Co-production of best practice recommendations for local authority reviews of double-handed homecare packages

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SYNOPSIS

Title	Co-production of best practice recommendations for local authority reviews of double-handed homecare packages
Short title	Local Authority Reviews of Double Handed Homecare Packages
Chief Investigator	Dr Phillip James Whitehead
Objectives	1. To identify, describe and evaluate current review processes and practices for double-handed homecare packages by local authorities with social care responsibilities in England. 2. To explore service user and practitioner experiences of double-handed homecare packages and local authority reviews of double-handed homecare packages in order to identify facilitators and barriers to implementation and outcomes that are important to service users and their families. 3. To co-produce recommendations for 'best-practice' doubled-handed homecare reviews with stakeholders including recipients of double-handed care packages, their family members, occupational therapists, social workers, and homecare workers.
Study Configuration	National survey, qualitative interview study and feasibility study
Number of participants	National survey: 151 local authorities Qualitative study: 40 to 60 Feasibility study: 20 (maximum)
Eligibility criteria	Survey – Local authority in England with social care responsibilities Qualitative study: Service user, family member, social care professional, or homecare worker with experience of double handed homecare review (no time limit) Feasibility study: Service user with double-handed homecare package about to undergo review; able to provide informed consent
Duration of study	The study will run for 28 months, commencing 1st October 2019.
Outcomes	The main outcome for the study is to co-produce best practice recommendations for local authority reviews of double-handed homecare packages with a range of stakeholders. We will iteratively test the delivery of these recommendations within two local authorities.
Analysis methods	Descriptive statistics will be used for the national survey and feasibility study. Framework analysis will be used for qualitative study data.

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STUDY BACKGROUND INFORMATION AND RATIONALE

What is the problem being addressed?
The projected shortfall in the number of care workers is regularly headline news in the UK(1). Skills for Care estimate that an increase of 21-44% in the social care workforce will be required by 2030 in order to meet growing demand(2). This increase will mainly comprise staff delivering frontline care to older adults in their homes(3). The social care system is reported to be facing a crisis in capacity to deliver and fund care(4). It is unclear how the sector will keep pace with projected demand.

An important yet overlooked issue is the provision of double-handed homecare. Double-handed homecare packages are indicated when people need assistance to transfer (i.e. from bed to chair) and particular pieces of moving and handling equipment are used. They may also be indicated when the transfer procedure is complicated. In a double-handed homecare package two care workers attend every visit in order to assist the service user to transfer safely and facilitate safe manual handling processes by the homecare workers. Homecare packages are often set-up rapidly in response to a crisis event, or to facilitate a hospital discharge; however, they may remain in place for the long-term. Thus, people may end up with an ongoing double-handed homecare package which might be safely reduced following further review once their home situation, medical condition or functional ability has stabilised.

Some local authorities are reviewing double-handed care packages in order to identify whether two care workers are needed on a continuing basis. These reviews are commonly led by local authority employed occupational therapists and aim to determine whether the care package can be safely reduced to a single worker through the use of specialist moving and handling equipment (such as ceiling track hoists) or with an additional programme of therapy or rehabilitation. Local authority occupational therapists have specialist skills in moving and handling techniques and providing specialist equipment, housing adaptations and advice which may facilitate safe handling processes(5).

Although such reviews are becoming increasingly commonplace, little is known about the views and experiences of service users, homecare workers, local authority staff and the roles and responsibilities of different professional groups in the assessment process (i.e. social work and occupational therapy). The implementation of the review process can be problematic and delicate, balancing often competing views of multiple stakeholders. It is important that service outcomes of cost savings are balanced with quality of life and impact for service users and families and the health and safety of service users and homecare workers.

Further evaluative research is required in order to investigate the effectiveness and cost effectiveness of reviews of double-handed homecare packages. However, before such research can be conducted we need to determine current ‘usual care’ practices. We also need to conduct research with stakeholders to explore facilitators and barriers and identify outcomes that are important to users, family members, homecare workers and reviewers. It is important to develop recommendations for best practice which can be standardised across local authorities and evaluated in comparison to usual care.

