

PROTOCOL: Version 1.0 (October 2025)

Supporting self-funders to make confident care decisions: 'Care Confidence in Action'

IRAS Project ID: 356117

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ABBREVIATIONS

CI:	Chief Investigator
HRA:	Health Research Authority
REC:	Research Ethics Committee
LA:	Local Authority
PDSA:	Plan, Do, Study, Act
NPT:	Normalisation Process Theory
NoMAD:	Normalisation Assessment Development instrument
NYCC:	North Yorkshire County Council
CYC:	City of York Council
HCC:	Hull City Council
DF:	Dementia Forward
PIS:	Participant information sheet
GCP:	Good Clinical Practice
NHS:	National Health Service
NIHR:	National Institute for Health Research
SSCR:	School for Social Care Research
PPIE:	Patient and Public Involvement and Engagement
GDPR:	General Data Protection Regulation
SPSS:	Statistical Package for the Social Sciences
AE:	Adverse Event
SAE:	Serious Adverse Event
PI:	Principal Investigator
TIDieR:	Template for Intervention Description and Replication
ICMJE:	International Committee of Medical Journal Editors

1 BACKGROUND AND RATIONALE

In England, more than a third of care home residents (137,480) and nearly a quarter of people using community care (83,844) self-fund, and most self-funders are older people [1]. Navigating the social care system is difficult, but for older people trying to find and fund their own care, it can be particularly challenging [2,3,4]. If people reach crisis before looking into care options, they may have to arrange care whilst under significant pressure [5], and making rapid decisions leaves little opportunity to fully consider options or their implications [6]. Funds can deplete quickly, but self-funders do not always receive advice on how to manage this. Despite Care Act [7] requirements for Local Authorities (LAs) to provide information and advice to *all* social care users, older self-funders report receiving little guidance from LAs [8] and most directors of Adult Social Services agree that they do not provide 'good' support to people planning care [9]. Instead, access to information relies heavily on the use of digital technology and/or social contacts and carers [6,8]. Yet not all self-funders will have the navigation capital (skills, experience, or helpful social contacts) required to find and make sense of relevant information to plan and procure care [8,10]. Certain groups of older people, such as those with dementia, can experience shrinking social networks just as their needs for care increase [11]. At the same time, older people are more likely to be digitally excluded than the general population, and there is an association between digital exclusion and functional dependence [12]. Older people whose first language is not English may be additionally excluded and thus require targeted support [13].

The Care Confidence online tool: In 2021, SSCR 3 funded the development of Care Confidence. Grounded in evidence and the experience of experts, this online planning tool contains information for self-funders on home care, aids and adaptation, residential care, finances and capital depletion. The tool is easy to navigate, with short videos, case studies and suggestions for further enquiries [14].

The problem: Care Confidence is a unique tool [15] that is freely available online for people to access independently, but others may need support to get the most from it. The tool has the potential to be a valuable 'hook' for LAs (and other services) to hang light-touch care navigation interventions on, which could be targeted and tailored for those in most need. Exactly how Care Confidence can be best operationalised will depend on local context, resources, and the service pathways in which it is embedded. In some instances, signposting may be all that is required, but in others the tool could provide the structure for a guided conversation with trained staff supporting action planning. The latter could be targeted for people who are socially isolated and/or lack the skills to research options or could be tailored to support people who are digitally excluded or face language barriers.

Approach to implementation and improvement: There have been calls to better align implementation science and improvement practice [16]. The use of service improvement tools such as the Plan, Do, Study, Act (PDSA) cycle is common practice in healthcare and more recently these have

been formalised by implementation scientists to maintain the action-research strengths of these approaches which empower staff to tailor and embed interventions to suit their specific circumstances [17]. An evidence-based approach is the ItFits model, which has been shown to effectively support tailored implementation [18,19].

Proposed research: This study will establish optimum ways to tailor and deliver interventions based on Care Confidence in different settings, reviewing and improving implementation through a formative process evaluation applying Normalisation Process Theory (NPT) [20]. It will be the first time the ItFits implementation model has been applied in social care settings, providing wider learning for implementation science.

2 RESEARCH QUESTION AND OBJECTIVES

2.1 Research questions

1. What are the optimum ways of implementing Care Confidence to support older self-funders?
2. Are there particular targeting and/or tailoring interventions that could improve the reach and inclusivity of Care Confidence?
3. Can a pragmatic approach to tailored implementation using a facilitated version of the ItFits tool support implementation in social care settings?
4. How successful is implementation (against NPT criteria)?
5. What are the expressed views and experiences of older people and their carers accessing these interventions?
6. What are the learning points for future implementation of this and other social care interventions?

2.2 Study aims and objectives

Aims: This study aims to ensure everyone who could benefit from Care Confidence has the opportunity to do so.

We have been working with local organisations to co-produce interventions using Care Confidence to support self-funders. In this research we will evaluate the implementation of these interventions using

an 'action research' approach, meaning we will feed in learning throughout to help optimise approaches.

Objectives:

- To support social care providers in four sites to implement a dedicated version of the Care Confidence care planning tool for older-self funders (**tailored implementation**)
- To find ways of tailoring the use of the tool to improve its reach and inclusivity, meeting the needs of a more diverse population of older self-funders (**diversity and inclusion**)
- To evaluate the implementation of Care Confidence against NPT principles (mixed methods, with staff) and qualitatively with older self-funders and their cares (**robust evaluation**)
- To feed learning from the initial stages of evaluation into later stages of service improvement (**continual improvement**)
- Share learning from the study, about implementing Care Confidence and the use of implementation thinking in social care settings, with a wider range of stakeholders to maximise impact (**knowledge mobilisation**)

2.3 Study outcome

This is a process evaluation not an efficacy study. It will produce rich learning about implementation of Care Confidence (including practical steps, costs to services, logic models and implementation outcomes) as well as learning about the application of implementation thinking (and ItFits in particular) in social care settings.

