Study Title: Understanding and using people's experiences of social care to guide service improvements: could an effective and efficient co-design approach be translated from health to social care using the exemplar of loneliness?

Short title: Exploring experiences of loneliness and improving social care support

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The chief investigator and all co-investigators declare no conflicts of interest.

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2. LAY SUMMARY

Local authorities need to find new ways of collecting and using data on people’s experiences of social care to improve service design and quality. We propose to adapt and test a service improvement approach successfully used in health care settings. We will use loneliness as our focus. Loneliness affects many people and is important to local policy makers. Based on rigorous qualitative research the approach will use carefully selected extracts of people describing their social care experiences in the form of a 20-25 minute film to prompt discussions about how services can be improved. Importantly these discussions involve local authority staff and lay people working as equal partners.

There are two stages: 1. DISCOVERY phase. Interviews with a national sample of 40-50 people exploring their experiences of loneliness and social care, and with 20 social care staff to explore opportunities for service improvement around loneliness. Interviews will be filmed or audio recorded if the person prefers, typed in full and analysed for ‘touch points’ which show positive care moments or areas where services could be improved. A 'touch points' film will be produced. 2. CO-DESIGN phase involves separate feedback workshops with staff and social care users followed by a joint meeting where the film is shown to both. Participants work together to agree a list of priorities to put in place for improving services.

Interviews will include those who are less often heard in research e.g. learning disabled people and people from black and minority ethnic groups. Doncaster will be the test site for stage 2 because loneliness is a high risk in many parts of the city and tackling it is a priority for the local authority. Given the challenges that social care research faces in engaging practice and the time it can take to build and sustain links with local authorities it is important to have a willing organisation who are interested in research and are committed to the topic area.

Working with social care service improvement colleagues from adult social care and Doncaster residents who experience loneliness, we will use observations and interviews to study how improvements are made over a nine month period. Key questions will include i) whether this approach using a film based on a national interview study of social care users and staff perspectives of loneliness would work in a local setting and ii) whether this quality improvement approach is acceptable, or needs adapting, for wider use in social care.

Outputs: a section on loneliness based on analysis of the interviews with users of social care services using around 250 film, audio and text extracts published on a new website Socialcaretalk.org; recommendations for the use of this service improvement approach in social care; conference presentations; a new interview collection for the Health Experiences Research Group data archive for secondary analysis; end of project event; three academic papers.

Anticipated impact: Local authorities need new ways of collecting and using data on people's experiences of social care to improve service design and quality. Our study will draw on and adapt as appropriate an approach from the healthcare improvement field to address this need. The touch point film will be transferable for use in improvement initiatives across other local authority settings. The project will provide valuable learning beyond the immediate project outcomes through a wider engagement strategy with social care partners.

3. SYNOPSIS

Study Title	Understanding and using people’s experiences of social care to guide service improvements: could an effective and efficient co-design approach be translated from health to social care using the exemplar of loneliness?
short title	Exploring experiences of loneliness and improving social care support.
Study Design, including methodology	Qualitative research project and testing an intervention – accelerated experience based co-design - within a social care setting using workshops and evaluation.

Study Participants, including sampling strategy	**Discovery phase**: A national sample of social care users who self-identify as lonely and a sample of social care staff who provide support or manage services with a remit of tackling loneliness. **Co-design phase**: Workshops with social care users who experience loneliness and social care staff to identify service improvement priorities and test whether this co-design approach will work in a social care setting.
Sample Size	Discovery phase: Social care users n40-50, social care staff n20 Co-design phase: 1 workshop with social care users(n10-15), 1 workshop with social care staff (n10-15) and 1 joint workshop (n20-30). Evaluation: interviews and evaluation feedback after workshops with co-design participants, service improvement facilitators , senior LA managers and other staff stakeholders.
Planned Study Period and Recruitment Period.	34 months project length.
Aim/Research Questions/Objectives	
Primary	**Aims**: Our aim is to assess whether an effective and efficient co-design approach called 'accelerated experience based co-design' (AEBCD) can be translated from health to social care, using experiences of 'loneliness' as an exemplar. **Objectives:** 1. To understand how loneliness is i) characterised and experienced by people who are in receipt of social care in England and ii) characterised by social care staff and the voluntary sector 2. To identify how services might be changed to help tackle the problem of loneliness experienced by users of social care 3. To test, with one local authority, whether an approach to service improvement, known to be effective in health care, could be adapted for use in social care 4. To disseminate all study outputs and publish resources on a newly established Socialcaretalk.org platform for public, family carers, service users, voluntary organisations, researchers, teachers, policy makers and providers.