Why is this research important in terms of improving the health and/or wellbeing of the public and/or to patients and health care services?
The sustainability of the social care system is rapidly becoming one of the top national priorities. Age UK estimate that 1.2 million people aged over 65 had some unmet social care needs in 2016-17(6). Hospitals are reported to be ‘log-jammed’ because of a shortfall in capacity to promptly commence homecare packages(7). Reviews of double-handed care packages are clearly of paramount importance for local authorities to increase capacity in the

care system. The potential cost savings were estimated to be circa £270,000 within one financial year following a small pilot of a double-handed homecare review scheme in Somerset County Council(8). Across England, 151 local authorities have social care responsibilities, thus the total potential cost savings are great.

Although outcomes other than cost savings have received scant attention, outcomes for service users are also potentially positive. It is probable that having two homecare workers will affect dignity in care and the feelings associated with 'being cared for' aspects which are consistent with constructs of Social Care related Quality of Life(9). Conversely, some service users may be unhappy if it appears that their services are being 'cut' in order to save costs and it is possible that reducing a care package to a single worker might increase the burden on other family or household members. These issues require further exploration.

Reducing care packages from two to one homecare worker may seem like a 'quick win' to increase homecare capacity, however a key issue facing the sector is the high rate of staff turnover for care workers coupled with low levels of recruitment(3). If care workers perceive that they are being placed at additional risk or facing a more challenging workload this may compound the recruitment crisis. It is therefore essential to incorporate the views and experiences of homecare workers into the implementation of the review process.

Whilst timely and judicious reviews of double-handed homecare packages have the potential for substantial and significant outcomes for service users, local authorities and homecare workers there is an urgent need to collate and synthesise information on practices and stakeholder views in order to ensure optimum implementation and maximum effectiveness.

Review of existing evidence – How does the existing literature support this proposal?
Despite the prevalence of double-handed homecare packages, there is a dearth of literature on double-handed homecare packages or reviews of them. The literature is comprised primarily of case studies or reports of pilot schemes in a few local authority areas(8, 10-13). The most comprehensive review was undertaken by Phillips et al.(10) which critically examined the perceived need for two homecare workers in the context of legislation and synthesised case studies from across local authorities. They reported 'conversions' of between 31-44% from double to single handed homecare across two local authorities; however, they also concluded that outcomes for service users and their families, including qualitative experiences, were not available.

Whilst all the identified pilot schemes demonstrate highly promising outcomes in terms of the potential cost savings for local authorities, they do not report outcomes for users or their family members or medium to long-term service outcomes. Thus, the trajectory for service user benefit is unclear. There is a particular paucity of literature on the views and experiences of people receiving double-handed homecare; thus, it is not clear what key issues are from service user perspectives, including how having two care workers impacts on quality of life, dignity and the practicalities and issues of receiving a double-handed homecare package. Furthermore, it is not clear whether reducing a care package from two to one care worker will lead to an increased responsibility for friends and family members. In the absence of robust data on service user and their families' quality of life, the evidence in terms of the cost effectiveness (cost utility) of double-handed homecare reviews is unclear.

The current literature focuses predominantly on the skills, training and expertise required by the occupational therapists to lead and implement the double-handed homecare review process within local authorities. There is a paucity of literature on the specific roles and responsibilities of different professional groups, especially from a social work perspective in terms of whether they overlap and where the distinct professional responsibilities lie. There is also an absence of literature on the perspectives of the homecare workers; they are the people

who are responsible for implementing the outcomes (i.e. whether are reduced to a single care worker or remain at two care workers) and the perspectives of the homecare workers are clearly important.

Despite the dearth of literature on double-handed homecare reviews, there is a plethora of literature on intervention strategies to reduce musculoskeletal injuries associated with moving and handling 'patients'(14-18). This literature emphasises the need for staff involved in moving and handling to employ appropriate techniques in order to reduce injuries. However, this literature is predominantly from a nursing and healthcare perspective and has limited relevance to reviewing practices for homecare packages within the social care sector.

In developing this application we conducted a search of the ongoing trials registries Clinicaltrials.gov and ISRCTN (search conducted 18/06/18). This search revealed no ongoing trials or related studies evaluating the effectiveness and cost effectiveness of double-handed homecare reviews.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

The purpose of this study is to identify the components that stakeholders believe should be included in local authority reviews of double-handed homecare packages.