Markers of implementation success will be:

- (1) Level of normalisation (embedding over time) - assessed using the NoMAD tool (see below)
- (2) Fidelity of implementation and use (the degree to which what is happening matches what was intended) - assessed qualitatively
- (3) 'Dose' (how much of the intervention is necessary to have benefit) - assessed qualitatively

The Normalisation Assessment Development (NoMAD) instrument, a validated staff questionnaire tapping into core concepts of NPT (Coherence, Cognitive Participation, Collective Action, Reflexive Monitoring), will be used to assess normalisation of the tailored Care Confidence interventions over time.

Staff interviews and focus groups, along with interviews with service users about their experiences of receiving interventions, will qualitatively inform our understanding of fidelity, dose and implementation success.

The research will produce new knowledge about how best to support older self-funders. We will work with services, networks of professionals and people with lived experience to ensure key messages reach the right people and the research has maximum impact

3 STUDY DESIGN AND METHODS

3.1 Study Design Summary

This is an implementation science informed process evaluation with co-produced elements.

Care Confidence is currently available to use online by anyone who knows the site exists or finds it through searching. However, we know that not everyone has equal access to the internet or has the skills or confidence to find and use online tools without support. This project therefore centres on the collaborative development and implementation of Care Confidence related interventions to improve access to, and use of, Care Confidence by older social care self-funders and their supporters. The focus of the evaluation will be the processes through which delivery partners develop and implement their chosen interventions.

The study has 5 stages (see below). Stages 1 and 2 were completed before this protocol was finalised as they contained co-productive elements which would influence Stages 3, 4 and 5. After the interventions were developed (in Stage 2) the details of the evaluation could be agreed and this protocol finalised. This protocol therefore focuses on Stages 3 to 5.

Stage 1: Relationship building, launch and approvals (complete)

Stage 1 included dedicated time to facilitate relationship building between researchers and service staff through site visits and face-to-face meetings, and a launch event which brought together stakeholders from all sites to create a 'buzz', brainstorm, and plan for the first site-specific workshops.

Stage 2: Develop strategies for tailored intervention:

Two face-to-face workshops in each site were held in July and August 2025 to identify strategies for implementing Care Confidence, structured using ItFits <https://itfits-toolkit.com/>. Workshops brought together the core site teams with wider stakeholders, including public advisors, local service

representatives and members of the public. They were facilitated by the research team, but co-productive in ethos and all decisions on strategies for implementation were made by the service teams. The interventions developed during workshops all fall within the following four level implementation model (developed collaboratively by stakeholders):

Level 1: Promotional activity (for example, posters and information on websites)

Level 2: Signposting to Care Confidence for independent use (for example, directing individuals who contact social services to Care Confidence by providing a link or QR code)

Level 3: Supported access, but without specialist support to make the most of the Care Confidence tool (for example, the availability of an internet enabled devices and support to use these at libraries)

Level 4: Supported use of Care Confidence (for example a guided conversation with a social worker or home visit from a Dementia Support Advisor who will help the self-funder and/or their carer to work through relevant sections of Care Confidence and make an action plan)

Work to support implementation at site levels includes writing standard operating procedures, raising staff awareness of new processes, purchasing equipment and adding links to websites. This is also the point where the research team will finalise the protocol for the evaluation (Stages 3 to 5) and apply for HRA ethical approval.

Stage 3: Process evaluation

A combination of quantitative analytics, staff survey and qualitative data (interviews and focus groups), collected from staff and people who are offered Care Confidence related interventions, will be used to examine the process and effectiveness of implementation, as well as the expressed views and experiences of self-funders and their supporters.

A NoMAD baseline has already been collected from all sites, with University of York departmental ethics approval. At three follow-up rounds, site staff will be invited to complete the NoMAD survey (n=90 staff members in total across the three remaining timepoints).

Staff working in any of the 4 sites, who have offered Care Confidence related interventions to older self-funders and/or carers, will be invited to take part in a qualitative interview (n=24) or a focus group (n=24).

People who are offered Care Confidence related interventions, including self-funders and carers (n=24), will be purposively sampled to take part in qualitative interviews.

Stage 4: Improve and consolidate

Learning from initial implementation will be fed back to sites to enable ongoing improvement. Intervention and delivery will continue to be evaluated throughout this stage.

Stage 5: Reflect and share

A final workshop in each site will ensure learning is fully incorporated locally, and a national launch and visits to share findings with diverse groups will ensure wider reach, accompanied by a range of publicity and resources (including practical steps for implementation with costs, logic models and expected outcomes).

The methods that will be used in the data collection and analysis stages (Stage 3 and 4) are set out in more detail below.

3.2 Projected timetable and duration of participation

The data collection and analysis stages (Stage 3 and 4) will run for a duration of 16 months, from 1st February 2026 to 31st May 2027. It is expected that 162 participants will be recruited to the study in that timeframe. The duration of their involvement will be from the time they give informed consent until they have completed a qualitative interview or focus group, or the time it takes to complete the NoMAD survey as a one-off (whilst the survey is longitudinal, different individuals may complete it at each timepoint, and completion at one point does not imply or commit a participant to completion at any further timepoints).

3.3 Participating sites

Three local authorities (LAs) and one charity are already collaborating to tailor implementation of Care Confidence related interventions to the needs of local self-funders. These will each be a study site delivering interventions and identifying participants. More sites may join the study if they are involved in intervention delivery in the localities in question.

