

What Should Trialists Consider When Adapting a Complex Intervention for Remote Delivery? A qualitative interview study

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Research Article

Keywords: Complex interventions, Adaptation, Remote Delivery, Decentralised Trials, Qualitative Research

Posted Date: July 7th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-9301843/v1>

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Additional Declarations: Competing interest reported. Smith declares receiving a personal consultancy payment from Lilly.

Abstract

Background: As remote healthcare delivery models become increasingly common, interventions evaluated within clinical trials need to be feasible and safe to deliver remotely. However, little guidance exists to support trialists in adapting complex interventions for remote delivery during evaluation. Intervention content does not always translate seamlessly from one mode of delivery to another, and may introduce new logistical, practical, and safety challenges for its implementation. This study explored the experiences of trialists who adapted complex interventions for remote delivery, as a result of the COVID-19 pandemic, to identify key considerations for planning.

Methods: Semi-structured interviews were conducted with 19 trialists involved in adapting a complex intervention for remote delivery as a result of the COVID-19 pandemic. Participants included chief investigators, trial managers, statisticians and process evaluation leads across a range of intervention types. Interviews explored decision-making around adaptation, preparation for remote delivery, and experiences of intervention implementation during evaluation. Data were analysed using framework analysis. The upper level of the Behaviour Change Intervention Ontology informed the interview topic guide and analytic framework.

Results: Adaptation decisions were often guided by a desire to preserve core intervention components while ensuring feasibility in a remote format. Three key considerations for evaluating interventions remotely were identified: (1) reconfiguration of costs and resource requirements, including increased preparatory work, technical support, and equipment provision; (2) implementation challenges affecting participant engagement and fidelity, such as limited privacy, poor internet connectivity, and reduced on-screen visibility during intervention delivery; and (3) safety management in remote contexts, including constraints on monitoring and the additional procedures required to mitigate risk (e.g., smaller group sizes or additional observers on call), which may affect feasibility.

Conclusions: Adapting a complex intervention for remote delivery within a trial is not a simple translation of in-person procedures, but a change that introduces distinct logistical, fidelity, and safety challenges. Trial teams should consider how remote delivery may change resource requirements, influence engagement and fidelity, and shape safety management. These findings provide practical insights to support the adaptation, and evaluation of complex interventions delivered in increasingly digital and decentralised trial environments.

Introduction

The COVID-19 pandemic accelerated a shift to more remote models of healthcare delivery (1). To operate within these evolving service contexts, interventions evaluated within clinical trials need to be feasible and safe to deliver remotely. However, little guidance exists to support trialists in making and implementing adaptations to support a move from in-person to remote delivery (2). Understanding the experience of trialists who adapted a complex intervention for remote delivery as a result of the COVID-

19 pandemic can help identify what must be planned for during the process of adaptation and remote intervention delivery during evaluation.

Complex interventions are typically defined as interventions with multiple different, interacting components (3,4). For a trial to continue during the COVID-19 pandemic, many interventions had to be rapidly adapted from face-to-face to remote delivery. However, intervention content does not always translate seamlessly from one mode of delivery to another (5). Adaptations would likely have been required that could mean the intervention is not equivalent to that designed or delivered previously (6). For example, limited equipment or space availability may have required changes to exercise-based interventions delivered via videocall (7), meaning exercises could not always be delivered as originally planned. Such adaptations may introduce variation in intervention delivery, with implications for internal validity and interpretation of findings (6,8).

In addition to changes to the intervention itself, remote delivery into participants' homes can introduce new logistical, practical, and safety challenges for its implementation. For example, trialists might have to consider how intervention materials and equipment can be provided to participants remotely, as well as how to manage new safety risks within the home environment (9–12). As the planning and conduct of a trial already requires substantial resources and coordination (13,14), a lack of understanding about how remote intervention delivery affects feasibility, safety, and resource needs risks undermining effective trial delivery.

In a previous scoping review (15), we synthesised the 'lessons learned' from trialists who adapted complex interventions for remote delivery as a result of the COVID-19 pandemic. The review identified challenges primarily related to implementation of the adapted intervention into the home setting, including managing safety risks, maintaining privacy and confidentiality, ensuring access to technology and equipment, and challenges assessing intervention fidelity remotely. The aim of this qualitative interview study was to build on these findings by exploring, in greater depth, what researchers and intervention developers should consider when adapting a complex intervention for remote delivery within a trial.

Identifying the practical and methodological considerations involved in adapting complex interventions for remote delivery within trials is an important first step towards developing guidance for trialists evaluating interventions in increasingly digital and remote healthcare systems such as the NHS (16).

