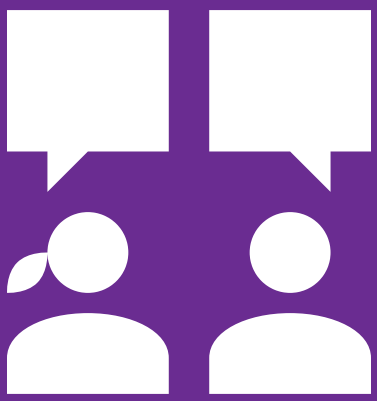
Towards Meaningful Connections with Participants:

Assessing two-way engagement strategies in clinical research



Prepared by
Matilda Haas and Rosie Brown
2023

Table of Contents

Published by: CT:IQ

Acknowledgement of Country

CT:IQ acknowledges Aboriginal and Torres Strait Islander peoples as the traditional custodians of the land on which we meet, work and learn. We pay our respects to Elders past and present.

Executive Summary

An estimated 20% of clinical trials close without having reached 85% of their enrolment goals (1), meaning that many trials close or are abandoned without reaching their recruitment targets. They also experience difficulties with retaining participants over time. This may be because they do not engage effectively with their participants. Trials that fail to reach recruitment targets and retain participants finish with incomplete or lower-quality data. However, having a performance record of successful trials is imperative as Australia positions itself as a globally competitive clinical trials hub (3).

'Beyond the Form', a joint project of CT:IQ and the VCCC Alliance, is looking for high value but achievable ways to improve participant engagement.

Evaluating previously trialled engagement strategies will save valuable time and resources when designing new approaches. This white paper explores the questions "which two-way engagement strategies or interventions have been trialled?", "what were the evaluation outcomes?" and "what policy or guidelines on two-way engagement strategies for research are available in Australia?".

The findings are based on systematic evaluation of engagement and communication strategies. 'Rapid evidence review' methodology was used to explore academic literature, supplemented by an internet-based search to also fulfil the aim of determining if there were any relevant Australian policies and guidelines to support researchers in this area.

The report finds that engagement strategies have been used throughout the life cycle of clinical research - during recruitment, for retention, completion of study tasks and dissemination. Strategies to engage with minority, underrepresented or underserved populations were a significant focus. Evaluation and impact measures need development, as do policies and guidelines fit for the Australian context.

We set out eight recommendations to inform development of new approaches to engage participants in clinical research:

- Co-design engagement interventions with and specifically for the target participant group
- Where using digital interventions, pair them with personal interactions
- Offer multiple modes of communication and engagement
- Employ study personnel from the community that the target participant group belongs to, and immerse them in the community
- Consider providing individualised feedback and study results
- Embed evaluation of engagement strategies in clinical research
- Consider a dissemination strategy that includes participants and the public
- Include engagement strategies at the funding proposal, funding agreement and research protocol stages

Recommendations

1. Co-design engagement interventions with and specifically for the target participant group

Engagement interventions are more likely to work if they are co-designed with the populations that will be involved in the research. They will bring unique perspectives not anticipated by researchers. Co-designed interventions should be piloted, evaluated, and iteratively adapted prior to widespread implementation.

2. Where using digital interventions, pair them with personal interactions

While digital interventions are increasingly used, they are likely to be more successful when paired with personal interactions. This includes familiarising participants with how to use digital tools at the beginning of the study, but also supplementing tasks that participants carry out using digital tools with personal interactions.

3. Offer multiple modes of communication and engagement

Participants in research have individual needs and preferences when it comes to communication. There will unlikely be a one-size-fits-all approach, so it is important to ask individual preferences upfront. Different formats can then be used for individual contact preferences (e.g. phone call, text message, email), as well as for communicating study information (written, videos, voice recordings, graphics). Ensure that different modes of communication are integrated to avoid repeated messages.

4. Employ study personnel from the community that the target participant group belongs to, and immerse them in the community

Research participants relate best to study personnel who understand their needs, concerns, motivations, and barriers to participation. Developing rapport and trust with study personnel from their own community can lead to improved study outcomes.

5. Consider providing individualised feedback and study results

In some clinical research, participants will desire real-time feedback from their study data. This can be to inform their own health, or as a comparison with other study participants' data. Care must be taken in the design of feedback so it doesn't become a study intervention or influence study outcomes.

6. Embed evaluation of engagement strategies in clinical research

Developing an evaluation plan for engagement strategies at the beginning of a study will ensure outcomes and impact are able to be measured via collection of relevant data from the outset. Importantly, research teams should first consider utilising existing relevant evaluation frameworks to allow the building of evidence via standardised approaches in this relatively new area.

7. Consider a dissemination strategy that includes participants and the public

Research that is only published in academic journals is unlikely to reach the people who were involved in and are impacted by the outcomes. Plan to disseminate research through policy briefs, social and traditional media, study newsletters, and community events with presentations by the research team. Allow time and space to receive feedback.

8. Include engagement strategies at the funding proposal, agreement and research protocol stages

Engagement strategies can be resource intensive, and as such should be incorporated into study protocols. They may not be fully designed by the time funding proposals are submitted, considering co-design with the participant population is recommended. However, writing a budget into funding proposals demonstrates commitment to following through with engagement plans.

Introduction

Health and medical research, including clinical trials (collectively referred to as clinical research), bring great promise to society through access to new and innovative medical technologies and treatments. However, many trials close or are abandoned without reaching their recruitment target and experience difficulties with retaining participants over time.

An estimated 20% of clinical trials close without having reached 85% of their enrolment goals, and many trials must extend the trial period to reach higher rates of recruitment (1). That figure may be even higher since the COVID-19 pandemic (2).

However, having a performance record of successful trials is imperative as Australia positions itself as a globally competitive clinical trials hub (3).

One reason trials may fail to reach recruitment targets is because they do not engage effectively with their participants. The success of trials that fail to engage participants may be compromised – they may finish with incomplete or low-quality data that don't reach statistical power and so the findings cannot be used. This has financial and policy implications and is also an ethical issue since neither the individuals who participate or the community benefit from the research (4).

Engagement is critical for reaching diverse participant populations, reducing obstacles to participation, building trust and transparency, participant knowledge, and empowerment ((5) Figure 1). Engaged participants also potentially have a greater willingness to participate in research again (Figure 2). The other advantage is research participants can turn into active community agents who further disseminate study findings and engage with political leaders and policy makers (6).

It is no longer acceptable to extrapolate findings from a participant group that has different characteristics to the target population and so diversity in research needs to be prioritised. Taking the time and effort to build rapport with communities also works toward dismantling the notion of 'helicopter research' where the community researched receives little to no benefit from the findings (7).

However, minority and underrepresented groups can experience barriers to participation, including mistrust, time and financial constraints, fear of unintended outcomes, limited access to tailored information, stigma about participating in research, fear of discrimination, and fears about impact on their immigration status (6).

We anticipated that in the past few years there has been a proliferation of engagement and communication strategies implemented and evaluated in various research settings. Piloting these strategies can be time and resource intensive and therefore learning from other reported and evaluated strategies is an excellent place to start when designing engagement strategies. This paper has been developed based on a systematic, rapid evidence review (see Appendices) and seeks to determine:

- Which two-way engagement strategies or interventions have been trialled?
- What were the evaluation outcomes? and
- What policy or guidelines on two-way engagement strategies for research are available in Australia?

This paper focuses on participant engagement, which is distinct from participant involvement ((1, 8) Figure 3).