North Yorkshire County Council (NYCC) is a large rural county with a high proportion of older self-funders. Staff at NYCC want to support choice and control for self-funders and have a strong interest in the value of research to improve practice.

City of York Council (CYC) have a high proportion of self-funders and are looking for cost-effective ways to optimise social care outcomes. Representatives at CYC recognise the value of Care Confidence in this aim and have capacity to support this implementation research.

Hull City Council (HCC) is a diverse, socioeconomically deprived city with fewer self-funders, but the self-funders it has may be nearer the threshold for council funding and/or face language or cultural 'barriers'. HCC has been piloting use of the Care Confidence tool in their community hub. Having had a positive experience of this, especially with residents who are digitally excluded, HCC is keen to expand implementation.

Dementia Forward (DF) is a regional dementia charity with a strategy of continuous, evidence-based innovation. DF leaders have expressed their vision for Care Confidence, including use with dementia advisers in home visits, and at Dementia Cafes.

3.4 Study Methods

We have collaborated with staff in the above sites to facilitate the development of discrete strategies for Care Confidence related intervention implementation suited to local context, building on existing or new care pathways. The data collection and analysis stages (Stage 3 and 4) are as follows:

Stage 3 will involve quantitative and qualitative data collection and analysis of Care Confidence related interventions, from different stakeholder perspectives across the 4 participating sites. Learning will be fed back to the sites as it emerges, so that any implementation challenges can be addressed.

Stage 4 will begin with a workshop in each site. Learning from initial implementation will be applied to improve ongoing delivery, which will continue to be evaluated through further quantitative and qualitative data collection and analysis of Care Confidence related interventions.

3.4.1 Stage 3: Process Evaluation

Implementation: Services will begin delivering tailored interventions to support older self-funders and their carers using Care Confidence. The interventions developed during workshops all fall within the four levels of implementation:

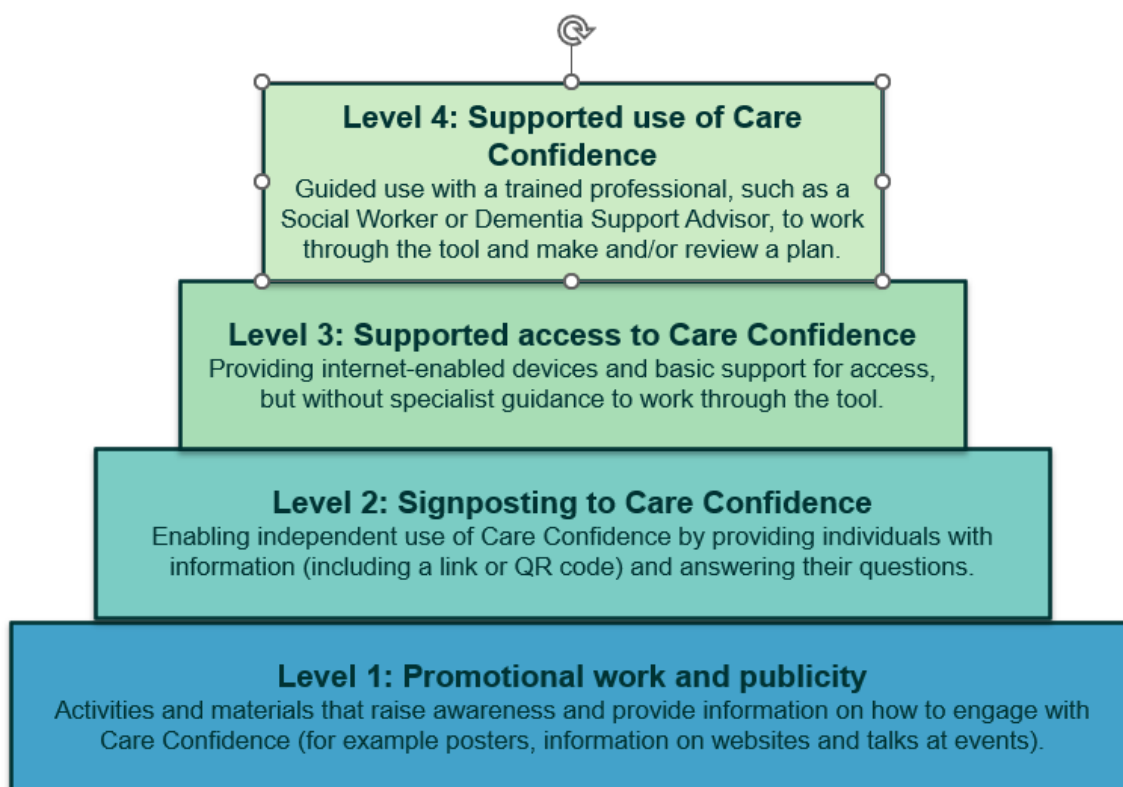


Figure 1: Four levels of implementation for Care Confidence related interventions

All four participating sites intend to deliver Care Confidence related interventions at each of the four levels of implementation. The exact nature of this delivery will be explored throughout Stages 3 and 4. From discussions with sites we think this may include offering the tool (with associated support and advice, where appropriate) at:

- council 'front-door' services
- carers' centres and voluntary service hubs
- prevention services/local area coordinators
- hospital discharge

Process evaluation: A combination of quantitative analytics and qualitative data, collected from service staff and people offered the interventions, will be used to examine the process and effectiveness of implementation in the 4 sites, as well as the expressed views and experiences of self-funders and their supporters. Data will be collected at multiple time-points over 16 months (February 2026 - May 2027), and we will communicate learning as it emerges to address implementation challenges. Specifically, we will:

Measure ‘normalisation’ using NoMAD: The NoMAD survey will be used to assess normalisation of the tailored Care Confidence interventions over time. A baseline has already been collected from all sites. At three follow-up timepoints (once at the start of Stage 3 and twice in Stage 4) staff across the study sites will be invited by email to complete the NoMAD survey. As the survey is anonymous, we will not know whether it is the same or different staff participating at each round.