4. ABBREVIATIONS

AEBCD	Accelerated Experience Based Co-Design
CI	Chief Investigator
HRA	Health Research Authority
ICF	Informed Consent Form
LA	Local Authority
MS & HERG	Medical Sociology and Heath Experiences Research Group
PI	Principal Investigator
REC	Research Ethics Committee
SCIE	Social Care Institute for Excellence

5. BACKGROUND AND RATIONALE

There is a need to find new, cost-effective ways to integrate the perspectives and experiences of social care service users into the design of prevention and care initiatives led by Local Authorities (LA) and their partners. Qualitative research into experiences of service users and providers can often provide insights into how services might be improved, but too often these insights are not followed through into changes in practice (Coulter et al, 2014). Even when improvements are achieved, practitioners may reasonably doubt whether the lessons are transferable to other settings within the same sector. While this challenge of knowledge transfer is recognised in health, it is arguably a greater challenge in social care where the routes for incorporating evidence into practice are less well established and supported.

In this project we will test a promising approach from health care (accelerated experience-based co-design or AEBCD) to see if it can offer a way for improvements in social care to be made based on people's experiences and whether it requires adaptation to be practical and acceptable in this different setting. If so it may be useful for wider social care. Loneliness will be used as the exemplar in this process. We first want to understand what loneliness is really like from the perspective of those who are or have been lonely, and how it affects all aspects of their lives, relationships and wellbeing. Then we will use those experiences to work with lonely people and social care services to find better ways to address their needs. Through this process we will evaluate the use of AEBCD in social care and make recommendations for any appropriate adaptations.

Main research question:

Can an effective and efficient co-design approach called ‘accelerated experience based co-design’ (AEBCD) can be translated from health to social care, using experiences of ‘loneliness’ as an exemplar?

Data collection methods include:

- In-depth face-to-face, telephone or online interviews with social care users who identify as lonely.
- Face-to-face, telephone or online interviews with social care staff who provide support or manage loneliness services.
- Half day workshops with 1) social care users and 2) social care staff. Joint workshop with 1 and 2.
- Interviews with workshop participants, service improvement facilitators, local authority managers and other staff stakeholders [Evaluation]
- Brief post workshop evaluation forms completed by workshop participants [Evaluation]
- Observations of service improvement meetings [Evaluation]

The potential risks are around social care user participants becoming upset when talking about being lonely. We will mitigate against this by making sure informed consent is given before the interview and advising participants that they can pause or stop at any point. They can also choose not to answer particular questions. Interviews will be conducted by a sensitive and experienced qualitative researcher using a clear protocol. Researchers will provide details of support organisations and help-lines, that they can leave with the participant if required.

There are two populations:

1. Social care users who identify as experiencing loneliness. We will aim for a diverse sample of participants including people who are often seldom heard in research. This includes people from BAME groups, learning disabled people and older carers.

2. Social care staff who are involved in providing support and services around loneliness.

6. AIM / RESEARCH QUESTIONS / OBJECTIVES

Aim / Research Questions / Objectives

Aim: Our aim is to assess whether an effective and efficient co-design approach called 'accelerated experience based co-design' (AEBCD) can be translated from health to social care, using experiences of 'loneliness' as an exemplar.

Research question: Can an effective and efficient co-design approach called 'accelerated experience based co-design' (AEBCD) can be translated from health to social care, using experiences of 'loneliness' as an exemplar?

Objectives:

1. To understand how loneliness is i) characterised and experienced by people who are in receipt of social care in England and ii) characterised by social care staff and the voluntary sector

2. To identify how services might be changed to help tackle the problem of loneliness experienced by users of social care

3. To test, with one local authority, whether an approach to service improvement, known to be effective in health care, could be adapted for use in social care

4. To disseminate all study outputs and publish resources on a newly established Socialcaretalk.org platform for public, family carers, service users, voluntary organisations, researchers, teachers, policy makers and providers.