Methods

Study design:

Semi-structured interviews were conducted to explore the experiences of trialists who adapted a complex intervention to remote delivery as result of COVID-19 pandemic. The study protocol was registered on the Open Science Framework (OSF: <https://osf.io/35yrw>). Reporting follows the

Consolidated Criteria for Reporting Qualitative Research (COREQ) (17). Ethical approval was obtained in February 2025 (SoMREC 2222).

Aims:

This qualitative interview study aimed to explore trialists experience of adapting a complex intervention for remote delivery within a trial during the COVID-19 pandemic.

The primary objective was to understand what should be considered by researchers and intervention developers when adapting a complex intervention for remote delivery within a trial.

Participant sampling, recruitment and informed consent

Eligible participants were trial team members who had been directly involved in adapting and/or delivering a complex intervention remotely within a clinical trial as a result of the COVID-19 pandemic.

Purposive and snowball sampling were used to identify individuals meeting these criteria. Sampling decisions were informed by role (e.g. chief investigator, trial manager, statistician, process evaluation lead) and intervention type (e.g. talking-based, exercise-based). To ensure diversity of trials, no more than three participants were recruited from any single trial. A combination of purposive and snowball sampling was appropriate because experience of adapting and remotely delivering a complex intervention varies by job role and intervention type.

Potential participants were recruited through multiple routes, including: the UK Trial Managers Network (UKTMN) and the Trials Methodology Research Partnership (TMRP) newsletters and email lists, and recruitment information shared on LinkedIn. Authors of papers included in a previous scoping review of lessons learned from trialists who adapted complex interventions for remote delivery during the COVID-19 pandemic were also considered as potential participants (15). A purposive subset of authors (n=8) was contacted directly via email with information about the study. Snowball sampling was also employed, with participants encouraged to share study information with colleagues who had worked on the same trial. Individuals expressing interest in participating were emailed a participant information sheet by the principal investigator (EH).

An a priori data saturation approach was used to guide sample size (18). This involved analysing a minimum of 13 interviews before applying a stopping criterion of three consecutive interviews when no new themes were identified. This number was informed by the breadth of the research question and the diversity of the sample. Recruitment continued until the stopping criterion was met. Participants received a £30 voucher as a token of appreciation.

Written informed consent was obtained from all participants prior to the interview.

Data collection

Semi-structured interviews were conducted online via Microsoft Teams by EH between May and August 2025.

An interview guide was developed a priori, informed by our scoping review of the 'lessons learned' from trialists that adapted a complex intervention for remote delivery as a result of the COVID-19 pandemic (15). As the scoping review had applied the upper level of the Behaviour Change Intervention Ontology (BCIO) to organise the challenges and facilitators of adaptation to remote delivery, this organising structure also informed the development of the interview questions._

The upper level of the BCIO provides a structured classification of the components of behaviour change interventions and their evaluation (19). Although developed for behaviour change interventions, it has broader applicability to complex interventions, which commonly include behavioural components (20). Development of the upper level of the BCIO was informed by established reporting frameworks, including CONSORT and TIDieR (21–23), aligning it with approaches used to report complex interventions in trials.

The interview guide explored the experience of trialists when adapting a complex intervention for remote delivery, including the considerations that had to be made for both adaptation and intervention delivery. The interview guide was piloted by EH in one interview. It was refined based on feedback from the pilot interview and EH's reflexive observations regarding question clarity, flow, and opportunities for deeper probing. The topic guide was flexible and adapted iteratively to capture unanticipated issues raised by participants. The final version of the interview guide is presented in Additional file 1.

Interviews were audio-recorded using Microsoft Teams. Automated transcripts were generated and subsequently checked and corrected by EH for accuracy. Field notes were taken after each interview by EH to capture reflexive and analytical observations. Transcripts were not returned to participants for comment and/or correction.

Data analysis

Data were analysed using Framework Analysis (24). This involved seven stages, including transcription, familiarisation, coding, development of an analytical framework, application of the analytical framework, charting of the data into framework matrices and interpretation of the data. A combined deductive and inductive approach was used.

A coding framework was developed using the interview guide to inform the top-level codes. Categories identified in the scoping review, which had been structured using the upper level of the BCIO, were used to inform deductive coding of data relating to considerations during remote intervention delivery (e.g. considerations related to setting, style of delivery, fidelity, and mode of delivery).

Data relating to other aspects of trialists' experiences, including adaptation decision-making and broader reflections, were coded inductively. The analytical framework was iteratively refined to incorporate inductively identified concepts. Initial drafts of the analytical framework were reviewed and discussed with SA and KG.

All coding was conducted in NVivo (version 14). EH completed primary coding of all transcripts. SA independently reviewed the coding of two transcripts and provided comments on code application and framework structure. As strong agreement was observed, and no substantial discrepancies were identified, further double-coding was deemed unnecessary. EH continued to refine the coding framework throughout analysis in consultation with SA to ensure consistency in coding and interpretation.