When planning this study, we anticipated that 40 managers and front-line workers would be involved in implementation across the 4 sites, from which 30 (75%) were likely to respond to the NoMAD questionnaire at each timepoint. In fact, there were 53 anonymous responses to the baseline NoMAD, demonstrating the success of Stage 1 in building initial support for the research amongst delivery partners. We will nevertheless still aim for the minimum of 30 responses in total at each follow-up time point, recognising that support for research can change over time.

Undertake qualitative interviews with staff and people receiving the interventions (n=48):

Interviews with staff and people offered Care Confidence related interventions will focus on four core aspects of implementation:

- Mechanisms (what is happening)
- Context (influence of setting/environment)
- Fidelity (does delivery match the plan)
- ‘Dose’ (how much is necessary)

Topic guides were developed by the project management group based on the four core aspects of implementation. They are to be used flexibly and cover questions like, “Did the delivery of Care Confidence related interventions go as planned?” We will also explore outcomes, to inform future evaluative research. Topic guides will be adapted as we progress and as we conduct the interviews, to allow for emerging topics to be explored.

Staff and people offered interventions will be recruited through sites, purposively sampled to cover a range of characteristics and points in the pathway. Interview processes will be flexible (e.g. face-to-face or remote to suit preferences, with or without a carer present). Interviews will be carried out over the 16-month data collection period. All interviews will last 30 mins and focus groups 2 hours (with a scheduled break).

Assess uptake and reach using routine analytics: Each site will use a dedicated sub-domain of Care Confidence enabling the collection of site-specific (anonymous) Google analytics.

Capture costs to services: Whilst it is beyond the scope of this study to measure cost-effectiveness, sites have emphasised the importance of understanding the costs of implementing and running the

tailored interventions. We have adapted a cost recording tool developed for the ImpleMentAll study, which captures costs as follows:

- Personnel costs, using the Unit Costs of Health and Social Care Manual [34]
- Other direct costs (consumables, equipment, travel etc.)
- Indirect costs (capital costs and overheads, calculated as 20% of direct costs)

This data will enable us to understand the cost of Care Confidence related interventions being implemented by service staff, which is currently unknown.

3.4.2 Stage 4: Improve and consolidate

Learning from initial implementation will be applied to improve ongoing delivery (which will continue to be evaluated). This stage will involve a workshop in each site, completion of the NoMAD survey at two timepoints, final qualitative interviews with staff and service users, and a staff focus group in each site.

Workshops: This stage will begin with a workshop in each site. The aim of this part of the research is to review and improve workshops using tools recommended in ItFits to reflect on progress and build consensus on next steps. Consensus techniques will include brainstorming and structured group discussion involving the core team and wider stakeholders, including a public advisor for the study and local members of the public. No research data will be collected at this workshop - it is part of the improvement cycle (i.e. not a focus group). Written notes may be taken (by any/all participants) as a record of their plans, but we will not audio-record or transcribe proceedings.

Implementation of improvements and continuing evaluation: A period of continued delivery (with improvements) and evaluation will follow.

Qualitative interviews: Final qualitative interviews will be undertaken with staff and service users.

NoMAD survey: The NoMAD survey will be completed at two timepoints during this stage (to coincide with key milestones in implementation) by staff delivering Care Confidence related interventions.

Focus groups: Focus groups with staff will be held in each of the 4 sites for research purposes and will supplement qualitatively the data collected through NoMAD on the implementation process. Whilst NoMAD can tell us how normal, integrated, well-supported, and sustainable staff think the intervention is at different timepoints, we need qualitative data to explain why that is and what made the difference.

3.4.3 Sampling

Interviews with people who are offered Care Confidence related interventions (n=24): People who are offered interventions will be recruited through the 4 sites and will be purposively sampled to cover a range of characteristics and points in the pathway. We will aim to recruit 6 people (older self-funders or carers) from each of the 4 sites (n=24) over the 16-month data collection period. We will aim for a sample that is representative of a range of intervention levels and participant characteristics, to achieve maximum variation. We have costed for interpretation and translation to ensure language is not a barrier.

Interviews with staff delivering Care Confidence related interventions (n=24): We will aim to interview 6 staff members from each of the 4 sites, that have offered Care Confidence related interventions to older self-funders and/or carers. This sample size is justified by the need to ensure a range of staff background and roles, and to capture Care Confidence being offered at different levels (e.g. signposting with a leaflet or a guided conversation and supported use of the tool).

Measuring 'normalisation' using NoMAD (n=90): We anticipate that 40 managers and front-line workers will be involved in implementation across the 4 sites, from which 30 (75%) are likely to respond at each of the 3 remaining timepoints (n=90). NoMAD has been used successfully in similar studies with small (n<30) samples.

Focus groups (n=24): We will aim to carry out 4 (online or face to face) focus groups (1 per site) with 6 staff members in each (n=24). Each focus group will last 2 hours (with a break). These will be NPT-informed qualitative focus groups to augment the NoMAD survey data. This sample size is justified by the need to ensure a range of staff background and roles present, whilst ensuring pressure is not put on staff teams, especially those at the front line who need to be reactive to caseloads.