7. STUDY DESIGN / METHODS

7.1. Study Design

We will employ qualitative interviews, and test an intervention – accelerated experience based-co design within a social care setting using workshops, observation and evaluation.

7.2. Methodology

The study is using a grounded theory approach to understanding how social care users experience loneliness and a co-design approach to test whether a service improvement intervention used in healthcare can be translated into a social care setting.

Grounded theory is a systematic and flexible methodology which will allow us to fully explore with participants their experiences while encouraging the close involvement of the researcher as data is generated and analysed simultaneously. This approach has been effectively used in over 100 projects published on Healthtalk.org covering different health issues. Loneliness is used as an exemplar in this project to enable us to assess whether the use of a co-design approach used in health settings can be used in social care settings. It is important for us to generate rich and in-depth understandings of the experience of loneliness in order to develop the 'catalyst' film to use in the co-design phase.

The co-design phase involves testing an intervention – accelerated experience based-co design (AEBCD) within a social care setting using workshops, observation and evaluation. This approach was previously used in co-applicant Locock's study (NIHR SDO 10/1009) within a health care setting.

7.3. Sampling Strategy

Interviews with users of social care services: We will use a maximum variation approach using a range of different recruitment strategies to generate a diverse sample. Drawing on the field review and the expertise of the project Advisory Group, the researcher will draw up a list of types of experiences and demographic variables likely to be of most importance. Early recruitment will focus on people who are seldom heard in research, including learning disabled people, BAME groups and the frail elderly before widening out to the wider population. As fieldwork is conducted recruitment will include unanticipated aspects of experience which have emerged through interviews. Existing recruiters may be asked to focus their efforts on specific categories, and the researcher may seek out new recruiters who have access to particular types of people.

We want to capture diversity in people's experiences of loneliness in order to generate rich data to develop the film for the co-design stage of the research and to produce a comprehensive resource for publication on Socialcaretalk.

Staff interviews: Interviews will be conducted with a national sample of social care staff who provide support or manage services with a remit of tackling loneliness.

Co-design phase: Researchers will work with social care improvement colleagues from adult social care and Doncaster residents who are users of social care services and experience loneliness.

7.4. Methods of Data Collection

DISCOVERY PHASE
This addresses objective 1

Interviews with social care users:

In-depth face-to-face, telephone or online interviews will be conducted by an experienced qualitative researcher using a narrative approach. An open question will be used to allow participants to highlight what is important to them, their values, meanings, priorities and experiences. Follow up questions will prompt further reflection on their initial narrative and generate richer understanding of participants' experiences of their wider lives including relationships and employment, with social care services and other sources of support. We will also explore how services could be improved. Guided by the field review, supplementary questions will prompt reflection on experiences of loneliness and interactions with social care. Participants will be interviewed in a place of their choosing, often their own homes (or workplace). If it is not possible to interview people face-to-face, telephone or online interviews will be conducted. The interviews will vary in length and, from previous experience, will last for anything between 45 minutes to two hours. We know from existing research (McInnis and White 2001) that while loneliness can be a state of 'silent suffering' people can be open to talking to researchers about their experiences and the importance of open questions and sensitivity is underlined.

All interviews will be audio recorded and filmed (where applicable) with permission. Participants will be given the choice of whether data extracts from their interviews are used in film, audio or text versions in the catalyst film and new section on Socialcaretalk.org. Analysis will be conducted alongside the fieldwork until 'data saturation' is reached (Morse 2015). This is when no new detail is being generated and the coded data is sufficiently robust to achieve the research aims. A coding book will be used to regularly review the development of new codes in order to monitor when data saturation is reached.

Interviews with staff:

We will interview a sample of 20 staff (at least 8 working in Doncaster) who provide support or manage these services with a remit to tackle loneliness from LAs, private or voluntary sectors. These interviews which we anticipate will last between 30-60 minutes, will explore how staff make sense of how loneliness is experienced by social care users, to explore what staff feel are priorities for service improvement and what gets in the way of providing the best care possible. The interviews will be held at a location that is convenient to the participants and, with consent, will be audio recorded. Where face-to-face interviews are not possible, researchers will conduct telephone or online interviews. A diverse sample of staff (geographical location, length of time since qualification, ethnicity, socio-economic class and gender) will be recruited via the Association of Adult Directors of Social Care newsletter, social media platforms.