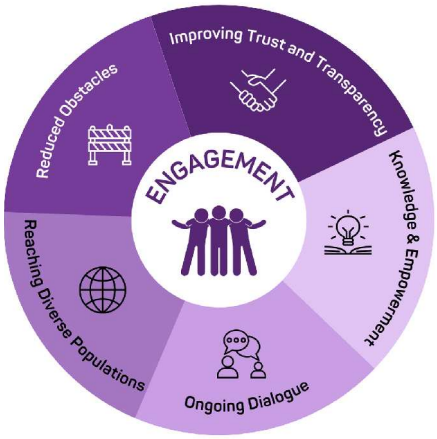


Figure 1: Advantages of effective engagement in research

"I encourage everyone to consider a clinical trial – it is a positive decision you can make, particularly when you have poor health or your quality of life is reduced."

~ Sarah Lukeman, Consumer Representative

Figure 2: Active Community Agent

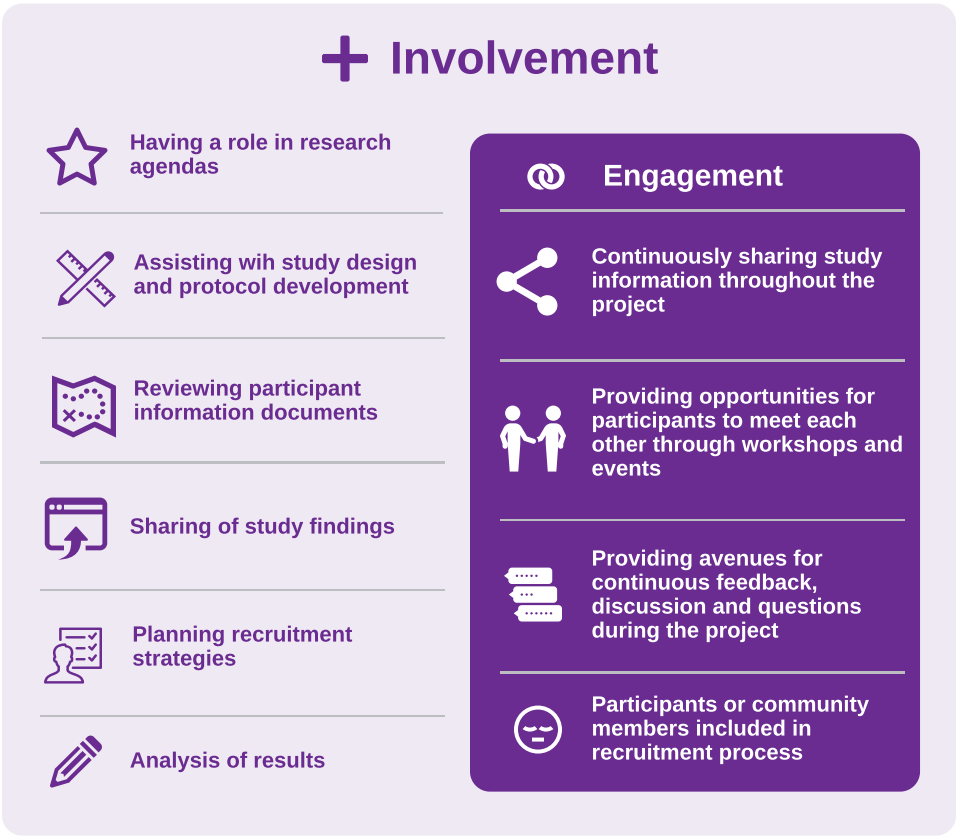


Figure 3: Participant roles in involvement strategies in comparison to research participant engagement strategies

Problem Statement

Clinical research that fails to engage participants well can be less effective and can lead to waste in research funding. At worst, they can alienate individuals and communities from the research process and conclude with insufficient data to produce reliable findings. An evaluation of previously trialled engagement strategies will save valuable time and resources when designing new approaches. This white paper systematically evaluates engagement and communication strategies and draws upon the evidence to propose recommendations for research organisations.

Approach

'Rapid evidence' systematic review methodology was used to explore the evidence to inform development of new approaches to engaging participants in clinical research. An internet-based search supplemented the findings from the academic literature and had the additional aim of seeking relevant Australian policies and guidelines. Data extraction and content analysis were framed by the three research questions and inclusion and exclusion criteria, from which a narrative synthesis was developed.

We found that engagement strategies for improving participant engagement have been used throughout the life course of research and clinical trial programs - during recruitment, for retention, completion of study tasks and dissemination. Strategies to engage with minority, underrepresented or underserved populations were often a focus. Evaluation and impact of engagement methods were not consistently reported, and policies and guidelines for the Australian context were lacking (Figure 4).