AIMS

1. To identify, describe and evaluate current review processes and practices for double-handed homecare packages by local authorities with social care responsibilities in England.
2. To explore service user and practitioner experiences of double-handed homecare packages and local authority reviews of double-handed homecare packages in order to identify facilitators and barriers to implementation and outcomes that are important to service users and their families.
3. To co-develop recommendations for 'best-practice' doubled-handed homecare reviews with stakeholders including recipients of double-handed care packages, their family members, occupational therapists, social workers, and homecare workers.

OBJECTIVES

In order to meet our aims we will convene a working group of recipients of double-handed homecare packages, their family members, occupational therapists, social workers, and homecare workers. We aim to recruit approximately 4 individuals from each of these stakeholder categories to form a pool of members that can be drawn upon to populate meetings of the working group. It is anticipated that some members might not be able to take part in some stages of the process, and so an extra capacity of members has been built into the pool to compensate for this. There will not be any cap on the number of members from the pool who can attend any meeting. The working group will inform and collaborate on the research and the production of best practice recommendations for double-handed homecare reviews through the following objectives:

1. Work Package 1 (WP1). We will carry out a national survey of all local authorities with social care responsibilities in England in order to identify, describe and evaluate current review processes and practices for double-handed homecare reviews.
2. Work Package 2 (WP2). We will carry out interviews with people receiving on-going double-handed homecare packages and/or reviews (n=10-15), their family members

(n=10-15), reviewers of care packages (n=10-15) and homecare workers (n=10-15) in order to explore stakeholder views and experiences, facilitators and barriers.
3. Work Package 3 (WP3). We will use a nominal group technique with our working group in order to identify and prioritise aspects of good practice based on the findings from workpackages 1 and 2. We will then co-develop recommendations for double-handed homecare reviews and test these in an iterative process including feedback from service users and staff.

STUDY DESIGN

STUDY CONFIGURATION

This is a mixed methods study that will be conducted in three phases:

1. National survey of practices within local authorities with social care responsibilities in England
2. Qualitative interviews with key stakeholders
3. Design and feasibility testing of best practice recommendations for local authority reviews of double handed homecare packages.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Working Group

The working group will be comprised of up to approximately 4 each of service users, their family members, local authority occupational therapists, social workers and homecare workers. The working group members will be purposively identified through the research team's own professional network. Practitioners will be recruited from local authorities in the North East and/or the East Midlands other than our two collaborating authorities. Service user and family members will be recruited from the North East and will be identified by the team at Sunderland City Council and the National Institute for Health Research's *Clinical Research Network*.

National Survey

We will make telephone contact with each local authority with social care responsibilities in order to identify a named person (email) with responsibility for double-handed care reviews. If we are unable to identify a named contact the questionnaire will be addressed in an email to 'The Lead Occupational Therapist' and will ask them to pass the email to the person with the overall responsibility for reviewing. This email will also be worded according to evidence-based recommendations to increase response rate including reasoned action approach (21-22). An email with a link to complete the survey electronically will be sent to each of the 151 'principal local authorities' with social care responsibilities in England (23-24).

Additional recruitment may also involve utilising organisations (such as the Royal College of Occupational Therapists and the Association of Directors of Adult Social Services) and individuals (such as those who have already made a questionnaire submission) who consent to pass on recruitment information to local authority staff likely to be eligible to make a questionnaire submission.

Qualitative Study

Service user and family interviews

Service users and family members will be purposively sampled on gender, those who live alone and those who live with support, self-funders and local authority funded, and whether they have experienced difficulties in the double-handed homecare review process or transition to single-handed care. Those who have been through the review process will be purposively sampled for those that had their homecare packages reduced after review and those that did not. Potential participants will be identified by local authority staff at a number of local authorities with adult social care responsibility and will be asked if they are willing to have their contact details passed to the research team for further information to be provided about the study.

Staff interviews

We will recruit local authority staff and homecare workers involved in the reviewing process. Participants will be purposively sampled based on staff group (likely to include local authority employed occupational therapists, social workers and community care officers), and whether they have experienced difficulties in the double-handed homecare review process or transition to single-handed care.