During the COVID pandemic discovery phase face to face research activities will not commence until it is safe to do so. Interviews will be conducted by phone or online using approved methods. Online interviews will be conducted using tools approved by Information Governance at the University of Oxford.

CO-DESIGN PHASE

This addresses objective 3

In line with an AEBCD approach two parallel feedback workshops will be held in Doncaster, one with social care users and one with staff.

Workshop 1. Bringing users together as a group builds confidence about speaking in a meeting environment before meeting with the staff later in the third, joint workshop. The catalyst film will be shown and a professional facilitator from the SCIE will encourage participants to talk about their response to the film using an 'emotional mapping' exercise (Bate and Robert, 2007). This will help participants highlight key aspects of their experience that could have been managed better. Participants are encouraged to place sticky notes on a timeline to highlight the 'touch points' (emotionally charged or key moments) along their journey. By the end of this exercise, participants will have created a visual representation of their experiences of loneliness with particularly positive points or those that may have benefited from improvement highlighted. Feedback will be narrowed down to a shortlist of potential areas for service improvement.

Workshop 2. The staff workshop brings together social care staff to discuss and share their views about the services provided with the intention of enabling staff to highlight their priorities for service improvements. The facilitator will open by explaining the purpose of the meeting and setting the agenda. The findings from the loneliness interviews are then fed back to the group and staff feedback and discussion about these findings are sought. The group are supported to identify issues needing service improvement and then to narrow this list down to 4 or 5 priorities for improvement.

Workshop 3. A joint staff and user workshop will then be held. The catalyst film will be viewed again – the first time staff have seen it. Improvement priorities identified separately by staff and users will be shared and discussed in small working groups of staff and social care users. The facilitator will bring the group back together to agree a final list of improvement priorities, and identify who wants to work on each one. Small co-design working groups will be set up to pursue each priority, with staff and users continuing to work as equal partners to design and implement service improvements. Consideration of the transferability of this approach to other social care issues such as care leavers, domestic violence and abuse and learning disability, will be incorporated into this workshop. Participants will be asked to reflect on which areas AEBCD might be particularly salient within social care or where particular adjustments might be needed.

Evaluation Methods that have been successfully used in evaluating AEBCD will be adopted including ethnographic observations of workshops, planning meetings and co-design groups; staff and users involved in the co-design phase of the project will be interviewed to gauge their reactions to the approach and how they felt it changed their thinking; a short evaluation form will be filled out by participants after each workshop; a service improvement log will be completed by staff working on the improvement projects recording changes planned and made. The York based researcher will observe training for local service improvement facilitators and the three workshops which will be recorded on film to assist the analysis. The researcher will spend a total of two months (across a period of nine months) on site in Doncaster, to gain sustained and repeated observations of the implementation of the service improvement priorities through attending meetings, reviewing relevant documents and interviewing stakeholders to understand their responses to the AEBCD approach. Participants will be encouraged to contribute their thoughts about the use of this approach and what the barriers and facilitators to the use of it in a social care setting are. Stakeholder interviews will include not just staff and social care users involved directly in co-design but also service improvement facilitators and senior managers at Doncaster Metropolitan Borough Council. Members of the project team will also be encouraged to keep reflective diaries of their experience of the process, to help capture additional detail.

The workshops and smaller co-design working groups will be held in-person or remotely via an online video conferencing platform, depending on COVID-19 pandemic restrictions. Online meetings will be conducted using tools approved by Information Governance at the host institution. Online meetings will not be audio or video recorded.

7.5. Methods of Data Analysis

DISCOVERY PHASE

The interviews will be transcribed verbatim, checked for accuracy against the recording and de-identified. The transcript will then be returned to participants to give them the opportunity to read and remove any sections they would not like included in the study. They will then be asked to sign a form giving their copyright for their contribution to Oxford University to enable their interview to be used in the production of online resources, including a new section at Socialcaretalk.org, and the catalyst film being developed for the co-design phase of the study. The copyright form has been approved for use in current studies Narratives of health and illness for healthtalkonline IRAS ID112111, and Finding and funding social care IRAS ID269961.