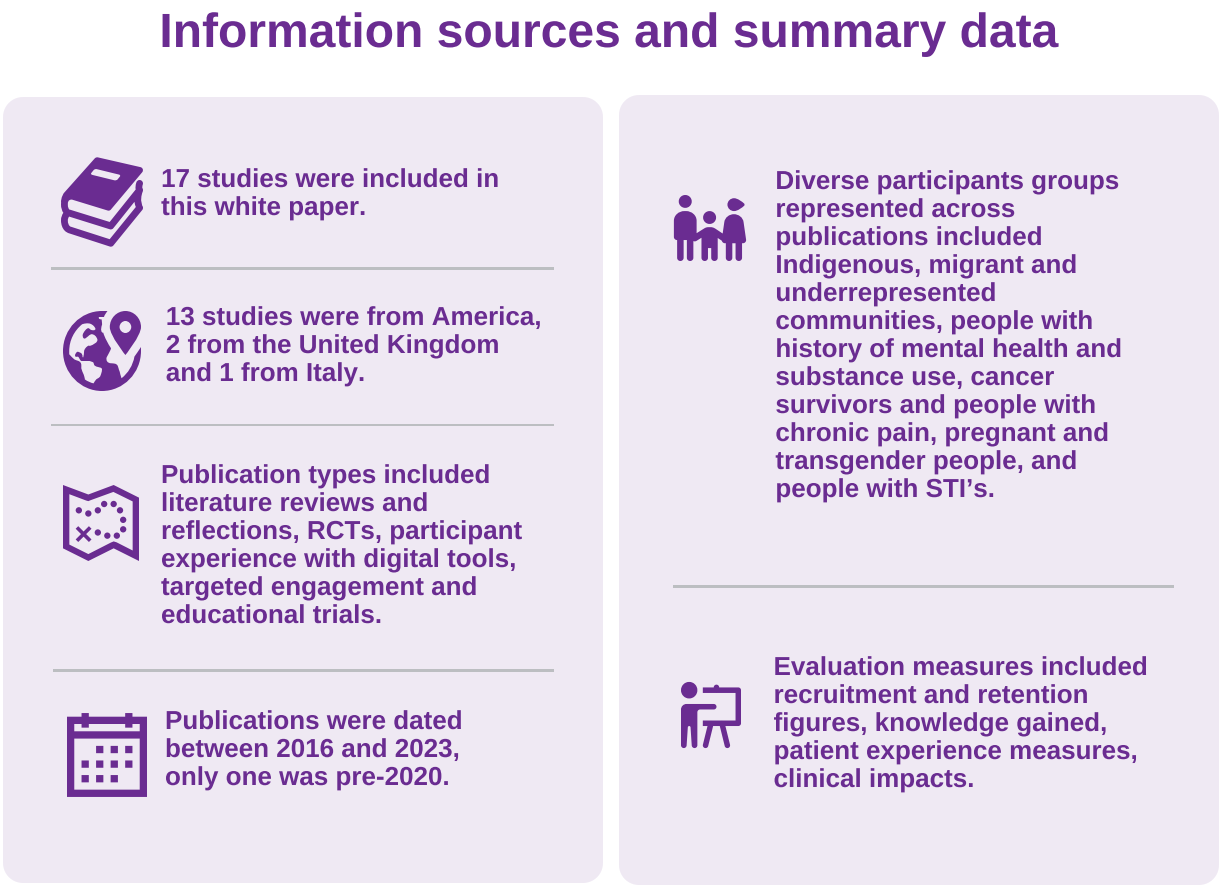


Figure 4: Summary of information sources and data characteristics

Improving Participant Engagement

Recruitment

The earliest stages of research planning should involve careful consideration of recruitment strategies. Recruitment should be inclusive, community-based, culturally tailored, and accommodate people's questions and concerns. Enhancing accessibility and acceptability should be priorities (5). Researchers should regularly revisit their recruitment strategies to assess potential biases, ethical considerations, and privacy issues (7). Stakeholders should be involved in decisions related to study design and materials, recruitment and retention procedures and timelines. This will improve the chances of successful recruitment (7).

Involving the target community

Collaboration and co-design with the community in which the research is being carried out is widely viewed a key to success (5, 6, 7, 9, 10, 11, 12, 13, 14, 15). Organisations embedded in communities have been identified as trusted messengers (5) and engaging community organisations by having them attend public cultural events, health fairs and other events, as well as health clinics, places of worship (9, 16) and language services (9) may help boost enrolment. In this role they can work with the study team to communicate research opportunities, being able to identify with and discuss the potential risks and benefits of research that are of importance to their community (5). Having bi- or multi-lingual research team members that live in the communities where participants are being recruited adds additional value to engagement efforts (9). Efforts to engage the community should be paired with establishing an enthusiastic and diverse research team with community-relevant experiences (7).

Building flexibility into the recruitment strategy

Incorporating flexibility into the recruitment process increases the chances of successful recruitment and is necessary to ensure recruitment remains accessible. For example, a single trial can facilitate options for enrolling participants in person, by telephone, or videoconferencing. The preferences of participants can be on a study-by-study basis or an individual basis, and so it is worth using consultation strategies to find out what types of recruitment will be most suited to the target recruitment population.

Digital recruitment

Increasing in frequency are methods to boost recruitment such as postings on and paid advertisements through social media sites (with geofencing) (7, 16), developing websites, and holding informational webinars (16). In the Canadian arm of a COVID-19 treatment study, its toll-free hotline number was included as a news ticker under the daily COVID-19 government news conference, which served to improve trust in the study at the same time as promoting it to a wide audience (16).

Multiple studies have shown that web-based recruitment strategies are most successful when paired with interpersonal engagement (6, 9, 14, 17, 18), and despite the increasing use of digital recruitment strategies, in at least one reviewed study the most effective recruitment approach was snowball sampling, where study participants recruited others via word-of-mouth (16).

There are additional considerations with web-based strategies. It must be determined whether virtual recruitment is culturally appropriate, as well as adhering to procedural, legal, and ethical considerations (7). They also need to consider how to confirm identity, check for data integrity and incorporate strategies to prevent fraudulent enrolment (7). Studies with digital recruitment can be especially vulnerable to multiple enrolments where there are cash incentives to participate (19).

Digital intervention studies can use a 'run-in and withdrawal design', where participants are only randomised if they are still active after an initial screening phase. Many digital studies face high dropout early in the study, so postponing randomisation until after this phase maintains intervention and control group numbers (20).

Feasibility and acceptability of virtual and web-based recruitment methods should be tested with a broad range of stakeholders through community consultation with citizen scientists, community champions, and health care professionals (7).

Dynamic consent

Dynamic consent provides participants with the opportunity to better engage in research by providing a way to update their personal details and manage preferences about secondary use of their health or research data (21) and re-contact for sub-studies and new research opportunities (22). It can also serve as a platform for ongoing communication between themselves and the study team (21). It can be used to tailor information to the needs of individual participants (17). Dynamic consent is gaining much attention as a promising tool for these reasons. However, whilst solving some of the issues with current static consent mechanisms, elements of dynamic consent need to be carefully considered for it to be effectively implemented.

Accommodations must be made for participants who struggle to access information digitally (9). Demonstrating the value of co-design with participants in the development of a dynamic consent tool, users with vision problems have provided valuable feedback on what colour schemes and themes were most suitable, including the best design for those who used screen readers (10). Other important study design elements such as how the participant is receiving the study information, the duration of the study, whether there are questionnaires or surveys and how the participant choices will be updated and saved need to be considered when planning to implement dynamic consent (21).

Telephone recruitment

Telephone recruitment is a practical method for many study designs (2, 6, 9, 16). For effective telephone (and email) outreach, the development of standardised scripts is essential (16). Scripts should undergo iterative development, including review by a communications specialist. Study personnel should be trained in conversational delivery, and periodically assessed by integration of an assessor into the call list so that performance feedback can be provided (16).

With telephone recruiting, managing practical obstacles to recruitment can be impactful. There is potential for participants to decline an unrecognised telephone number when study personnel call. Therefore, ensuring all study team telephone calls are identifiable as the research organisation on the recipient's end is helpful (16). In one study, participants were asked to save research team contact information on their phones at enrolment (2). Developing recruitment material that could be delivered via text messaging (16) is another option. Having research personnel immediately call a participant to complete orientation after they have provided consent has been shown to increase activation at the beginning of the study (2).

For trials where recruitment is done via phone, but the intervention or study tasks are to be administered online, study personnel should assess the participant's level of comfort with technology (text messaging, mobile applications, use of a computer or tablet, navigating the internet) during phone screening (9). That way, they can tailor ongoing support to the needs of each individual participating in the study.

Improving written consent materials

Improvements to consent and study information materials are also important and review and co-design with the participant population can reveal unexpected needs. For example, consultation in this area has shown that it is important to participants that they know why researchers collect each type of data (12) and what they intend to do with each biospecimen (9). Another study that trialled participant recruitment materials with its target population (Latina women living in California) found the word "documentation" was a potential trigger for deterring undocumented persons and their families from participation in the research (5). This example highlights the importance of piloting recruitment materials with the intended study population.

Aside from improving written materials, many studies have been making efforts toward providing information materials in multiple formats, including infographics, videos, different languages, and easy read formats.

Maintaining engagement (retention)

There are many characteristics associated with attrition (also known as drop out), including age, sex and socio-economic status (20). Attrition may occur due to lack of proper and ongoing engagement that meets an individual's needs. The strategies for engagement reviewed are diverse and practical, with good potential for adaptation to other trials and research.

Digital tools

As well as using digital tools for recruitment, they can be used to maintain engagement over time. However, the usability of the technology is critical to maintaining engagement and avoiding attrition.

To create a relevant, useful web-based engagement and interventions tools that are acceptable to target users, they should not be one size fits all approach. The target population should be consulted, preferably using co-design methodology, during the development process and usability tests and pilot studies conducted with users with similar characteristics to the inclusion criteria of the study (6, 20, 23).

According to research, participants value easy opt-in and opt-out options to take part in research studies and receive notifications to let them know whether they were eligible to participate. They also value significant findings from the research in which they participated being fed back to them (10). Critically, patients' ongoing autonomy over consent to their data was considered transformative (10) and a secure messaging system between clinicians and patients is considered a high priority (10).