3.4.4 Recruitment process

Recruitment strategies have been co-developed with our network of lived experience advisers, Local Authority delivery partners and project management group to ensure they are inclusive. Recruitment will be ongoing throughout stage 3 and 4.

Recruiting self-funders and carers: We plan two main routes to recruitment for self-funder/carer interviews, but we will not limit our recruitment strategies to these should ongoing discussions with stakeholders highlight other potential recruitment strategies. In order to recruit 6 self-funders and/or

carers in each site, we anticipate having to obtain consent to contact from twice that number (12 potential participants per site) over the recruitment period.

Route A: staff implementing Care Confidence related interventions will give clients some brief information about the study verbally, and if appropriate, they will also give a summary information sheet and ask permission for the client's contact details to be shared directly with the research team via a secure Google Form.

Route B: a poster will be displayed in areas where level 2 interventions (signposting) are offered (such as hubs, hospitals, carers centres) so that self-funders/carers who have been signposted to Care Confidence can contact the research team directly if they would like to take part in an interview. The poster contains contact information (email and telephone number) for the research associate, and a QR code for a Google Doc consent to contact form.

In each of these routes, participants are invited to approach the researcher to receive more information. Once we have consent to contact, whether this is provided via a gatekeeper or a potential participant contacts us directly via email or the Google Form, we will make up to 3 attempts to contact each potential participant. If we don't hear back, we will take this as a decline. If we do get through, we will give further information (participant information sheet), answer any questions and if they are still interested in taking part we will move onto the consent process outlined at 3.5.

We will monitor the number of consent to contact forms received on a monthly basis to ensure we do not over recruit. If appropriate, we will consider pausing recruitment to avoid having to let people down.

Recruiting staff (interviews): The research team have been building relationships across different locality teams in each of the 4 sites. We would like to speak to staff members who work with older self-funders and their carers in different settings within the local authorities and voluntary organisation. These include: frontline practitioners (social workers, therapists, dementia support assistants); customer facing teams including staff taking calls in the customer service centres and carers centres. We will invite staff members directly via email and/or ask managers of teams within each of the sites to share our contact details with them, along with some brief information about the interviews. If staff members would like more information, we will send them a PIS and an informed consent form via email. If, after considering the information they are still interested in taking part, we will obtain written informed consent and agree an interview date/time. Interviews will take place either online or face-to-face, depending on the participant's preference.

Recruiting staff (focus groups): We will invite staff from each of the 4 sites who have been implementing Care Confidence related interventions to a focus group (1 per site). We will not have all potential participants' email addresses so will be reliant on key contacts within delivery sites to

circulate invitations. If staff members would like more information, we will send them a PIS and an informed consent form via email. If, after considering the information they are still interested in taking part, we will obtain written informed consent and arrange a date/time for an online focus group.

Recruiting staff (NoMAD survey): All staff who have participated in the co-development of Care Confidence related interventions (through workshops) and staff who implement Care Confidence in practise will be invited by email to complete the NoMAD survey at 3 more timepoints during the study. We do not have access to the email addresses of all potential participants so will be reliant on key contacts within delivery sites to cascade information in meetings and via email. Staff will receive a link to the survey via email and can complete it if they wish.

3.4.5 Inclusion criteria

The following inclusion criteria apply for staff participating in surveys, interviews and focus groups:

- Staff (including volunteers) involved in any capacity in delivering a Care Confidence related intervention
- Staff involved in managing the implementation or delivery of a Care Confidence related intervention

The following inclusion criteria apply for self-funders and carers participating in interviews:

- Any adult offered, signposted to, or using any Care Confidence related intervention designed and/or delivered as part of Care Confidence in Action

3.4.6 Exclusion criteria

The following are the exclusion criteria for the study:

- Staff not involved in the delivery, management or implementation of Care Confidence related interventions for the Care Confidence in Action research or research sites
- People without capacity to give informed consent
- People under 18 years of age

3.4.7 Participant withdrawal or declining to take part

Participants can withdraw from the study at any time without giving a reason. Any data collected up to the point of withdrawal would continue to be used in the study unless there was something specific the

participant requested removing. If a participant would like us to remove some of their data, they can ask us to do so up to two weeks after it was provided. After that, it might not be possible, as their responses may already be included in the overall study findings. This is clearly detailed in the information sheets for the study.

3.5 Consent

All research activities will follow the same approach to obtain informed consent. The following steps will be taken to provide information about the study and opportunities to discuss it:

A full participant information sheet will be provided. Participants will have the opportunity to read through the information and consider whether they would like to take part. When the researcher first contacts potential participants, there will be an opportunity to discuss the study and ask the research team any questions they have (either in person, over phone, by email or a virtual meeting). It will be made clear that they do not have to participate. If they are happy to continue, we will arrange an interview/focus group. There will be a period of at least 24 hours between the person receiving the information sheet and participating in an interview/focus group, to ensure they have had adequate time to consider the information. At the start of an interview, the researcher will discuss the information sheet with the participant again and they will be able to ask further questions about the study before signing a consent form, unless they have already provided consent remotely (for those being interviewed online or over the telephone). Remote consent can be provided over email or audio recorded using an encrypted voice recorder at the start of the interview. For the latter, we will audio-record the participant verbally agreeing to each statement and stating their full name, and that they agree to taking part in the research. This recording will be stored separately from the interview data. All professional focus groups participants will be asked to provide remote consent by email in advance of the online focus groups.

All participants will be provided with a copy of the participant information sheet and a copy of the consent form for their future reference, regardless of the method with which the participant gives consent.