Results

Participant characteristics:

Nineteen participants from 16 trials were interviewed, representing a range of interventions and professional roles. Participant and trial characteristics are presented in Table 1. Of the eight authors of studies identified in the scoping review who were contacted directly via email, five responded and four agreed to participate in an interview.

Table 1: Participant and Trial characteristics

Participant characteristics (n=19)	
Role	n
Chief or Co-investigator	6
Trial manager	5
Process evaluation lead	3
Statistician	3
Programme manager	1
Trial administrator	1
Trial characteristics (n= 16 trials represented)	
Characteristic	n
Intervention type	
Exercise-based	7
Talking-based	4
Education and training based	4
Combination intervention (exercise and talking based)	1
Delivery format	
Group-based	9
One-to-one	5
Both group and one to one	2
Country	
UK	11
Ireland	3
USA	2

The trials spanned multiple clinical areas, including stroke, multiple sclerosis, arthritis, motor neuron disease, and depression. Two trials involved parents and carers of children with autism, and one involved adolescents with depression. Most trials involved adult participants, including five focused on adults aged over 60. When COVID-19 lockdown measures were introduced, five trials were actively delivering the intervention, whereas eleven had not commenced intervention delivery.

Interviews averaged 62 minutes and ranged from 42 minutes to 71 minutes.

Findings:

Three overarching themes were identified that describe how trialists planned, implemented, and reflected on the adaptation of complex interventions for remote delivery:

- (1) Planning for adaptation and remote delivery, which describes how trialists made decisions about whether and how to adapt interventions.
- (2) Considerations during implementation of the remotely delivered intervention, which outlines the practical and methodological challenges encountered when delivering interventions remotely, including issues related to setting, mode and style of delivery, safety, and fidelity.
- (3) Trialists’ reflections on adaptation to remote delivery, which presents participants’ retrospective insights, including feasibility considerations and perceived benefits of remote delivery.

The themes are presented in the sequence of the interview topic guide, moving from initial adaptation decisions through implementation and subsequent reflection. An overview of the themes and their linked sub-themes is presented in Table 2.

Table 2: Overview of themes and sub-themes	
Overarching theme	Sub-themes
1. Planning for adaptation and remote delivery	Adaptation goal Anticipating feasibility and safety constraints Approaches to intervention adaptation Selecting an appropriate mode of delivery Preparing for remote delivery
2. Considerations during the implementation of the remotely delivered intervention	Setting Mode of delivery Style of delivery Safety Fidelity
3. Trialists reflections on adaptation to remote delivery	Feasibility considerations Benefits of remote delivery

Theme 1: Planning for adaptation and remote delivery

The first overarching theme, *Planning for adaptation and remote delivery*, encompassed trialists' accounts of adaptation decision-making and the preparatory work required before remote implementation. This theme is organised into five subthemes reflecting the progression from defining adaptation goals, through anticipating feasibility and safety constraints, to selecting the appropriate mode of delivery and the preparation required for participants and intervention deliverers.

1a. Adaptation goal

Many trialists described the goal of adaptation as keeping the intervention as close as possible to its original form to protect trial integrity and interpretability.

We wanted to be sure that what we were now evaluating was the same, that it wasn't a totally different programme (P09, Trial manager)

Some trialists highlighted a concern for preserving the core components of the intervention so that the remotely delivered intervention remained equivalent to the original.

The key thing we were trying to do is make sure that the intensity of the exercise was kept the same (P11, Process Evaluation Lead)

This goal was reinforced by a desire to not move too far away from what had already been tested in earlier feasibility work. For some trialists - particularly those delivering talking-based interventions - this led to the perception that remote delivery did not constitute a substantive adaptation at all. One chief investigator described the shift as *"just like the blip of a switch,"* reflecting a view that the intervention itself remained unchanged despite the change in mode of delivery.

1b. Anticipating feasibility and safety constraints

Trialists described having to anticipate whether remote delivery would be feasible and safe given the characteristics of the intervention, the participant population, and the delivery context.

Trialists had to judge practical feasibility, including whether interventions could be delivered without specialist equipment, whether adequate space and resources would be available in the home, and whether therapists were willing and able to deliver the intervention online.

But it was quickly decided that this is an intervention that can be delivered remotely because it doesn't require any kind of equipment that's in hospital (P13, Trial Administrator)

These decisions were also shaped by organisational and funder constraints. One process evaluation lead described this as a process moving from what was theoretically possible to what was pragmatically and safely deliverable.