For one dynamic consent tool, the ongoing communication strategy was designed to allow a flow of information before, during and after the decision of participating in the study. Participants could give their preferences for re-contact (mobile phone, home phone, email) and their preferred language. In this way, adopting digital communication also decreases costs associated with re-contact for follow-ups and sub-studies (22).

The potential impacts of technology-based interventions on health inequality have been a growing concern in the literature. Disadvantaged individuals may experience greater challenges with technology-based interventions. One intervention evaluated found the opposite effect — where the intervention disproportionately benefited disadvantaged, or high-risk, patients (18).

Engagement with the research team

Ongoing engagement with the research team requires time, effort, and resources. However, reviewed studies show that investing this effort throughout the study period brings benefits to the research as well as to participants and the community more broadly.

Types of ongoing engagement include introducing the function of a web chat with study personnel (17) and providing that personal support from a named member of the study team (20). Participants working with the same study personnel from baseline to completion strengthens the relationship and comfort (2, 6). In one randomised controlled trial with a sub-aim of trialling strategies to increase tuberculosis treatment adherence in Kenya, patients could interact with study team members (who were themselves former patients and recipients of the intervention being trialled) for support and advice (18). However, the evaluation of the service did conclude that interaction with study team members is a limited resource that cannot be provided to all patients at scale, and therefore, motivates considerations like prioritising high-risk patients for human contact (18).

Introducing flexible scheduling of appointments including evenings and weekends (6, 9) removes barriers to participation and facilitates participants' ongoing engagement with research. Home visits also accommodate participants with limited access to transport and individuals who need to consider their childcare or eldercare commitments (9). Study personnel may need to be attuned to the needs of individuals to improve engagement (e.g., knowing that they should only contact a certain participant at a specific time of day) (2).

Specific recommendations for in-person interactions during study visits include thanking participants for their time, providing clear directions before their appointment, giving them a facilities tour and introductions, and asking about their gender pronouns (5).

Multi-modal communication

Adopting multiple modes of communication is one of the most frequently cited ways to effectively engage with research participants over time (2, 6, 7, 9, 19, 23). Attrition can be reduced by adapting to participants' needs and their communication preferences, and by personalising interactions. This participant-centricity is more easily achieved by taking advantage of the flexibility afforded by digital technologies (19).

Examples of multi-modal engagement with participants include phone check-ins, individualised text messages and videos (9), personalised reminders to complete study tasks (19) and providing study resources in various formats (e.g., videos, hard copy resources, web-based resources). Developing glossaries (23), providing videos with study background information and expected conversations is successful (6). One study that was exclusively a web-based intervention called participants monthly, which was reported by participants to be helpful (6). Checking in frequently and maintaining an open line of communication with participants facilitates more personal interaction and establishes trust and rapport (2). Some studies sent research participants birthday and holiday cards (2, 9), as well as regular newsletters (9).

Box 1. Tips for research teams to effectively engage with research participants using videoconferencing:

1. Determine participants level of comfort with the videoconferencing platform during study onboarding (2).
2. Provide necessary equipment (i.e., tablet, webcam) to participants as needed.
3. Contact participants to decide the most convenient time for sessions.
4. Provide participants with FAQs and instructions for joining via their preferred format: email (2, 5), phone (2), or text (2, 19). Send an infographic and video recording demonstrating how to use the videoconferencing platform (9).
5. Provide participants access to a research team member who can provide technical support (7).
6. Resend videoconferencing links via preferred format 10–15 min before meetings (2).
7. For those participants still having difficulty connecting to the live videoconferencing sessions, personally contact them by phone for further assistance (9).
8. Provide pre-recorded videos of the content for those who miss the session (9).

Community champions

Training and resourcing community champions or navigators can bring unique advantages as an implementation strategy because of the already established relationships between them and their community (14). This can be beneficial when working in marginalised communities or communities that face health disparities. The role of a community champion or navigator is specific to the needs and requirements of the study. An example of how the need for community navigators was identified in a study was through a community-driven needs assessment at the beginning of the project, ensuring enough time was given to effectively implement the strategy (14).

One study developing interventions to reduce sexually transmitted infections within specific communities utilised community navigators in a multi-faceted role to increase uptake and accessibility of information to their study population. They used one-on-one and group in-person meetings as well as intervention-related social media accounts. Community navigators were also involved in creating the content they were asked to share including online video testimonials and written content (14).

Community navigators were members of the communities in which they worked, they had official titles and roles that were linked with well-respected institutes, received formal training, and had flexibility to share information with participants through a variety of mediums. All these aspects were believed to contribute to the success of the intervention (14).

The community navigators reported a sense of intrinsic motivation to engage with the study and assist their community to improve the level of engagement in the study. Sufficient training for community navigators or ambassadors is vital to outline their roles and responsibilities within the study and to ensure they are best prepared to deliver the correct information to their communities (23). They can also assist with ongoing engagement strategies by providing updates on the research findings and other research opportunities to the community. One limitation specific to this study was that the study outcomes were primarily reported by the community navigators themselves and therefore are at risk of bias (14).

Creating a study community

Participating in a study community is now becoming more frequently available to participants in the form of groups on social media sites (9, 11, 20). These are usually led and moderated by study personnel and are created via a Facebook (11), WeChat (23) or WhatsApp (9, 23) group so that participants can ask questions and share their experiences (9, 11). In the Black People Like Me study, participants were encouraged to join and those who did were asked to share their experiences by posting images, quotes, or poems (11). Important to note, none of the studies reported here were clinical trials - there are complex circumstances when considering whether a study community is appropriate for a clinical trial, and in any research context such groups should be managed carefully and moderated by study personnel to avoid the spread of misinformation.

Feedback as a motivating factor

Providing real-time, personalised feedback to study participants during the data collection phase is an incentive (20), or in some cases even be seen as necessary for participants to stay motivated and engaged in research (12).

Examples of feedback include visualisations of inputted data and providing overviews of participants' self-reported symptoms for themselves, or to share with a clinician (20). In one study aiming to increase adherence to tuberculosis (TB) treatment, participants could use a digital tool to access information on their adherence performance compared with other anonymised patients (18). Participants in a depression study expressed that they expected return of information from researchers and for the app (or researchers) to provide them enough feedback to act on the data. They also wanted a visualisation of the data being collected that allowed them to see trends in their symptoms, help them to identify triggers for their depression, and give cues as to when to act (seek help) (12). A large study of maternal mental health took a simpler approach to feedback, where results shared with participants included the number of pregnant women participating in the study and information about common pregnancy concerns and behaviours (19).

However, researchers and trialists must carefully consider the design of such feedback – as it might inadvertently become an intervention in itself which could conflict with the research goals. Additionally, recognising that research goals and individual participant goals may differ (12), and this may affect the design and usefulness of the feedback.

Providing incentives

Although not a two-way engagement strategy, in some countries, particularly the USA, financial or other incentives are becoming more commonplace and there is a growing expectation from participants that they will receive such incentives (6). This can range from simple gestures like supplying water, snacks, or a "goodie bag" during visits (5) to reloadable debit cards given at in-person visits (9). In one study where the intervention was delivered via webinar, at the end of each session an electronic gift card was emailed to the first 100 attendees who stayed for the whole session (11). In another study, dedicated emails were sent specifically to chronic non-responders, asking them to return to active participation in the study and reminding them of the potential to earn new entries in a sweepstakes (19).

Other studies focus more on compensation. For example, to help offset the cost of the internet and the use of their own technology device, participants have been provided a USD 5 incentive after each session they attended (9), mobile hotspot to obtain internet access or gift card to add data to their mobile phones (7).