Capacity to give informed consent to take part in this research will be assessed (using MCA guidance) by a researcher in person, online, or over the telephone. If there is any reason to doubt capacity, we will carry out a capacity assessment and log these on an excel sheet. People without the capacity to consent will not be interviewed.

4. DATA COLLECTION

4.1 Schedule of data collection

Data collection will focus on the processes through which delivery partners develop and implement their chosen interventions, together with the experiences and views of service users. We will be flexible in our approach to data collection to maximise participation and participant wellbeing. Members of the research team will collect demographic data prior to interviews and focus groups.

4.1.1 *Demographic data*

Demographic information collected will include:

- Age bracket
- Postcode (first part only)
- Gender
- Ethnicity

This anonymous information will be recorded on a Word document by the participant, with the help of a staff member or the researcher, if appropriate, and collated on an Excel sheet along with the participant's ID number.

4.1.2 *NoMAD survey*

A NoMAD baseline has already been collected from all sites, and a summary of the data has been fed back to sites. One more NoMAD survey will be administered in stage 3, and two further NoMAD surveys will be administered in stage 4 (3 months apart). Whilst NoMAD can tell us how normal, integrated, well-supported, and sustainable staff think the intervention is at different timepoints, we need qualitative data to explain why that is and what made the difference.

4.1.3 *Qualitative interviews*

The qualitative part of the study will include in-depth interviews with staff and older self-funders and/or their carers, and focus groups with staff. The interviews will be flexible in approach. Those with older self-funders will most likely be face to face, unless telephone or online is preferred. All interviews will last approx. 30 mins and the focus groups up to 2 hours (with a scheduled break).

Topic guides will be used for the differing groups of participants. These were developed with input from the project management group to cover the four core areas of implementation (mechanisms, context, fidelity and dose).

Qualitative interviews with staff: Staff interviews will take place over the 16-month data collection period (stages 3 and 4). Topics covered in the interviews will include implementation processes (what is happening), did they do what they planned to do, and what helped/hindered.

Qualitative interviews with self-funders and/or carers: Self-funder/carer interviews will take place over the 16-month data collection period (stages 3 and 4). Self-funders and carers who have been offered Care Confidence related interventions will be interviewed about their views and experiences of the interventions. Interviews will take place over the 16-month data collection period (stages 3 and 4). Topics will include inclusivity, how helpful was the intervention, and was it what they expected. Self-funders can be interviewed in a dyad with their carer if requested.

Qualitative focus groups with staff: Focus groups will be held in each of the 4 sites for research purposes and will supplement qualitatively the data collected through NoMAD on the implementation process. Staff who are involved in the delivery of Care Confidence related interventions will be invited to one of 4 online focus groups (each with approx. 6 participants). Topics will include barriers and facilitators to Care Confidence related interventions, study processes and inclusiveness. The focus groups will take place in stage 4.

4.1.4 Routine analytics

We will assess uptake and reach of Care Confidence related interventions using routine analytics (via Google Analytics). Each site will use a dedicated sub-domain of Care Confidence, enabling the collection of site-specific (anonymous) analytics, including numbers of new or returning users, geographical region, popular days/times, popular sections of the tool, events (e.g. viewing a video) and how users arrived at the site (i.e. browser search, via a link on social media or email).

4.1.5 Capture costs to services

Activity data logged by sites will help us to understand the personnel related costs of implementing Care Confidence related interventions in local authorities and voluntary sector organisations. We will obtain these data via an activity log that staff members will complete detailing any Care Confidence related intervention they have delivered. The activity log is a Google Form and these data will be transferred directly to the research team once the respondent submits.

We will have information on other direct costs and indirect costs from our ongoing communication with sites regarding consumables, equipment and travel. We will record this information on our adapted cost recording tool (one per site).

5 DATA ANALYSIS

A combination of quantitative analytics (Google analytics of the Care Confidence website, and NoMAD survey data) and qualitative data (interviews and focus groups) collected from staff and people offered the interventions, will be used to examine the process and effectiveness of implementation, as well as the expressed views and experiences of self-funders and their carers.

5.1 Google analytics

Each site will have a dedicated Care Confidence subdomain which will collect site-specific (anonymous) analytics giving insights into uptake and reach by site. Google produces standard and custom reports of website traffic and user behaviour covering numbers of new or returning users, geographical region, popular days/times, events (e.g. viewing a video) and how users arrived at the site (i.e. browser search, via a link on social media or email). We will use these descriptively to track the impact by site of activity to implement Care Confidence over time (using Realtime features where appropriate - for example to assess the immediate impact of a specific activity).

5.2 NoMAD data

The survey is anonymous so it is possible that different sets of individuals will respond at each time point. We will therefore approach these data with study sites, not individuals, as the unit of analysis.

We will take a descriptive approach, plotting changes over time in each site's mean scores on items and core constructs (coherence, cognitive participation, collective action, and reflexive monitoring) and noting differences in mean scores between sites taking different approaches to implementation. Differences will be set in context by the free text answers to questions in the NoMAD and further explained by our analysis of the qualitative data (see below).

5.3 Qualitative data (interviews and focus groups)

Interview and focus group transcripts will be analysed abductively, starting with a Framework informed by NPT but allowing for the inductive development of additional themes using a reflexive approach informed by Braun and Clarke. The research associate will lead the initial coding and discuss initial interpretations with other members of the project management team to reduce the influence of any one person. The process of analysis will begin as soon as the first transcripts are received and will continue so that learning from early interviews can be fed into Stage 4 workshops, and insights from those workshops can feed back into further improvements and analysis. Findings will be considered alongside the quantitative data analysis to consider the acceptability and feasibility of the study processes.