Yeah, so, so it's almost like that funnelling thing. Do you know what I mean? We go. Oh, yeah, it's possible. Then we start to go down pragmatics (P17, Process Evaluation Lead)

Trialists anticipated a range of participant-level feasibility and safety considerations. For exercise-based interventions, this included participants' physical capability, balance, and ability to cope with high intensity exercise without in-person supervision. For talking-based interventions, trialists considered privacy, emotional safety, and whether participants could speak freely at home. Across both intervention types, trialists anticipated variability in participants' health and digital literacy, and the need for flexible and accessible delivery approaches.

1c. Approaches to intervention adaptation

Trialists described using a range of pragmatic and iterative approaches to adapt interventions for remote delivery. This included brainstorming as teams, identifying core components of the intervention, and testing activities informally before or alongside intervention delivery. Many trialists drew on feedback from previous participants and clinicians to refine adaptations and assess whether the changes were acceptable.

Whether it's digital or not is, you know, let's start and then let's continuously get feedback from the patients we're working with and make tweaks and changes to optimise it. (P03, Co-Investigator)

Consultation and co-design with PPI groups were central to many adaptation processes, helping to identify support needs, acceptability issues, and practical barriers.

Interventions were perceived as more adaptable when they were not overly prescriptive and allowed flexibility in how content was delivered.

So it is quite tailored to the individual. And so I think that meant that we didn't have to adapt as much (P01, Statistician)

1d. Selecting an appropriate mode of delivery

One of the decisions trialists had to make when adapting an intervention for remote delivery was which mode of delivery to use (e.g. videocall or telephone). Videocall was reported as often being preferred because it enabled visual engagement, helped build rapport, and allowed trialists to monitor participants for safety. The visual nature of some interventions, particularly those involving movement, influenced this choice.

But where you're trying to read somebody's face... You need to see them to establish a rapport. So there was never a question we'd do it by telephone (P05, Chief Investigator)

However, trialists also described how videocall was not appropriate or feasible for all participants. Decisions were tailored to participants' needs and capabilities.

Some groups of people with inflammatory arthritis have problems with their eyes and don't like screens, so you have to... It's just about offering choice (P13, Trial Administrator)

Trialists also had to consider participants' and carers' digital skills, access to devices and Wi-Fi, and comfort with technology. With videocall delivery, trialists had to decide which platform to use. These choices were constrained by organisational policies, data governance requirements, and the systems supported by individual NHS trusts.

1e. Preparing for remote delivery of the adapted intervention

Trialists described a number of processes necessary to enable remote delivery before implementation in the trial began. These related to logistics and materials, preparation for the participant and preparation for the intervention deliverer.

- **Logistics and materials**

Trialists described substantial logistical and administrative work to prepare interventions for remote delivery, particularly for exercise-based interventions that required specific equipment for participants. This included sourcing, posting, tracking, and retrieving items that would previously have been available on site, such as resistance bands, heart rate monitors and tablet devices. For some trials, this extended to large equipment, including exercise bikes, which required procurement processes, specific approvals, loan agreements, and specialist courier arrangements.

Trialists highlighted the administrative burden of delivering equipment within tight timeframes and managing equipment return.

So for us it was, you know, how do we get a bike...Eventually we had to order bikes from Europe. That was the biggest kind of barrier we had, and we needed more money to get the bikes as well. And then it was like how are we going to afford to deliver bikes to participants houses? (P07, Trial manager)

While some logistical aspects were eased by remote delivery (e.g. reduced room booking and more efficient scheduling), overall trialists emphasised that preparing equipment and materials for home delivery introduced significant new planning, coordination, and resource challenges.

- **Participant facing preparation**

Trialists described substantial participant-facing preparatory work to ensure that remotely delivered interventions could be delivered both safely and effectively. This preparation included technology set-up, familiarisation with online platforms, equipment orientation, and checks of the home environment to anticipate potential safety risks and barriers to engagement.

A lot of it was around speaking to the patient about what their environment was like. To make sure there's nothing you're going to trip on, and if you need to have a chair nearby to hold on to. (P06, Chief Investigator)

Participant preparation was often delivered through one-to-one calls, extended "Zoom literacy" sessions, written instructions, and follow-up support, with trialists aiming to ensure participants felt confident

using the technology before intervention delivery began.

The research assistant had additional meetings with people to make sure that they were happy with the online setup, and they knew how to log on. (P08, Co-Investigator)

Several trialists emphasised that this preparatory work was intended to offload logistical and safety-related issues from intervention delivery, reducing disruption and allowing intervention time to focus on delivery rather than troubleshooting.

- **Intervention deliverer preparation**

Trialists reported having to adapt training sessions for intervention deliverers. This was both a direct result of the COVID-19 pandemic, as well as the additional training needs that remote delivery of the intervention demanded.