Completion of study tasks

Completion of study tasks can be a burden to participants and so strategies should be introduced to make it as easy as possible for both participants and researchers.

Practical strategies for in person visits include offering participation opportunities during weekends, early mornings, or later afternoons/evenings to allow the experiences of people who are unable to participate during the traditional workday to be included (7). In addition to that, allowing participants to select the format of an interview or focus group (e.g., via telephone, virtual platform, or in-person) (7) or offer access to a private area to participate in the virtual interview or focus group (7). Organising contact with a person prior to an in person visit for a COVID-19 symptom checklist over the phone the day before the scheduled visits and sent a reminder text message the day of the visit can help with non-attendance (9).

With the expansion of use of digital tools, they can also be used to reduce active data collection and instead incorporate sensor data collection (20), although this needs to be done with a high level of transparency so as not to risk trust (12). Where study apps are used, they should ensure that study app tasks are designed with minimal burden to participants but can still support researcher goals (12).

Study reminders

Study reminders can be delivered in various forms, including both automated and targeted, personalised reminders to those participants identified as at risk of drop-out (20).

Utilising SMS/email reminders is a particularly common strategy (6, 17, 18, 19). These reminders could be daily, for example for medication reminders with a necessity to respond to the text message to confirm treatment adherence (18), to confirm their attendance at follow up study visits (6) or to complete a survey or assessment, which has been shown to improve completion rates (19).

Research from the UK shows that most clinical trial units are intending to expand on the use of SMS/email reminders more than any other study tool, despite some uncertainty surrounding their effectiveness (17).

Minority, underrepresented and underserved groups

Minority and underrepresented groups include Indigenous communities and ethnic minorities, culturally and linguistically diverse communities, as well as low-income individuals (5) pregnant women (19), the elderly, homebound and disabled (20).

The types of barriers they can face include mistrust, time and financial constraints, fear of outcomes, limited access to information, stigma, fears about discrimination related to health insurance coverage, fear of deportation, and concern about their immigration status being affected (6).

Research programs that have successfully recruited from these groups advise that researchers should form concrete goals for the recruitment of diverse and underrepresented populations (7).

Practically, they should use sampling strategies to target recruitment toward underrepresented communities or populations who are under-enrolled in the study (7), use trained bilingual research personnel (6), develop culturally and linguistically relevant policies, programs, and resources and invest in the professional development of workforce to promote relevant evidence-based materials and tools (15). Hard copy documents and phone calls have been used more successfully to capture underserved people (23). Dissemination of study findings to bring the data back to the community is an important step in the research process, particularly for trials involving minority communities (6).

In relation to the use of digital tools, evidence suggests that the combined use of web-based recruitment with in-person strategies such as face-to-face contact and follow-up with a research team fluent in the participants preferred language have been successful. However, word-of-mouth, and community-level recruitment have been the most successful in recruiting racial and ethnic minorities (6).

Evaluation

This review has uncovered limitations associated with reporting of strategies for two-way engagement with research participants from the literature. Publications often do not describe their intervention in sufficient detail to replicate or adapt. This is especially the case with digital technologies (17, 20), which often also do not report essential information on study design. Introducing reporting guidelines would address this issue (20).

Nor are engagement interventions rigorously evaluated. The development of an evaluation framework could satisfy calls for people to produce higher quality evidence for digital interventions (17). This could include measures such as expected and unexpected costs of digital intervention studies (20), the costs of setting up and maintaining digital tools (17), engagement, dropout rates and the consequences of drop out for data collection and analysis (20).

In most cases, only simple evaluations targeted to narrow research questions were included in the studies reviewed here (see appendix for summary of peer reviewed literature). Examples include measuring the effect of the intervention on the group of participants most vulnerable to study drop out (18) and measuring effects of interventions on health and medical knowledge, knowledge about research participation opportunities and feelings of empowerment (11). Using participant surveys, focus groups and interviews are a common way to evaluate participant experience (10, 12, 19).

Evaluating the types of digital tools in use and whether they support recruitment and retention will help to inform funders and sponsors, as well as the wider research community, about their value (18).

Dissemination

All research should have a clear dissemination plan, and to be truly collaborative, dissemination should involve participants and community members in a two-way dialogue about the research findings (13). Dissemination in the literature usually refers to passive, unidirectional strategies such as press releases, policy briefs and newsletters (13). However, more collaborative, and flexible dissemination has been modelled, where the research team establishes a community liaison, engages community members at every step, tailors presentations to community groups, and allows plenty of discussion time and time to continue the dialogue after presentations. Dissemination is highly effective when researchers share their personal experiences, are receptive to feedback and then implement community members' input (13). It is also not necessary to wait until the end of a study to start sharing the findings. Study progress can be shared through written means, or voice or video recording (6).

Other dissemination plans have included publishing information on the website from which participants were recruited (19). Highly impactful research and policy organisations like the World Health Organisation also support outreach and publicity opportunities (16).

Given the labour-intensiveness of community dissemination, funders should be prepared to designate resources so that research participants and community members can take an active role in disseminating outcomes and influencing public policy (13).

The Australian Policy Context

Our review has highlighted that while Australian policy and guidelines relating to participant and community involvement in research are growing, there is a lack of guidance about how to engage participants in clinical research.

The National Health and Medical Research Council National Statement on Ethical Conduct in Human Research ('National Statement') is "an ethos that should permeate the way those engaged in human research approach all that they do in their research" and is the primary Australian source of guidance on ethical research practice (24).

The National Statement touches on principles of engaging participants in research, stating that consent strategies should be appropriately tailored to participants, and that obtaining consent should be considered as part of an ongoing, broader process of consultation, engagement, and negotiation, such as in the context of research involving Aboriginal and Torres Strait Islander Peoples. Researchers need to know about the communities they are working in, and how to engage with them (24).

Otherwise, policies developed in Australia are targeted to specific communities and activities and don't provide the level of guidance required to inform whether or how effective two-way engagement should be addressed. The WH&Y - Ethics and Engagement - Wellbeing Health & Youth Engagement Framework (25) talks about the need for co-design, producing meaningful technologies where the language used, activities planned and technologies created are easy to understand, easy to join in with, and make young people feel comfortable. The Framework also describes mutual ownership and shared responsibility and providing opportunities to contribute and feedback (25).

The Australian Government's digital service standard criteria provide specific guidance on ensuring that digital services are accessible and inclusive of all users, outlining the legal responsibility to ensure services are acceptable to people with disabilities. The criteria relate to the requirement to demonstrate design is inclusive to people with disabilities and cultural and linguistically diverse communities and emphasise usability testing (26). While these criteria may not be mandated in research contexts, they would represent best practice for designing digital technologies.

The themes arising from these policies harmonise with the peer-reviewed literature on engaging participants in research, however, the policy advice is specific in nature. This warrants the prioritisation of development of Australian policy on engaging participants in research.

Engaging with Aboriginal and Torres Strait Islander peoples

Research involving Aboriginal and Torres Strait Islander peoples must follow the Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (27) as well as ensuring that other relevant national, regional and research area specific guidelines are used to guide all stages of research.

Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders provides a set of principles upon which research with communities should be conducted. The guidelines centre on six core values of spirit and integrity, cultural continuity, equity, reciprocity, respect, and responsibility. Engagement should be carried out in an equitable and respectful way, with inclusion, recognition of values and culture, and where the benefits of the research are defined by Aboriginal and Torres Strait Islander values. Trust is established through openness and engagement with participating individuals and communities. The guidelines emphasise the importance of voluntary participation in research and fully informed consent, ensuring that both are satisfied for the research and all related activities to progress (from engagement and consultation in the design process through to knowledge translation) (27). Engagement and partnership with Aboriginal and Torres Strait Islander communities early in the research process is essential.