The transcribed interview will also be deposited in a University of Oxford data archive which is available to other bona fide research teams for secondary analysis.

The data analysis will be conducted using a modified grounded theory approach underlining the importance attached to grounding theoretical formulations and insights in empirical evidence. This approach is appropriate because it enables us to understand how people make sense of their experiences of loneliness. Theory about loneliness will emerge from the data rather than informed by external social theory or constructs. Analytic bracketing will be used which involves temporarily putting aside some matters of empirical focus in order to examine others reducing the risk of granting analytic primacy to one component of the data (Gubrium and Holstein 2009). Each component is seen as mutually constitutive allowing a more robust analysis to develop. We are interested in the substantive content of what was said but also the ways in which participants 'construct' loneliness and how this construction interacts with different areas of their lives.

The interview transcripts will be carefully read by the researcher and SR and then open coded using the qualitative data analysis software Nvivo12. The data will initially be coded into two projects; social care users and staff.

In each project the codes will be generated from the data rather than pre-determined tags to ensure that meaning emerges rather than is shaped by the researcher. The researchers and SR will independently code the first three interviews and meet to discuss the different codes generated. The codes will then be reordered into a more formal tree structure allowing the identification of broader categories and the researchers will continue coding the remaining transcripts. The next stage will involve using a mind mapping technique (Ziebland and McPherson 2006) to develop a more conceptual and interpretive analysis of the datasets leading to the identification of key themes. The original recordings will be returned to as appropriate in order to aid this stage of analysis.

Both datasets will be brought together at this point to examine and better understand how loneliness is conceptualised by those experiencing it and social care staff. We know from existing research that loneliness is multi-dimensional and shifting (McInnis and White 2001) and our rich data and careful analytic attention will enable us to identify touch points (points at which participants highlight examples of good practice or action which have had an impact on them or an example of when service provision could be improved), patterns, commonalities and divergences across the two projects. This process will generate material to be shared in advance with participants in the social care user co-design workshop in Objective 2. In addition, a catalyst film of around 20 minutes will be produced drawing on video, audio or text extracts from the social care user interviews.

The rigour and trustworthiness of the analysis will be addressed in the following ways:
Credibility and **confirmability** will be established by a set of embedded techniques in the analysis process for both datasets. A second researcher, the research 'buddy' will review the interview schedule, read and comment on the first two interview transcripts to provide feedback on the researchers' interaction with participants and raise any points at which a particular issue could have been followed up and probed further.
The buddy will independently code the first two interviews and meet with the researchers to compare codes. This will ensure that the developing coding framework is comprehensive and will highlight if the researchers' motivations may be skewing interpretation of the data. When the data has been coded and emerging themes identified, the buddy will independently conduct the next layer of conceptual analysis

using the coding reports to again compare findings with the researcher. This additional layer will ensure that the social care user material which is published on the new Socialcaretalk section captures all the perspectives and experiences within the dataset. The summaries written for Socialcaretalk will be shared with members of the advisory group (including PPI members) as a form of **participant validation**.

Transferability will be achieved by the robust sampling approach. For the social care user interviews we will aim to recruit a diverse sample in terms of participant demographics (including age, gender, ethnicity, social class, sexuality) and experience (including family and geographical context, intensity and length of loneliness, use of different interventions or strategies and so on). The sampling framework will be designed in collaboration with the co-applicant team and members of the advisory group. For the staff interviews, we will recruit participants with a range of experience and demographic factors. The diverse samples and generation of rich data will ensure that the study findings are applicable to wider contexts.

CO-DESIGN PHASE

Observations and brief conversations will be recorded as field notes; interviews will be transcribed for framework analysis (Ritchie and Spencer, 1994). Framework analysis is a widely used matrix based approach to organising and analysing qualitative data. It can be used to generate descriptive accounts, identify themes and develop explanatory theories. The following questions will guide our evaluation of this approach; what kind of improvements did the co-design groups complete? Was the process acceptable to staff and service users? What suggestions might they have for improving the process? What adaptations might be needed for future use in social care? The research team will keep a note of ongoing reflections across Objective 3 to identify lessons to assist in the adaption of the approach in social care settings.