5.4 Capture costs to services

Data recorded on the adapted cost recording tool will be presented descriptively by site and level of activity.

6 END OF STUDY PROCEDURES

The end of the study is defined as the end of data collection, analysis and output generation, including publications arising from the research.

The CI will notify the REC of the end of the study.

7 ETHICAL AND REGULATORY CONSIDERATIONS

7.1 Research Ethics Committee (REC) and other Regulatory review & reports

The study will be subject to appropriate Research Ethics Committee (REC) and HRA approvals. It will be conducted in accordance with the protocol and GCP guidance where applicable.

Amendments will be reviewed by the Sponsor to assess whether they are substantial or non-substantial. Amendments will be submitted to the HRA for consideration. Participating NHS sites will be notified of all amendments. An amendment history will be kept within the study master file.

7.2 Peer review

The study design was discussed and agreed internally, both in the university and in individual sites/settings during workshops. This study was independently peer reviewed by experts, as part of the NIHR School for Social Care Research commission process, prior to funding being awarded. The chief investigator and all co-investigators declare no conflicts of interest.

7.3 Patient & Public Involvement (PPI)

Care Confidence was developed with older self-funders and carers in the first NIHR SSCR Study, and a PPIE group advised throughout. Two members of the group then advised on the Care Confidence in Action proposal (e.g. suggesting we build in opportunities to share learning between sites and co-writing the plain English summary) and York's standing PPIE group also gave feedback. They felt that a webtool alone might exclude some people but, with the right support, Care Confidence could be 'a great step towards helping people through the self-funding process which is quite daunting at present.'

Since receiving funding, the Care Confidence in Action advisory panel has grown and diversified. Full details are below:

7.3.1 Study advisory group

We have established a flexible, multi-modal stakeholder advisory network combining meetings with other forms of communication including email, telephone, discussion at existing groups and digital platforms. The study advisory group will meet quarterly for independent oversight and input into dissemination and impact of the research. The group has two strands:

1. Practitioners: This group consists of a range of Local Authority staff members with a mix of skills and knowledge.
2. Lived experience: This group consists of 7 core PPIE members with lived experience. Two public advisors from the initial study have continued to advise on the study, providing invaluable continuity, and we have now recruited a further 5 advisors with experience of self-funding. Advisors will act as critical friends to the research team through various modes, including email and one-to-one discussion, and they will also act as expert advisors to sites. Having a team of public advisors will mean that not too much burden will be placed on any one individual and if individual advisors have to take time out for sickness or caring responsibilities there will still be sufficient experience in the PPIE team to advise the project.

The study advisory group has already contributed to the development of workshop related materials and Care Confidence related interventions. They have provided insightful feedback on Care Confidence promotional and training materials, recruitment approaches, and information documents for potential participants. The schedule for further involvement will be responsive to the needs of the project but is expected to include input on data collection and implications of findings.

7.3.2 Project management group

The project management group will have responsibility for overall study management and to ensure a collaborative approach throughout. It includes a range of stakeholders, including co-applicants advisory group members and the core research team. This group meets quarterly to input into study documentation and approvals, monitor study progress, and discuss analysis and dissemination.

7.4 Data protection, participant confidentiality and research data management

All investigators, research staff, and PPI will comply with the requirements of the Data Protection Act 2018 and General Data Protection Regulation (GDPR) 2016/679 with regards to the collection, storage, processing and disclosure of data including any personal information.

Personal data (names, contact details) will be stored securely on University of York's secure server and only members of the research team and research administration staff will have access to it. This data will be stored separately to any research data and will only be used to contact participants about the research, follow up visits, and dissemination of findings. The recruiting sites will provide the research team with consent to contact information for potential participants via a secure online Google Form.

Personal information for participants who decide not to take part or do not meet the inclusion criteria will be destroyed. All paper consent forms will be scanned and stored electronically away from any research data. The paper version will then be securely destroyed. Any paper documentation containing identifiable information waiting to be scanned and stored electronically will be stored in a locked cabinet in the CI's office, which only members of the research team have access to.

Information containing personal identifiable information will not be removed from the sites apart from when securely transferring data directly to the research team. Participant details will be anonymised in any publications or reports resulting from the study.

At the point of informed consent all participants will be given a unique study ID which will then be used on all study documentation.

7.4.1 Quantitative data

The online platform Qualtrics will be used to collect the anonymous NoMAD survey responses before they are exported to Excel or SPSS for analysis. Qualtrics can be accessed securely via the internet to manage the survey responses.

7.4.2 Qualitative data

The qualitative interviews and focus groups will be audio recorded using a University of York encrypted voice recorder and transferred as soon as possible onto the secure server. The recording will then be deleted from the voice recorder. Audio recordings will be transcribed by a University of York approved transcription service that has the necessary confidentiality agreements signed. Audio recordings and transcripts will be labelled with a study ID number and stored securely in line with the University of York's data storage policies.

Anonymised quotes may be used in publications and presentations, and anonymised data may be made available for secondary data analysis by the research team or other researcher studying a relevant topic, upon request. This will only be for participants who have indicated their agreement to the ongoing use of their anonymous data on their consent forms.

7.4.3 Archiving data

At the end of the study, audio recordings will be destroyed and all other data will be archived for 10 years in accordance with the University of York Research Data Management Policy <https://www.york.ac.uk/about/departments/support-and-admin/information-services/information-policy/index/research-data-management-policy/>. Any personal identifiers relating to individual participants will be held until the information is no longer needed for the study. Some anonymised transcripts may be uploaded to NIHR approved repositories and used in relevant future research, including by researchers in other institutions. This will be clearly stated on the study consent form. The data will not be used or released in such a way that any participant could be identified.