Conclusions

Utilising engagement and communication strategies in clinical research have a common goal: to build trust, transparency, and connection to lead to improved research outcomes. Consistent messages arising from this exploration of effective engagement strategies are that they need to be community engaged, collaborative and co-designed with the target population. Multi-modal communication strategies have worked well, and while the use of digital tools is on the increase, they must be usability and pilot tested with the intended target population and be iteratively improved. Digital engagement tools are also best paired with personal interactions.

Engagement strategies should be designed for the specific trials under consideration. For example, engagement efforts can be tailored toward improving medication adherence, providing self-reported data, sharing sensor data, or educational content. Finding the right strategies also depends on the participant population, duration of the study and geographical spread of potential participants – as well as other factors.

This white paper has not been able to identify specific information about the Australian context: that is, what communication and engagement approaches clinical research organisations have been trialling, how effective they have been, and the views of those working in the sector and participating in research about how these approaches could be improved.

While the strategies presented here provide a starting point, further investigation with stakeholders could inform both the development or adaptation of existing engagement strategies, but also much-needed guidelines and policies for the sector.

Having clearer guidelines and evidence-based strategies will support and inspire researchers to improve participant experience through enhanced engagement, and potentially lead to better outcomes for clinical research in Australia and internationally.

References

1. Carlisle B, Kimmelman J, Ramsay T, MacKinnon N. Unsuccessful trial accrual and human subjects protections: An empirical analysis of recently closed trials. Clinical Trials. 2015;12(1):77-83.
2. Buro AW, Gray HL, Ruble K, Soca Lozano S, Sauls R, Albizu-Jacob A, et al. Challenges and adaptations for a cluster-randomized control trial targeting parents of pediatric cancer survivors with obesity during the COVID-19 pandemic. Translational behavioral medicine. 2023;13(2):98-103.
3. MTPConnect. Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth.: Australia's Clinical Trials Sector; 2021 05/2021. Report No.: 2.
4. Huang GD, Bull J, Johnston McKee K, Mahon E, Harper B, Roberts JN. Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative. Contemp Clin Trials. 2018;66:74-9.
5. Castellon-Lopez Y, Landovitz R, Ntekume E, Porter C, Bross R, Hilder R, et al. A Community Partnered Approach for Diversity in COVID-19 Vaccine Clinical Trials. Journal of Clinical and Translational Science. 2022.
6. Hwang DA, Lee A, Song JM, Han HR. Recruitment and Retention Strategies Among Racial and Ethnic Minorities in Web-Based Intervention Trials: Retrospective Qualitative Analysis. J Med Internet Res. 2021;23(7):e23959.
7. Hoeflich CC, Wang A, Otufowora A, Cottler LB, Striley CW. Virtual recruitment and participant engagement for substance use research during a pandemic. Current opinion in psychiatry. 2022;35(4):252-8.
8. ACTA. About involvement and engagement. 2023 [Available from: https://involvementtoolkit.clinicaltrialsalliance.org.au/toolkit/understanding/about-involvement-and-engagement/.
9. Cortes YI, Duran M, Marginean V, Harris LK, Cazales A, Santiago L, et al. Lessons Learned in Clinical Research Recruitment of Midlife Latinas During COVID-19. Menopause (New York, NY). 2022;29(7):883-8.
10. Gilbert RM, Sumodhee D, Pontikos N, Hollyhead C, Patrick A, Scarles S, et al. Collaborative Research and Development of a Novel, Patient-Centered Digital Platform (MyEyeSite) for Rare Inherited Retinal Disease Data: Acceptability and Feasibility Study. JMIR formative research. 2022;6(1):e21341.
11. Graham L, Hart M, Stinson M, Moise R, Mitchell L, Winders TA, et al. "Black People Like Me": A virtual conference series to engage underserved patients with asthma in patient centered outcomes research. Research involvement and engagement. 2023;9(1):13.
12. Kolovson S, Pratap A, Duffy J, Allred R, Munson SA, Arean PA. Understanding Participant Needs for Engagement and Attitudes towards Passive Sensing in Remote Digital Health Studies. International Conference on Pervasive Computing Technologies for Healthcare : [proceedings] International Conference on Pervasive Computing Technologies for Healthcare. 2020;2020:347-62.
13. McDavitt B, Bogart LM, Mutchler MG, Wagner GJ, Green HD, Jr., Lawrence SJ, et al. Dissemination as Dialogue: Building Trust and Sharing Research Findings Through Community Engagement. Preventing chronic disease. 2016;13:E38.
14. Robles Arvizu JA, Mann-Jackson L, Alonzo J, Garcia M, Refugio Aviles L, Smart BD, et al. Experiences of peer navigators implementing a bilingual multilevel intervention to address sexually transmitted infection and HIV disparities and social determinants of health. Health Expect. 2023;26(2):728-39.
15. Sabo S, Lee N, Sears G, Jimenez DJ, Tutt M, Santos J, et al. Community Health Representatives as Trusted Sources for Increasing Representation of American Indian Communities in Clinical Research. International journal of environmental research and public health. 2023;20(5).
16. Hu K, Tardif J-C, Huber M, Daly M, Langford AT, Kirby R, et al. Chasing the storm: Recruiting non-hospitalized patients for a multi-site randomized controlled trial in the United States during the COVID-19 pandemic. Clinical and translational science. 2022;15(4):831-7.
17. Blatch-Jones A, Nuttall J, Bull A, Worswick L, Mullee M, Peveler R, et al. Using digital tools in the recruitment and retention in randomised controlled trials: survey of UK Clinical Trial Units and a qualitative study. Trials. 2020;21(1):304.
18. Boutilier JJ, Yoeli E, Rathauser J, Owiti P, Subbaraman R, Jonasson JO. Can digital adherence technologies reduce inequity in tuberculosis treatment success? Evidence from a randomised controlled trial. BMJ Global Health. 2022;7(12):e010512.
19. McGee B, Leonte M, Wildenhaus K, Wilcox M, Reps J, LaCross L. Leveraging Digital Technology in Conducting Longitudinal Research on Mental Health in Pregnancy: Longitudinal Panel Survey Study. JMIR pediatrics and parenting. 2021;4(2):e16280.
20. Beukenhorst AL, Druce KL, De Cock D. Smartphones for musculoskeletal research - hype or hope? Lessons from a decennium of mHealth studies. BMC musculoskeletal disorders. 2022;23(1):487.
21. Haas M, Vidgen, Miranda., Walczak, Adam., Newson, Ainsley., Patel Hardip., Teare, Harriet., Kaye, Jane., Bell, Jessica., Boggs, Kirsten., Young, Mary-Anne., Waddel, Nic., Murray, Sean., Easteal, Simon., Boughtwood, Tiffany and Stark, Zornitza. Introducing CTRL: a new online research consent and engagement platform. 2019 [A web-based dynamic consent platform available freely for use and some supporting consent material.]. Available from: https://www.australiangenomics.org.au/introducing-ctrl-a-new-online-research-consent-and-engagement-platform/.
22. Mascalzoni D, Melotti R, Pattaro C, Pramstaller PP, Gogele M, De Grandi A, et al. Ten years of dynamic consent in the CHRIS study: informed consent as a dynamic process. European journal of human genetics : EJHG. 2022;30(12):1391-7.
23. Seale H. Research about encouraging engagement from CALD communities in Covid (health) 2021 [Available from: https://www.unsw.edu.au/medicine-health/our-schools/population-health/research-impact/our-impact/supporting-covid-19-communication-and-engagement-with-people-from-culturally-and-linguistically-diverse-communities
24. NHMRC. National Statement on Ethical Conduct in Human Research 2007 [updated 2018. National Statement on ethical guidelines.]. Available from: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1.
25. Collin P, Dawson, A.,. WH&Y - Ethics and Engagement - Wellbeing Health & Youth Engagement Framework. 2019 [Values, questions and guiding practices for ethical engagement with young people in health research and translation.]. Available from: https://www.why.org.au/why-research/ethics-of-engagement/overview.
26. Government A. AusGov DTA - Make it accessible 2016 [Criteria outlining legal and ethical requirements for online accessibility and guidelines of how to increase accessibility of online content.]. Available from: https://www.dta.gov.au/help-and-advice/digital-service-standard/digital-service-standard-criteria/9-make-it-accessible
27. Council AG-AR. ARC codes and guidelines 2018 [cited 2023 24/04/2023]. ARC codes and guidelines to support ethical research conduct.]. Available from: https://www.arc.gov.au/about-arc/program-policies/research-integrity/codes-and-guidelines.
28. Garritty C, Gartlehner G, Nussbaumer-Streit B, King VJ, Hamel C, Kamel C, et al. Cochrane Rapid Reviews Methods Group offers evidence-informed guidance to conduct rapid reviews. J Clin Epidemiol. 2021;130:13-22.
29. Tricco AC, Langlois E, Straus SE, Organization WH. Rapid reviews to strengthen health policy and systems: a practical guide: World Health Organization; 2017.