7.6. Study Sequence and Duration

N/A

8. PARTICIPANT IDENTIFICATION

8.1. Study Participants

Discovery phase -

Social care users: 40-50 people aged 18 and over who self-identify as lonely and are in receipt of social care services.

Staff: 20 local authority staff (including at least 8 based in Doncaster) who provide support or manage services with a remit to tackle loneliness. Fewer staff interviews are being conducted as this part of the project will not directly contribute to the production of the Socialcaretalk section.

Co-design phase -

Social care users who live in Doncaster: n10-15

Social care staff: n10-15

Co-design participants will also take part in an evaluation.

8.2. Inclusion Criteria

- Participant is willing and able to give informed consent for participation in the study.
- Participant is aged 18 years or above.

8.3. Exclusion Criteria

None

9. STUDY ACTIVITIES

DISCOVERY PHASE INTERVIEWS

Users of social care services, 1 or 2 interviews conducted by University of Oxford researcher at participants home or place of choosing, or by telephone/online

Social Care staff, I interview conducted by University of York researcher at participants home or place of choosing, or by telephone/online

CO-DESIGN PHASE

Workshops with social care users and social care staff to be held in a suitable meeting venue in Doncaster or remotely via an online video conferencing platform, depending on COVID-19 pandemic restrictions.

Co-design team based activity based in Doncaster Council premises, or remotely via an online video conferencing platform, depending on COVID-19 pandemic restrictions.

EVALUATION

Interviews with co-design participants, service improvement facilitators ,senior LA managers and other staff stakeholders.

Post workshop evaluations.

9.1. Recruitment

DISCOVERY PHASE
In pursuit of a diverse sample we will use various recruitment strategies. Within Doncaster we already have the support of the Loneliness and Social Exclusion Alliance who can support recruitment locally. We further have the support of an outreach service in socially and economically disadvantaged area of Manchester to recruit those from South Asian populations at risk of social exclusion. Posters and participant information packs will be distributed via these contacts and our wider networks of contacts within local

authorities. We will contact local and national social care related organisations like Age UK and befriending groups such as The Archway Foundation in Oxford and Rotherham. The Longsight Moss Side Community Partnership (third sector community development organisation supporting local residents in Manchester) has a diverse cultural heritage and has agreed to support recruitment in particular. Furthermore, the Social Policy Research Unit who are part of the NIHR School for Social Care have research links with many local authorities across England and will seek additional recruitment routes as required by the sampling strategy.

We will also use existing networks of seldom heard people and share details of the study in the form of a poster on social media platforms, such as Facebook and Twitter. In addition, we will seek support from the Clinical Research Networks which have growing capacity for assisting with recruitment in local authorities.

Information packs including the participant information sheet, reply form and SAE will be given to potential participants via contacts listed above or in response to social media requests. People will be asked to confirm their willingness to participate by return email, letter or telephone call. Having had an opportunity to read the information sheet, potential participants will be encouraged to contact the researcher regarding any issues they are unclear about or questions they may have. Participants can decline to participate or withdraw from the study at any time up to and including the date of the interview or meeting. Easy read versions of the recruitment documents will be used to facilitate the participation of people who may not understand written English. The researcher has experience in supporting the involvement of 'seldom heard' people in research.

The social care staff interviews will be recruited from geographically diverse areas with participants with differing employment status, length of service and experience. Staff at Doncaster will be invited to take part via letter and information sheet. Staff within England will be recruited via newsletters and social media. A dynamic recruitment table will be produced by the York researcher and co-applicant Baxter to ensure we capture a wide range of diversity in both national samples.

CO-DESIGN PHASE

In Doncaster, the user group will be recruited through the various third sector partners forming the Alliance, and their local networks. The Alliance has sufficient diversity in membership (including: Age UK Doncaster, a housing-based charity, organisations that support people with sensory impairments, Doncaster Mind, a community arts society, an adult learning centre, amongst others) to engage a diverse group of people experiencing loneliness in different contexts.

Co-applicant Boneham, an employee of Doncaster Council, will support the recruitment of staff from the Doncaster Metropolitan Borough Council social care team. Local voluntary organisation representatives will be recruited by the York based researcher. Potential staff interviewees will be identified through discussions between Boneham, co-applicant Wilberforce and other relevant managers of the selected services.