After 10-years, research data not deposited in a repository (including consent forms) will be securely destroyed using the appropriate procedure advised at that time by the University research data team.

7.4.4 Data access, copyrights and indemnity

Access to study data will be limited to relevant individuals of the research team and the CI will act as data custodian.

The University of York will be the owner of the copyrights and associated intellectual rights in the study data.

7.4.5 Indemnity

The University of York will act as Sponsor for the study and provided legal liability insurance. Contained within the PIS's is a statement regarding indemnity.

7.5 Study conduct

The protocol will be adhered to throughout the study period, any deviations from the protocol will be documented and reported to the CI and sponsor if required.

A serious breach of the protocol will be reported to the sponsor immediately who will determine the seriousness of the breach and whether the REC need informing.

The research team will maintain regular contact with the four sites to address any issues as they arise. The sites will have ongoing supervision throughout the set up and delivery of Care Confidence related interventions to support with any issues.

The research team will document all processes and management of the study, including any deviations from the protocol.

7.6 Monitoring and audit

The study will be monitored in agreement with the sponsors policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All study documentation will be made available upon request for monitoring or auditing purposes by the sponsor, and authorising REC.

The research team will be responsible for monitoring. This is likely to include:

- Consent processes (taken by appropriate person and documented correctly)
- Data collection is consistent and adheres to protocol
- Adverse events, protocol deviations procedures are being followed and documented correctly
- No key data missing
- Data is valid
- Review of recruitment rates and withdrawals

7.7 Adverse events

Safety reporting is an integral part of research and should be built into any participant contact and research activities. It is therefore important to record adverse events. Adverse events can either be because of study conduct (deviation from study documents or processes such as consent), intervention, or they could be completely unrelated to the study (missing a focus group through physical ill health). These events vary in severity dependent upon the nature of the deviation. It is important to report adverse events, particularly those which may have serious or unintended consequences as patterns may be detected on reviewing the records. Adverse events may be reported by the participants, observed or identified by site teams, or by researchers when data collecting.

Any serious or other adverse events will be reported according to GCP guidelines as to whether it is an adverse event that needs documenting at a site level or whether it is a serious event which needs reporting to the CI. We will provide an Adverse Event (AE) log and Serious Adverse Event (SAE) reporting form to all the sites. If an adverse event is detected by a local team, they will report it to the site PI, who will log it on the appropriate form and monthly updates will be provided to the research team of any AEs. Serious adverse events must be reported immediately to the Sponsor; it is important

to gather as much information about the event as possible. Anyone can report a serious event, and best practice is to err on the side of caution if unsure of whether an adverse event needs reporting.

7.8 Expenses and Benefits

Whilst there are no perceived direct benefits for research participants, there is the satisfaction of taking part in a research project and the knowledge that participation could benefit other people, including older people and those who support them.

A £20 gift voucher will be offered as a thank you to each service user, carer and staff interviewee.

7.9 Other Ethical Considerations

Capacity will be assumed by the researcher if the participant is able to understand the information about the study and is able to communicate their decision about taking part in the study. The research team will comply with research best practice and host University policies regarding safeguarding. Stage 3 and 4 may involve some lone working by researchers and the relevant lone working procedures will be followed, including notification of location, start and end times of visits and reporting in.

8 STUDY MANAGEMENT

The CI will have overall responsibility for the project and have oversight of the different components. The project will be managed from the University of York.

8.1 Project Management Group

The Project Management Group consists of all the co-applicants on the project alongside wider stakeholders, including advisory group members and university researchers. The group meets quarterly online to input into all aspects of the ongoing set up and delivery of the project, including development of study documentation, monitoring approvals and progress, discussing any issues as they arise and contributing to reports and dissemination.

8.2 Sponsor and funding

University of York are the sponsors for this study and the National Institute for Health and Care Research (NIHR) School for Social Care Research (SSCR) are the funding body (Reference NIHR-SSCR-CR13).

9 DISSEMINATION

9.1 Dissemination strategy

The research will produce new knowledge on the inclusive implementation of Care Confidence related interventions. A strategic impact plan has been developed co-productively with the project management group. It aims to:

1. Improve the experience of older self-funders and their carers, especially marginalised groups
2. Share learning on the use of Implementation Science in social care settings

Impact activity will start from day one and will include:

- Creation of a communication and engagement plan to identify and respond to the needs of diverse stakeholders
- Regular engagement through a website, blogs, social media and established networks
- Project launch and findings events, each with associated, tailored publicity
- Co-production sessions to design resources for different audiences

Outputs are likely to include:

- a) An optimised Care Confidence platform (with multiple 'front doors', tailored to specific contexts)
- b) Accessible summaries of findings in written, video and audio formats, as well as newsletters disseminated by the sites, and webinars, blogs and conference presentations tailored to different audiences
- c) Specific resources to support implementation of Care Confidence interventions (with TIDieR checklists)
- d) Peer reviewed articles about study findings and the use of Implementation Science in social care

We will focus on equity in our impact work, prioritising activity that can empower self-funders who face the most significant barriers and attending to factors that enable transfer of learning into practice, including targeting, co-design and attention to context.

9.2 Authorship eligibility guidelines

Data arising from the study will be owned by the Sponsor, University of York. The researchers will aim to publish a research article in a peer-reviewed academic journal.

The research team will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by NIHR SSCR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

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11 SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol.

For and on behalf of the Study Sponsor:

Signature:

Date:

...../...../.....

.....
Name (please print):

.....
Position:

Chief Investigator:

Date:



Signature 1:

30/10/2025

Name: (please print): Kate Gridley