Feasibility Study

Development of Recommendations

The working group will complete a nominal group technique. The nominal group process will be facilitated by the principal investigator and PPI lead (PW & CB) who will set out the outline of the process and ask the working group to generate, without conferring, their own individual ideas in response to the question “What elements should be included in the review process for people receiving double-handed care packages?” This will be followed by a 'round robin' sharing of ideas. Each participant in turn will contribute one idea which will be recorded on a flip chart. There will be no discussions during this process which will continue until each member has contributed all the suggestions from their list. This will be followed by a group discussion in which the facilitators will ensure that all group members have the opportunity to contribute further to the 'round robin', that the discussion is non-judgmental and neutral, and that all items are relevant to the research question. Where appropriate, new items will be added or amalgamated based on the findings from the previous work packages, but none will be eliminated. The process will end with each working group member anonymously selecting and ranking their top ten items from the combined list.

Iterative Testing of Recommendations

Service users referred for double handed-homecare reviews will be screened consecutively at each of our sites (several local authorities) and those who meet the eligibility criteria will be approached. Recruitment will temporarily cease when five participants have been recruited at each site. Pilot data from our sites indicates that approximately five to ten participants per month will be eligible. Assuming a conservative consent rate of less than 50%, we believe that recruiting five per site is realistically achievable within the proposed timescales. The working group will meet to review how the implementation of the recommendations has been progressing. The recommendations will be updated accordingly. Recruitment will commence and a further five participants per site will be recruited.

Eligibility criteria are: a.) referral for first time review of double-handed care package and b.) capacity to provide informed consent. Exclusion criteria are: a.) being on an end-of life care pathway. Although this may be an important social care intervention for service users who lack mental capacity, in this phase our purpose is to obtain feedback from people with experience in order to further shape and refine the recommendations and implementation process; we envisage that people who lack capacity would be involved in future research.

Where the service user has a carer (friend or family member providing support) we will also approach the carer for informed consent.

Expected duration of participant participation

National Survey – completion of the survey (approximately 15 to 30 minutes)

Qualitative Study – duration of interview (approximately 30 minutes to 1 hour and 30 minutes)

Feasibility Study – six weeks

Removal of participants from therapy or assessments/Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

Participants in Work Package 2 will provide audio-recorded verbal informed consent. Verbal informed consent from the participant will be obtained remotely and recorded before they enter the study. The Investigator will explain the details of the study and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation. If willing to proceed, the Informed Consent Form will read out to them by the researcher and the responses audio-recorded. Remote contact will be made by telephone or Microsoft Teams and recorded using a separate audio recorder, and then uploaded to a secure server, in line with security recommendations from Newcastle University and Northumbria University. No video or images will be recorded.

Participants in Work Package 3 will provide written informed consent. The Informed Consent Form will be signed and dated by the participant before they enter the study. The Investigator will explain the details of the study and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Informed consent will be obtained from each participant before any data collection commences. The audio consent recording will be stored separately to the audio recorded interview. For written informed consent, one copy of the Informed Consent Form will be kept by the participant, and one will be kept by the Investigator.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended consent form, recorded agreement to which will be obtained from the participant.

OUTCOMES

National Survey

Questions for those authorities which are reviewing will cover the following topic areas:

1. Identification of eligible reviews and referral process
2. Number of reviews completed (within a specified time-period)
3. Time-point for reviews
4. Time spent on the review process

5. Procedures surrounding the review process, including staff reviewing, staff involved in the process
6. Review outcomes and recommendations
7. Involvement of service users and their families
8. Review reporting and documentation
9. Whether care packages are subsequently reviewed
10. Plans for continued reviews.

Qualitative Study
Interviews schedules will cover the remit given to assessing staff about the reviews; how decisions to reduce care packages are made and communicated; what the outcomes of the assessment look like; what happens when the double-handed care package remains in place. We will particularly explore facilitators and barriers to the review and implementation of the review process, and we will explore implementation practicalities with the homecare workers. We will also explore the roles and responsibilities of different staff groups (occupational therapy and social work).