Appendices

Rapid evidence review protocol

The literature review protocol is registered with the Open Science Framework (OSF) and is available at DOI 10.17605/OSF.IO/V7JXS

Briefly, a rapid evidence review was carried out utilising the methodology of the Cochrane Institute (28) and World Health Organisation (29). We searched MEDLINE, EMBASE and PubMed (using MEDLINE search strategy, or with minor modifications for other databases, below) and Google (using grey literature search strategy below). Methodological choices consistent with the guidelines on performing rapid reviews included limiting articles to English language, publication dates in the last 10 years, and forward and backwards searching was not done. Inclusion and exclusion criteria can be found in the protocol registered to OSF.

Title and abstract and full text screening were carried out by two content expert reviewers (MH and RB) for the first 20% articles. When consensus was reached, one reviewer screened each remaining articles. Excluded articles were checked by the second reviewer. Similarly, once the data extraction method was piloted with the first 20% of articles, remaining data extraction was performed by one reviewer and checked by the second reviewer. A PRISMA diagram is included below. A content analysis and narrative synthesis approach was taken to develop the white paper.

MEDLINE search strategy

Set	Search Statement
1	exp *patient compliance/ or *patient dropouts/ or *patient participation
2	(adherence or retention or engagement or involvement or participation or nonadherence or retain* or recruit*).tw,kf
3	1 or 2
4	*cell phone/ or *smartphone/ or *text messaging/ or *social media/ or *webcasts as topics/ or *internet/ or *information technology/
5	*Mobile Applications/
6	*Electronic Mail/
7	(texting or text-messag* or email* or app? Or two-way or dynamic-consent or ict or sms or digital* or pci or participant-centric-initiative* or event*).tw,kf.
8	4 or 5 or 6 or 7
9	Exp Clinial Trials as Topic/ or Registries
10	follow-up studies/ or longitudinal studies/
11	((study or trial? Or studies or research) and (clinical or medical or biomedical)).tw,kf.
12	9 or 10 or 11
13	(improv* or receptiv* or change* or increas*).tw,kf.
14	(trust or transparen*).tw,kf.
15	*Trust/ or *treatment outcome/
16	14 or 15

Set	Search Statement
17	evaluation study/
18	*evaluation studies as topic/ or *program evaluation/
19	*Program Development
20	(intervention* or evaluation or implementation or pilot* or strateg* or frame-work* or program* or framework*).tw,kf.
21	17 or 18 or 19 or 20
22	3 and 8 and 13 and 16 and (12 or 20)
23	limit 22 to (english language and yr=”2013-Current”)
24	limit 23 to (case reports or comment or editorial or letter or preprint)
25	23 not 24

Grey literature search strategy

engagement | participation | compliance digital | event | internet |“dynamic consent” |“Two way” medical | health trust | transparency | research evaluation | policy | guideline | framework

Summary of included peer reviewed literature

Title	Authors	Year	Location	Study design	Participant characteristics	Intervention characteristics	Outcomes assessed
Smartphones for musculoskeletal research - hype or hope? Lessons from a decennium of mHealth studies	Beukenhorst et al.,	2022	USA	Literature review, narrative synthesis of 18 studies.	Arthritis / chronic pain etc. All ages.	Smartphone use in muskuloskeletal studies.	Benefits and limitations of smartphone studies, for participants and research organisations.
Using digital tools in the recruitment and retention in randomised controlled trials: survey of UK Clinical Trial Units and a qualitative study	Blatch-Jones et al.,	2020	UK	Mixed methods (survey, non systematic lit review, and interviews).	Study personnel, patients, administrators etc.	Digital tools used for recruitment and retention into RCTs.	Frequency of use of digital tools in RCTs. Personal impressions of study personnel about digital tools.
Can digital adherence technologies reduce inequity in tuberculosis treatment success? Evidence from a randomised controlled trial	Boutilier et al.,	2022	USA	RCT in Kenya	1189 patients, had TB, spoke English or Swahili, had access to mobile phone.	SMS reminders (response required), access to education and support, info about adherence performance, interaction with study personnel (via digital tool).	The proportion of patients with unsuccessful treatment outcomes.
Challenges and adaptations for a cluster-randomized control trial targeting parents of pediatric cancer survivors with obesity during the COVID-19 pandemic	Buro et al.,	2023	USA	Clustered RCT	Parents of paediatric survivors of cancer (in remission) with obesity.	Physical activity intervention delivered by zoom.	BMI
A Community Partnered Approach for Diversity in COVID-19 Vaccine Clinical Trials	Castellon-Lopez et al.,	2022	USA	Deliberative Community Engagement	Panel members selected from recommended candidates from the target community.	Panel members developed, tested, and customised study materials and developed recommendations.	Ethnic makeup of participants in the target clinical trial compared to other clinical trials.
Lessons Learned in Clinical Research Recruitment of Midlife Latinas During COVID-19	Cortes et al.,	2022	USA	A two-group (intervention, waitlist control), repeated measures study.	Women aged 40 to 60 years; self-identification as Hispanic/Latina; spoke English or Spanish; perimenopausal or early postmenopausal.	CVD risk education, coping skills training, physical activity, and stress management. 12x2hr sessions delivered by videoconferencing.	Body mass index, waist circumference, blood pressure, psychosocial factors, menopause symptoms, pregnancy history, and health behaviours were assessed. Biological data.
Collaborative Research and Development of a Novel, Patient-Centered Digital Platform (MyEyeSite) for Rare Inherited Retinal Disease Data: Acceptability and Feasibility Study	Gilbert et al.,	2022	UK	Trial of a digital platform and co-design during focus groups and workshops.	Patients of the eye hospital.	Development of MyEyeSight platform to collate and manage health data but also for data sharing for research.	Qualitative and quantitative analysis / descriptive statistics about patients opinions of the platform (usability, features).
"Black People Like Me": A virtual conference series to engage underserved patients with asthma in patient centered outcomes research	Graham et al.,	2023	USA	Six-month series of one-hour virtual information sessions.	Black patients living with asthma.	6x monthly zoom sessions to engage Black patients living with asthma and their caregivers in education and discussions about asthma, and encourage involvement in research.	Attendance rates, post session tests to assess satisfaction, knowledge, health inequity, disease management, preventative measures, and research engagement. Qualitative assessment of Q&A during sessions.

