatr Soc. 2023;71(2):620–31.
45. Baldwin JN, Napier S, Neville S, Wright-St Clair VA. Impacts of older people's patient and public involvement in health and social care research: a systematic review. Age Ageing. 2018;47(6):801–9.
46. Rogers WA, Kadylak T, Bayles MA. Maximizing the Benefits of Participatory Design for Human–Robot Interaction Research With Older Adults. Hum Factors. 2022;64(3):441–50.
47. Bradbury AW, Hall JA, Popplewell MA, Meecham L, Bate GR, Kelly L, et al. Plain versus drug balloon and stenting in severe ischaemia of the leg (BASIL-3): open label, three arm, randomised, multicentre, phase 3 trial. BMJ. 2025;388:e080881.
48. Cooper C, Vickerstaff V, Barber J, Phillips R, Ogden M, Walters K, et al. A psychosocial goal-setting and manualised support intervention for independence in dementia (NIDUS-Family) versus goal setting and routine care: a single-masked, phase 3, superiority, randomised controlled trial. Lancet Healthy Longev. 2024;5(2):e141–51.
49. The Lancet Healthy L. Increasing patient and public involvement in clinical research. Lancet Healthy Longev. 2024;5(2):e83.
50. Walter S, McArdle R, Largent EA, Edelmayer R, Sexton C, Sandoval SL, et al. Public and participant involvement as a pathway to inclusive dementia research. Alzheimer's Dement. 2025;21(1):e14350.

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