Ethnographic observation will take place at Doncaster Council including attendance at meetings (in-person or remotely via an online video conferencing platform, depending on COVID-19 pandemic restrictions), document review and staff interviews. The presence of the observer will be renegotiated with both staff and social care users as required.

9.2. Informed Consent

The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific activities are undertaken. The Participant Information and Informed Consent will be provided to the participants. It will be clearly stated that taking part is voluntary and the participant is free to withdraw from the study at any time. Easy read material may be used alongside participant information and consent.

DISCOVERY PHASE: Where interviews are being conducted virtually, the study information will be sent in advance of the interview and the researcher will go through the study details and what is involved by phone or online. Telephone or online interviews will require the participant to give oral consent at the start of the interview. The consent discussion will be audio recorded using the agreed wording on the consent form, and will be transcribed in full, as a detailed record of the consent conversation. A paper record will also be retained. A copy of the consent form will be sent to the participant.

Social care users taking part in an interview will also complete a copyright form after they have approved the interview content and chosen whether they want their clips to appear in video, audio or completely de-identified written version. The copyright form is signed giving copyright to the University of Oxford to use the material in research, teaching, publications and broadcasting and on Socialcaretalk.org run by the DIPEx charity.

CO-DESIGN PHASE: Where workshops are being conducted remotely, the study information will be sent in advance of the workshop and the researcher will go through the study details and what is involved by phone or video call. Before the workshop commences, participants will be required to complete the consent form. A remote consent form will be used for workshops that are being conducted remotely. Participants will be asked to say that they consent to each clause and to take part after the study has been carefully explained and any questions answered. This will be recorded by the researcher on the remote consent form. A copy of the consent form, signed by the researcher, will be sent to the participants.

9.3. Subsequent Visits

During the Co-design phase the participants will attend 2 workshops either in-person or remotely, depending on COVID-19 pandemic restrictions. Participants taking part in the co-design groups will attend a number of meetings (around 5-6) over a period of around 7 months.

9.4. Discontinuation/Withdrawal of Participants from Study

During the course of the study a participant may choose to withdraw at any time. The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

DISCOVERY PHASE

Service user interviews: If a participant withdraws from the study their interview transcript/s and all recordings will be securely destroyed and the interview will not be used onSocialcaretalk.org. If a participant withdraws after interview excerpts and clips are published on Socialcaretalk.org the interview and clips will be removed. However because the interview is in the public domain clips may have been copied from the website

Staff interviews: Staff may withdraw from the study at any point but data obtained up until the point of the withdrawal will be retained for analysis.

CO-DESIGN PHASE

Participants may withdraw at any point but data obtained up until the point of the withdrawal will be retained for analysis.

9.5. Definition of End of Study

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

10. DATA MANAGEMENT

10.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

De-identified data may be shared with the co-investigators for quality control and analysis purposes.

Socialcaretalk.org: Oxford and co-applicant DIPEx (AB) work in close collaboration to facilitate the creation and presentation of resources which are published on Socialcaretalk.org. Socialcaretalk is owned and administered by DIPEx with Oxford undertaking the qualitative interviewing and research which forms the basis of the video and audio interview clips and text which is published on the website. Oxford and DIPEx will be subject to a license agreement governing all such research material disseminated on the website. The DIPEx charity have a Third Party Suppliers Agreement with the Nuffield Department of Primary Care Health Sciences.

10.2. Data Recording and Record Keeping

Digital data (e.g. interview audio/video recordings) will be transferred to password protected storage on University computers / servers as soon as possible after collection. Interview audio recordings will be given a unique identifier and will be sent securely (via University owned file transfer interface requiring authentication) to approved transcribers who have signed a confidentiality agreement with the University (Oxford and York). Transcripts will be returned in the same way. Transcribers will not retain a copy of audio files following completion of transcription. Interviews will be transcribed verbatim and de-identified at the earliest opportunity by the University researchers. Data (interview recordings and transcripts) will be stored in computer files on password protected University servers. Contact details will be stored in separate password protected folders. The identifier key will be kept in a password protected study sub-folder separate to the folders where the data is kept. Paper records [consent, copyright, evaluation forms]will be stored in locked filing cabinets.

11. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol and relevant regulations.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

12.2. Approvals

Following Sponsor approval the protocol, informed consent forms, copyright form, participant information sheets, study advertising material, outline interview guides and questionnaires (where applicable) will be submitted to a Social Care Research Ethics Committee (REC), HRA, and host institution(s) for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

12.3. Other Ethical Considerations

This is a low risk study involving volunteer participants. There are no identified risks to participants. There are no direct benefits to participants but knowledge gathered may help influence and inform social services in future. Staff and stakeholder participants in Objective 3 will receive feedback which may be beneficial in service planning and decision making.

Experienced qualitative researchers will follow the principles of the Mental Capacity Act (2005). 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. The Discovery Phase will 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.
COVID pandemic

For the discovery phase of the study face to face research activities will not commence until it is safe to do so. Interviews will be conducted by phone or online using approved methods. Online interviews will be conducted using tools approved by Information Governance at the host institution.

Risk assessments will be carried out before face to face activities resume and researchers will follow government and University guidelines. The Co-design Phase workshops and smaller co-design working groups will be held in-person or remotely via an online video conferencing platform, depending on COVID-19 pandemic restrictions. Online meetings will be conducted using tools approved by Information Governance at the host institution.

12.4. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

12.5. Participant Confidentiality

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. The Principal Investigator (Ryan) is the data custodian. University of Oxford is the data controller.

At the end of the study research data including interview transcripts and consent forms will be stored for 10 years (this excludes Social care user interviews). Audio recordings will be destroyed. After the 10 year retention all research data (including consent forms) will be securely destroyed using the appropriate procedure advised at that time by the University research data team. Any personal identifiers relating to individual participants will be held until the information is no longer needed for the study.

Social care user interviews (Socialcaretalk) : At the end of the study the interview data (including consent and copyright records), with permission, will be stored in the Medical Sociology and Health Experiences Research Group data archive. Summary information is collated on a computer file and other documents are scanned for secure storage, backed up in the University computer archive. It is necessary to preserve this information so that we can remove people's interviews from the archive, and their clips from the website, if they ever decide that they would like to withdraw.

12.6. Expenses and Benefits

Non staff participants taking part in phase 1 discovery interviews will have any travel expenses, and reasonable caring costs reimbursed. Participants will receive a £30 shopping voucher to thank them for their time.

Service users taking part in the Co-design phase will receive a £20 shopping voucher per meeting attended, and travel expenses will be reimbursed.

13. FINANCE AND INSURANCE

13.1. Funding

The study is funded by National Institute of Health Research (ref: 128616).

13.2. Insurance

The University of Oxford maintains Public Liability and Professional Liability insurance which will operate in this respect.

13.3. Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

14. PUBLICATION POLICY

The Investigators 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 . Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

15. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the study, conforming to contractual arrangements specified by the funder.

16. ARCHIVING

Where possible and subject to relevant consent and copyright interviews conducted with service users will be de-identified, and archived in the Medical Sociology & Health Experiences Research Group data repository at the University of Oxford and made available to other bona fide researchers for secondary analyses under licence arrangements.

17. REFERENCES

Bate P, Robert G. (2007) *Bringing user experience to healthcare improvement: the concepts, methods and practices of experience-based design*. Radcliffe Pub, Oxford.

Coulter A, Locock L, Ziebland S, Calabrese J. (2014) Collecting data on patient experience is not enough: they
must be used to improve care. *BMJ*, 348:g2225

McInnis, G.J, White, J.H. 2001. A phenomenological exploration of loneliness in the older adult. *Archives of psychiatric nursing*. 15(3), pp128-39.

Morse, J. M. 2015) “Data Were Saturated . . . .” *Qualitative Health Research*, 25(5), pp587–588.

Ritchie J, Spencer L. (1994) Framework analysis. In: Bryman A, Burgess RG, eds. Qualitative Data Analysis. London: Routledge: 173–194

Ziebland, S. and McPherson, A., 2006. Making sense of qualitative data analysis: an introduction with illustrations from DIPEx (personal experiences of health and illness). *Medical education*, *40*(5), pp.405-414.

APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
Minor amendment 1	2	14.12.21	AEBCD study team, Vanessa Eade	Provision of online workshops and co-design working groups, in addition to existing in-person arrangements, due to possible COVID-19 pandemic restrictions.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee, and HRA (where required).