So it was like the training of the therapist as well as the actual delivery of the intervention sessions that had to be switched. (P01, Statistician)

Trialists reported having to teach clinical staff how to use digital platforms such as Zoom or Teams, including basic functions like logging in, muting, and managing group interaction.

Theme 2: Considerations during the implementation of the remotely delivered intervention

The second theme captures the challenges that emerged during the remote delivery of the adapted interventions. Trialists described a range of interrelated factors that shaped how the adapted intervention was delivered in practice. These considerations have been organised into five key domains: setting, mode of delivery, style of delivery, safety, and fidelity.

2a. Setting

Trialists described how delivering interventions into participants' homes introduced challenges that were largely absent in controlled clinical or community settings. These challenges predominantly related to the difficulty of securing a quiet, uninterrupted space, particularly for participants living in shared or crowded households.

We're generally working with people that have lower income so there is a lot of shared spaces, right?' (P02, Chief Investigator)

Trialists highlighted confidentiality as a particular concern for group-based therapeutic interventions, primarily because participants could be overheard by others in their home environment. Facilitators had to establish clear ground rules around privacy, regularly remind participants about confidentiality, and, in some cases, ask individuals to move to a different space when it became apparent that conversations could be overheard.

For exercise-based interventions, limited space and unsuitable home layouts constrained delivery, particularly where activities had been designed for gyms or in-person group settings. This made it difficult to replicate whole-body movement, shared warm-ups, and interactive group activities.

So you want people to move and it's like you don't know how much space they have... How do you see the group and then how does your body show up on frame? Because that's important for dancing with other people, right? (P03 Co-investigator)

2b. Mode of delivery

Trialists reported using several modes of remote delivery, including videocall, telephone, and printed materials, each of which presented distinct implementation considerations.

Videocall

Intervention delivery via videocall was valued for enabling visual engagement, however trialists described substantial technical, practical, and accessibility challenges.

Participants' access to devices, variable IT literacy, unreliable Wi-Fi, and differing NHS and university platforms disrupted delivery.

For trialists of exercise-based interventions, positioning cameras to see participants' whole bodies was difficult.

How do you manage it [intervention delivery] when actually you can't see the person's whole body? (P17, Process Evaluation Lead)

Some participants were also reluctant to appear on camera. These challenges often required additional staff support during sessions and, in some cases, the purchase or loan of devices.

Telephone

Trialists reported that telephone delivery offered flexibility but limited their ability to build rapport, as facial expressions and non-verbal cues were not visible. Intervention delivery via the telephone was particularly challenging for participants who were hard of hearing or had limited dexterity, with some struggling to hold a phone for extended sessions.

We had a number of challenges. The commonest one was participants who were hard of hearing and on occasions we did struggle to go through the phone script that we had to run through with them.' (P10, Programme manager)

To mitigate these issues, therapists encouraged hands-free set-ups and, in some cases, relied on family members to help relay information.

We sent everybody out little mobile phone stands so they wouldn't have to be messing with it or trying to hold it because again that would be a problem, particularly people with MS [Multiple Sclerosis] if they're trying to hold their phone for the entire hour. (P08, Co- Investigator)

Printed and email materials

Printed materials were used to support participants to engage with intervention materials, with trialists favouring physical handbooks that were easier to handle and did not rely on participants having printers or specific digital skills. Email was used occasionally to deliver intervention content, particularly for participants with hearing impairments.

2c. Style of delivery considerations

Trialists reflected that remote delivery appeared to alter the style in which intervention content could be communicated, particularly through a reduced ability to pick up on non-verbal cues. This was particularly discussed by trialists of talking-based interventions.

There's just an intuition you have in person that you don't always get remotely. (P03, Co-investigator)

Trialists of group-based interventions also reflected that group interaction styles changed, with the loss of informal pre- and post-session chat. One trialist also discussed how group conflict was harder to manage remotely as participants could disengage quickly.

Trialists noted that participant visibility, camera use and screen layout influenced how facilitators were able to communicate and guide activities as planned.

2d. Safety

Trialists described how managing safety became more complex when interventions were delivered remotely. This was particularly the case for exercise-based interventions when assessing physical risk was more difficult.

Reduced visibility on screen, limited ability to physically intervene, and uncertainty about what was happening off-camera made real-time assessment of participant wellbeing more difficult. Trialists reported concerns about how to respond if a participant fell, became unwell, or disappeared from the call. Trialists also reported concerns about increasing exercise intensity without in person supervision.

We worried about what to do if someone fell or disappeared off-screen. (P06, Chief Investigator)

To mitigate these risks, trialists introduced additional safety procedures, including home-environment checks, falls-risk questionnaires, requirements for cameras to be on where possible, additional observers on calls to monitor safety, and ensuring another person was present in the home. Some trialists also reduced group sizes so instructors could more easily monitor participants.