Title	Authors	Year	Location	Study design	Participant characteristics	Intervention characteristics	Outcomes assessed
Virtual recruitment and participant engagement for substance use research during a pandemic	Hoeflich et al.,	2022	USA	Reflection/narrative review of interventions to improve recruitment in substance abuse research.	People with history of substance abuse.	Interventions to improve recruitment rates.	Recruitment rates
Chasing the storm: Recruiting non-hospitalized patients for a multi-site randomized controlled trial in the United States during the COVID-19 pandemic	Hu et al.,	2022	USA	Covid-19 RCT	People with early COVID symptoms.	Oral colchicine started within 2 days getting COVID-19. A 30-day course of drug or placebo delivered to the participant's home. Followed by telephone assessment.	Recruitment rates
Recruitment and Retention Strategies Among Racial and Ethnic Minorities in Web-Based Intervention Trials: Retrospective Qualitative Analysis	Hwang et al.,	2021	USA	Comparison of recruitment strategies to increase breast screening uptake.	Women in America of Korean descent.	Web-based health literacy education/ follow-up phone counselling for 6 months.	Surveys, interviews, recruitment and retention logs, phone counselling logs, team meeting minutes.
Understanding Participant Needs for Engagement and Attitudes towards Passive Sensing in Remote Digital Health Studies	Kolovson et al.,	2020	USA	Reviewing participant experiences using a research app.	Representatives of people experiencing depression.	In-person testing of mobile device features during the interviews.	Participant experiences and expectations from study app.
Ten years of dynamic consent in the CHRIS study: informed consent as a dynamic process	Mascalzoni et al.,	2022	Italy	Reflection on longitudinal study	~13,000 people in Italy.	Dynamic consent and engagement.	Attrition rates, engagement levels (narrative).
Dissemination as Dialogue: Building Trust and Sharing Research Findings Through Community Engagement	McDavitt et al.,	2016	USA	Interactive presentations during a 6-month period.	Black men and women living with HIV.	Iteratively developed process for dissemination of findings.	Reviewed presentations: content, challenges, process. Debriefing sessions after presentations. Themes identified.
Leveraging Digital Technology in Conducting Longitudinal Research on Mental Health in Pregnancy: Longitudinal Panel Survey Study	McGee et al.,	2021	USA	Lessons learned in a participant-centric adaptive digital recruitment multiple timepoint survey study.	Pregnant and post-partum women.	A combination of adaptive digital strategies to recruit, communicate with, and build trust with participants to minimize attrition over time.	Attrition rates and end of study feedback.
Experiences of peer navigators implementing a bilingual multilevel intervention to address sexually transmitted infection and HIV disparities and social determinants of health	Robles Arvizu et al.,	2023	USA	Developed intervention strategies to reduce STIs and HIV within the Impact Triad intervention.	Young GBMSM and transgender women of colour.	15 community navigators.	Data from interviews with community navigators, reflecting on their experiences.
Community Health Representatives as Trusted Sources for Increasing Representation of American Indian Communities in Clinical Research	Sabo et al.,	2023	USA	3 step intervention strategy to engage with communities to improve general understanding of COVID-19. Development of education materials.	Community Health representatives of targeted Indigenous populations.	Pre- and Post-intervention surveys	Community Health Representatives as Trusted Sources for Increasing Representation of American Indian Communities in Clinical Research

Summary of included grey literature

Title	Authors	Year	Location	Design / Development Process	Targeted Participants / Audience	Intervention / Document Focus	Outcomes / Resources available
WH&Y - Ethics and Engagement - Wellbeing Health & Youth Engagement Framework.	Philippa Collin & Angus Dawson	2019	Australia	Developed framework through round table discussions with young people involved in research.	Young people involved in research.	Values, questions, and guiding practices for ethical engagement with young people in health research and translation.	Framework to better engage with young people in a study that can be referred to during the study design.
NHMRC Guidelines for Guidelines	Alderson et al.,	2016	Australia	Consultation with selected experts.	Resource designed for policy makers.	Guidelines for making research guidelines.	NHMRC guidelines for developing research guidelines.
National Statement on Ethical conduct in Human Research (2007) - updated 2018	NHMRC	2018	Australia	Consultation with selected experts.	Researchers	National Statement on ethical guidelines.	NHMRC guidelines for conducting ethical research.
Good clinical practice guidelines	Australian Government	2018	Australia	Consultation with selected experts and evidence review.	Researchers and clinicians.	ICH Guideline for good clinical practice.	ICH clinical guidelines for conducting good clinical practice.
Consumer and Community Engagement Framework for Research	NSW Government	2019-2023	NSW Australia	Consultation with community engagement experts, members of the community and evidence review.	Researchers and community members.	Framework for consumer and community engagement in research.	Framework to assist with consumer and community engagement in research.
SALHN Consumer Engagement in Research Framework	SA Government	2021	SA Australia	Consultation with community engagement experts, members of the community and evidence review.	Researchers and community members.	Framework for consumer and community engagement in research.	Framework to assist with consumer and community engagement in research.
ARC codes and guidelines	Australian Government - Australian Research Council	~2018	Australia	Consultation with selected experts and clinical evidence review.	Researchers and clinicians.	Codes and guidelines to support research.	ARC codes and guidelines to support ethical research conduct.
Introducing CTRL: a new online research consent and engagement platform.	Australian Genomics	updated 2022	Australia	Consultation with researchers, web-design/developer team, user groups and community members. Existing evidence review.	Researchers and research participants.	Dynamic consent platform.	A web-based dynamic consent platform available freely for use and some supporting consent material.
Research about encouraging engagement from CALD communities in Covid (health)	A/Prof Holly Seale	2021 - present	Australia	60 in-depth interviews with key stakeholders involved in delivering services to CaLD communities in Australia. Consultation with a team of experts working in vaccine development in policy. Further collaboration with translators and communication experts.	People from culturally and linguistically diverse backgrounds and researchers.	Supporting Covid-19 communication and engagement with people from culturally and linguistically diverse communities.	A plain language glossary of complicated covid vaccine terms and that has been translated into 29 different languages and guidelines on how to engage with people from culturally and linguistically diverse backgrounds.

Title	Authors	Year	Location	Design / Development Process	Targeted Participants / Audience	Intervention / Document Focus	Outcomes / Resources available
NRHA - Inequities in research engagement between rural, remote, and metropolitan health care providers.	Bonnie Eklom	2019	Australia	Review of literature and evidence of health funding mechanisms and regional hospitals accessibility.	Government and funding organisations.	Inequities in research engagement between rural, remote, and metropolitan health care providers.	A review highlighting inequities of research opportunities between rural, remote, and metropolitan health care providers.
AusGov DTA - Make it accessible	Australian Government	2016 - present	Australia	Review of current legal and ethical requirements for online accessibility and consulting with experts for relevant guidelines.	Researchers	Making online health data accessible for all.	Criteria outlining legal and ethical requirements for online accessibility and guidelines of how to increase accessibility of online content.