Subject to service approvals, we will also gather documentary evidence to investigate contextual factors that stakeholders may not readily articulate. This will be in the form of service specifications, monthly and annual reports and paperwork used by the teams as part of their day-to-day reviewing activities. These will be used to inform and expand on interpretation of the interview data.

Feasibility study
We will collect measures of health and social care related quality of life (Adult Social Care Outcomes Toolkit (ASCOT)(9); EuroQol EQ-5D-5L(19)) and independence in personal activities of daily living (Barthel Index(20)).

At the follow-up, participants (service users and carers) will also take part in informal interviews with practitioners at site. They will use an adapted topic guide from WP2. The interviews will be informed by the framework developed in WP2 in order to facilitate the identification of similarities and differences in experiences of the review process following the implementation of the 'best practice' recommendations. The interviews will be targeted specifically on feedback from the review process in order to identify "what worked well" and "what didn't work so well". Findings will be linked to the findings from work package two we will seek direct feedback on those aspects which we aimed to alter seek views on whether and how this is working. We will also focus the interview on user and family perspectives on outcomes following the review process.

Reviewing staff and homecare workers will complete a purposely designed pro forma and a checklist after each double-handed homecare review which will detail the content of the review. The pro forma will include a freetext section for staff to record their comments on the updated review process including facilitators and barriers to delivery. To supplement the information recorded on the pro formas, practitioners at site will conduct informal debriefing sessions with the staff involved in delivering the best practice reviews in order to explore and clarify any issues recorded on the pro formas.

Stopping rules and discontinuation
Individual participants may be withdrawn at their own request or at the discretion of the Chief Investigator

STUDY MANAGEMENT

The study is funded by the National Institute for Health Research (NIHR) Research for Social Care (RfSC). It is sponsored by Newcastle University. It will be managed and co-ordinated from the Population Health Sciences Institute.

The Chief Investigator has overall responsibility for the study and shall oversee all study management. The data custodian will be the Chief Investigator.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: The overall study duration is 28 months. The national survey will be conducted from Months 4 to 8; the qualitative study will be conducted from Months 9 to 20; the feasibility study will be conducted from Months 21 to 28.

End of the study: The end of the study will be the last visit of the last participant in the feasibility study (phase three).

ANALYSIS

Methods

Sample size and justification

National Survey – All local authorities with social care responsibilities in England (n=151). As social care practices vary between the devolved nations the survey will be sent only to local authorities in England. In order to maximise participation we will send the survey to every local authority in England with social care responsibilities.

Qualitative Study – 20-30 service users and family members; 20-30 staff members (occupational therapists, social workers, homecare workers). This has been deemed sufficient to gain the depth and breadth of data required to meet the study objectives.

Feasibility Study- 20 participants. Our aim in the feasibility study is to gain some initial feedback on the implementation and 'deliverability' of the best practice recommendations in practice. Thus, we are taking a pragmatic approach and aim to recruit five participants from each of our two sites over two rounds of iterative development.

Analysis

Descriptive statistics will be used to summarise the results from the national survey of practice and the results from the outcome measures in the feasibility study. Results will be presented in text and tables with a narrative summary of findings. Outcome measures will be analysed using descriptive statistics in order to describe the characteristics of our sample. We will not conduct any inferential or before-and-after analysis as this is not appropriate for feasibility work.

Interviews will be analysed using an inductive approach with framework analysis(25). Framework analysis is a process where more than one researcher can input into the analysis process. The framework will be developed iteratively by five researchers, including our public member (Senior Research Assistant, PW, TR, CB, AR) and then discussed and refined with input from the research team and Working Group 3. The process will involve coding the data

and developing a framework, before applying the rest of the data to the framework and finally organising and presenting it in themes.

ADVERSE EVENTS

We are not anticipating any adverse events as part of this intervention; however, we will monitor adverse events for participants in the feasibility study in accordance with the conditions below:

Definitions

An adverse event is any unfavourable and unintended sign, symptom, syndrome or illness that develops or worsens during the period of observation in the feasibility study.

An AE does include a / an:

1. exacerbation of a pre-existing illness.

2. increase in frequency or intensity of a pre-existing episodic event or condition.