2e. Fidelity considerations

Assessing fidelity remotely was particularly challenging because of difficulties recording sessions and managing data securely across different platforms and NHS systems. These challenges were heightened where ethical approval for online recording was not in place or where interventions involved sensitive discussions. Recording via videocall also raised practical and ethical issues, including uncertainty about how to observe facilitators without recording participants and concerns that recording could deter participation. Data storage and transfer were also problematic, with differing NHS trust policies, security restrictions, and GDPR requirements making it difficult to upload or share large files.

Some trialists attempted to use separate audio recorders to assess fidelity, but these introduced additional risks and logistical challenges.

I sent Dictaphones to therapists. We couldn't work out a way for them to get the tape back to us... we were terrified of somebody getting hold of a tape with patient details on. (P13, Trial Administrator)

In response to these challenges, some teams relied on field notes to assess fidelity while avoiding session recording. One trialist delivering an exercise-based intervention reported adding a small number of online-specific checks, such as recording how much of a person the facilitator can see. However, most trialists reported not modifying existing fidelity measures, often because they perceived the intervention content to remain unchanged following adaptation.

So, the actual therapy stayed the same. So, there wasn't really a need to change. (P05, Chief Investigator)

Alongside challenges with fidelity assessment, trialists also reflected on difficulties maintaining fidelity of intervention delivery. Trialists delivering exercise-based interventions described challenges progressing exercise intensity from afar, particularly in the absence of specialist equipment or in-person supervision.

You know, there's only so much progression you can do with, like, exercise bands. (P06, Chief Investigator).

Another trial manager, of a group-based exercise intervention for individuals with depression, described how the change to remote delivery changed the essence of what they were trying to achieve.

It changed the other factors of it, it changed the group dynamics, it changed them getting out of the house. It didn't have the same aim as what we thought it would be (P12, Trial Manager)

A small number of trialists noted that remote platforms occasionally facilitated supervision or improved recording quality compared with in-person delivery.

Theme 3: Reflections on adaptation to remote delivery

The final theme captures trialists reflections on adaptation to remote delivery, including considerations of feasibility and perceived benefits of remote delivery.

3a. Feasibility considerations

Trialists reflected on how adapting interventions for remote delivery had implications for the feasibility and cost of trials. While some aspects of remote delivery reduced costs, such as travel and venue use, other elements increased resource demands, including additional staffing, technological support, and the delivery (and return) of equipment to participants' homes.

Yeah they wore heart rate monitors during [the intervention] and they did have to be sent out and that was a nightmare because we didn't get some of them back, which was costly. (P12, Trial Manager)

Trialists sometimes described having to alter budgets to enable remote intervention delivery.

They even had the taxis costed in the budget, which is kind of what we use to kind of fund for things like the bikes and the iPads and things. (P19, Trial Manager)

3b. Benefits of remote delivery

Increased accessibility was frequently identified by trialists as a key benefit of remote delivery. Trialists reflected that remote delivery could reduce the time, cost, and effort associated with attending hospital or clinic-based sessions, potentially supporting participation among people with health conditions, caring responsibilities, or those living in rural areas.

It's logistically so much harder to get into the clinic to come to these sessions twice a week than it is to like log into a zoom call. And so I do think that that increased access. (P04, Chief Investigator)

Trialists reflected on how remote delivery increased flexibility around scheduling. It made it possible for sessions to take place outside standard clinic hours to better fit around work, study, and family commitments.

We saw quite a lot of students in the trial and for instance, in the past, if they went home for Christmas, the therapy would stop, whereas it could just move online. Or if it was online, it could just continue (P05, Chief Investigator)

Trialists suggested that wider geographical reach could improve generalisability of trial findings and improve trial efficiency by more easily enabling combination of intervention groups if recruitment numbers were small. One trial manager reflected on what remote delivery could mean for reducing the trials carbon footprint.

So it was. It was nice, I suppose, from a carbon perspective, I think our our carbon footprint was much less than it would have been (P07, Trial Manager)

Discussion

In this qualitative interview study of trialists who adapted a complex intervention for remote delivery as a result of the COVID-19 pandemic, multiple factors requiring consideration were identified. These are discussed as three overarching considerations: 1) Reconfiguration of costs and resource requirements;

2) Implementation challenges affecting engagement and fidelity; and 3) Safety management in remote contexts and its implications for intervention feasibility.

Consideration 1: Reconfiguration of costs and resource requirements

Clinical trials depend on careful resource planning and capacity management (13,14). Findings from this study indicate that delivering complex interventions remotely reshapes these resource demands, with implications for staffing, budgeting, and trial feasibility.

Consistent with prior research, trialists reported increased preparatory time and resources required to set participants up for remote intervention delivery via videocall, including additional pre-intervention calls, provision of equipment to participants' homes and increased technical support (5,25). While some of the additional work discussed in this study was likely exacerbated as a result of the COVID-19 pandemic, the findings highlight an important consideration for trialists adapting complex interventions for remote delivery. Changes in patterns of resource use could complicate both planning decisions and the conduct of economic evaluations (5). In particular, higher set up costs might influence estimates of cost-effectiveness depending on the time horizon adopted (26–28).

Beyond economic evaluation, changes in cost and resource requirements may also affect assessments of intervention feasibility and applicability beyond the trial setting (29). For example, trialists described substantial administrative and logistical work required to prepare participants for remote delivery, including organising equipment delivery to participants' homes and scheduling additional set-up calls. These requirements could influence the level of organisational expertise and digital infrastructure needed for routine implementation. Together, these findings highlight key cost and resource categories that trialists should consider when planning for remote intervention delivery and making adaptation decisions.

Consideration 2: Implementation challenges affecting engagement and fidelity

Fidelity is already challenging to assess in complex interventions (30,31), and the results of this study support previous findings that these challenges are amplified when an intervention is delivered remotely (32–34).

An important aspect of intervention fidelity is the extent to which participants engage with the intervention as intended (35). In this qualitative study, trialists described several remote-specific challenges that could disrupt engagement, including poor internet connectivity, limited privacy within the home environment, and reduced visibility on screen, particularly for group-based interventions. Similar challenges have been reported in other remotely delivered interventions (36,37) and may compromise fidelity of receipt, with implications for interpreting intervention effectiveness (6,35,38).

Potential sources of variation in participant engagement should be captured in fidelity assessments to support understanding of how interventions are implemented in practice; however, there is currently limited guidance on how to assess intervention fidelity remotely (39). Furthermore, as this study has

highlighted, assessing fidelity remotely was particularly challenging due to difficulties recording sessions and managing data securely across different platforms. As a result, trialists sometimes relied on alternative methods, such as taking field notes. This might further constrain their ability to identify where and why variation in intervention delivery occurs.

Bonar et al. (38) describe the use of a technology-specific fidelity checklist that captures factors such as whether sessions were conducted in private locations, the clarity of video and audio, and interventionists' ability to manage equipment and group dynamics online. Extending this approach may support trialists to identify sources of implementation variance and prompt consideration of practical strategies to mitigate them, including the use of additional equipment (such as bigger screens, and heart rate monitors), guidance on lighting and home set-up, and adaptations to communication styles to support remote engagement (40). This is particularly important for group-based interventions, where implementation challenges might impact group processes and dynamics central to the intervention's mechanism of action and intended outcome (41). Fidelity assessment methods should account for these additional sources of variation to support accurate interpretation of trial outcomes when interventions are adapted for remote delivery.

Consideration 3: Safety management in remote contexts and its implications for feasibility

This study identified several safety-related considerations that varied across intervention types and modes of delivery with implications for feasibility.

Exercise-based interventions were impacted by reduced visibility on screen and limited ability to physically intervene, while talking-based interventions raised safeguarding and privacy concerns. Similarly, video formats were sometimes preferred over telephone to enable visual safety monitoring. These distinctions align with wider telehealth and telerehabilitation literature (42–45). For example, a systematic review comparing modes of delivery suggests that video-based formats, compared with telephone, may enhance engagement and are preferable where visual assessment is required (44).

To address these constraints, trialists introduced mitigation strategies such as home-environment checks and additional observers on the call. In some cases, group sizes were reduced to support closer monitoring. Ensuring participant safety remains paramount in intervention delivery; however, these mitigation strategies have resource implications that need to be anticipated during adaptation decision-making (46). While heart-rate monitors may provide additional insight into participant safety (47), trialists in this qualitative study noted that their use introduced additional costs and logistical demands, particularly when devices were lost or not returned. Reducing group size could also increase resource requirements, as more sessions and staff time may be needed to deliver the intervention to the same number of participants.

Beyond their feasibility and resource implications, these same safety mitigation strategies may also shape intervention fidelity. Trialists described hesitancy in progressing exercise intensity without in-person supervision. Increased practitioner risk aversion in remote contexts has been reported elsewhere

(43) and could influence adherence to planned progression protocols. Monitoring tools such as heart-rate monitors may help strengthen confidence in advancing exercises safely and in line with the intended protocol (47). Smaller group sizes or enhanced visual oversight (e.g., wide angle cameras or dual screens) could enable closer observation of participant engagement and exercise technique, supporting both the monitoring and maintenance of intervention fidelity (48). These findings highlight how safety management decisions can influence both feasibility and intervention fidelity, with the implications varying across intervention types and modes of delivery. For example, reducing group sizes to increase safety of the remote delivery of an exercise-based intervention might increase costs but could also provide opportunities to enhance fidelity. Alternatively, requiring cameras to be on for the delivery of a group based talking intervention might increase safety monitoring, but could inhibit participant engagement. Trialists should consider these trade-offs and unintended consequences when adapting a complex intervention for remote delivery.

Together, these findings suggest that even when intervention content remains unchanged during adaptation, the remote context introduces distinct logistical, feasibility and safety challenges that can undermine the implementation of an intervention as intended. As remote delivery of complex interventions becomes increasingly common within trials and health care systems (49), trialists need to explicitly consider how changes in resource requirements, implementation challenges affecting engagement and fidelity, and safety considerations in remote contexts may influence planning and adaptation decisions. By identifying these considerations, this study provides practical insights to support trial teams adapting complex interventions for remote delivery and interpreting trial outcomes (4,46).

Limitations:

This study has several limitations. Firstly, only trialists who managed to adapt interventions for remote delivery were interviewed. Therefore, perspectives from trialists who were unable to adapt or chose not to proceed with remote delivery were not captured, and some relevant considerations may be missing. Furthermore, high staff turnover in the post-pandemic period (50) may have limited participation from individuals who experienced more challenging adaptation processes. Secondly, while the trialists interviewed in this study all had experience of working on trials that were adapted for remote delivery, they were speaking about the COVID-19 period that had happened up to 5 years before. Therefore, some contextual details and challenges that were not prompted in the interview guide may have been forgotten. Finally, the findings reflect trialists' experiences during the COVID-19 pandemic, when rapid shifts to remote delivery and limited familiarity with digital platforms may have amplified certain challenges. As digital infrastructure and familiarity with remote delivery continue to evolve, the nature and magnitude of some challenges may change. However, the findings still provide valuable insight into the practical considerations trial teams may encounter when adapting a complex intervention for remote delivery.

Conclusions

Adapting a complex intervention for remote delivery within a trial is not a simple translation of in-person procedures, but a change that introduces distinct logistical, fidelity, and safety challenges. Trialists must consider how adaptation impacts costs and resource allocation, participant engagement in a remote context and safety management across intervention types and modes of delivery. To support prospective planning and decision-making beyond the context of COVID-19, there is a need to consolidate the considerations identified in this study across a wider range of trials and stakeholders.

Declarations

Clinical trial number: not applicable

Ethics approval and consent to participate

The study was approved by the University of Leeds Ethics Committee (SoMREC 2222). Written consent was obtained from all participants before any study-specific activities were undertaken.

Consent for publication

Not applicable.

Availability of data and materials

The final version of the developed analytical framework are available from the corresponding author on reasonable request. Informed consent forms are available on request. Interview schedules are presented in Additional file 1.

Competing interests

Smith declares receiving a personal consultancy payment from Lilly.

Funding:

This project is supported by funding from MRC DTP (MR/W006049/1). Samuel Smith is funded by a National Institute for Health Research NIHR Advanced Fellowship (NIHR300588). Katie Gillies is funded by a Medical Research Council Senior Non-Clinical Fellowship (MR/X007646/1). The views expressed here are those of the author(s) and not necessarily those of the NHS, the National Institute for Health and Social Care Research, Department of Health and Social Care, or the Medical Research Council. The funders had no role in the design of the study, data collection, analysis, interpretation of data, and in the writing of this manuscript.

Author's contributions

Under supervision from AJF, KG and SS, EH devised and conducted this qualitative interview study and drafted the manuscript. EH analysed the data and developed the initial themes which were iteratively

updated through discussion with KG and SA. SA was involved in data analysis and acted as a second reviewer of the data. All authors engaged in a peer discussion of developing themes throughout the project. All authors reviewed and commented on the manuscript drafts. All authors approved the final manuscript.

Acknowledgements:

We would like to thank all the participants in this research. We would like to acknowledge Ellen Thompson (University of Leeds) for participating in a mock interview. We would also like to acknowledge the Trial Managers Network (TMN), Trials Methodology Research Partnership (TMPR), The HRB - Trials Methodology Research Network (HRB-TMRN) and anyone else who shared information about the study to facilitate recruitment.

Authors information:

EH is a PhD candidate at the University of Leeds investigating what to consider when adapting a complex intervention for remote delivery within a trial. This was EH's first experience of designing and leading a qualitative research study, and she was supported and guided by KG, SS, SA and AF who have experience of using qualitative methods in the context of clinical trials.

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