3. condition detected or diagnosed after treatment administration even though it may have been present prior to the start of the study.

4. continuous persistent disease or symptoms present at baseline that worsen following the start of the study.

5. A fall or injury.

An AE does not include a / an:

1. medical or surgical procedure (e.g., surgery, endoscopy, tooth extraction, transfusion); but the condition that lead to the procedure is an AE.

2. pre-existing disease or conditions present or detected at the start of the study that did not worsen.

3. situations where an untoward medical occurrence has not occurred (e.g., hospitalisations for cosmetic or elective surgery, social and / or convenience admissions).

4. any sign or symptom associated with the disease or disorder unless more severe than expected for the participant's condition.

5. overdose of concurrent medication without any signs or symptoms.

A Serious Adverse Event (SAE) is any adverse event occurring following study mandated procedures, having received the intervention that results in any of the following outcomes:

1. Death

2. A life-threatening adverse event

3. Inpatient hospitalisation or prolongation of existing hospitalisation

4. A disability / incapacity.

Important medical events that may not result in death, be life-threatening, or require hospitalisation may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

All adverse events will be assessed for seriousness, expectedness and causality:

A distinction is drawn between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined using the criteria above. Hence, a severe AE need not necessarily be serious.

Causality

Not related or improbable: a clinical event including laboratory test abnormality with temporal relationship to study intervention administration which makes a causal relationship incompatible or for which other treatments, chemicals or disease provide a plausible explanation**.** This will be counted as “unrelated” for notification purposes.

Possible: a clinical event, including laboratory test abnormality, with temporal relationship to study intervention administration which makes a causal relationship a reasonable possibility, but which could also be explained by other interventions, chemicals or concurrent disease. This will be counted as “related” for notification purposes.

Probable: a clinical event, including laboratory test abnormality, with temporal relationship to study intervention administration which makes a causal relationship a reasonable possibility, and is unlikely to be due to other interventions, chemicals or concurrent disease. This will be counted as “related” for notification purposes.

Definite: a clinical event, including laboratory test abnormality, with temporal relationship to study intervention administration which makes a causal relationship a reasonable possibility, and which can definitely not be attributed to other causes. This will be counted as “related” for notification purposes.

With regard to the criteria above, professional judgment shall be used in deciding whether prompt reporting is appropriate in that situation.

Reporting of adverse events

Feasibility study participants will be asked about any adverse events during the feasibility study follow-up visit. All adverse events will be recorded and closely monitored until resolution, stabilisation, or until it has been shown that the study intervention is not the cause. The Chief Investigator shall be informed immediately of any serious adverse events and shall determine seriousness and causality in conjunction with the practitioner advisory group representatives.

All treatment related serious adverse events will be recorded and reported to the REC as part of the annual reports. Unexpected serious adverse events will be reported within the timeframes to the REC as stated below. The Chief Investigator shall be responsible for all adverse event reporting.

Study Intervention Related SAEs

A serious adverse event that is unexpected in its severity and seriousness *and* deemed directly related to or suspected to be related to the study intervention shall be reported to the ethics committee that gave a favourable opinion as stated below.

The event shall be reported immediately of knowledge of its occurrence to the Chief Investigator. The Chief Investigator (in conjunction with the practitioner advisory group representatives) will:

- Assess the event for seriousness, expectedness and relatedness to the study intervention.
- Take appropriate medical action, which may include halting the feasibility study and inform the Sponsor of such action.
- Take appropriate action in relation to the homecare package, in conjunction with our collaborators at site.
- If the event is deemed related to the study intervention, shall inform the REC using the reporting form found on the NRES web page within 7 days of knowledge of the event.
- Within a further eight days send any follow-up information and reports to the REC.
- Make any amendments as required to the study protocol and inform the REC as required.

Participant removal from the study due to adverse events

Any participant who experiences an adverse event may be withdrawn from the study at the discretion of the Chief Investigator.

Interview Study

With regard to the interview study, the occurrence of adverse events as a result of participation is not expected and no adverse event data will be collected. However, there are relevant matters of sensitivity and ethics.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, informed consent forms and participant information sheets have received approval / favourable opinion from the a Research Ethics Committee (REC) who are authorised to review research within social care settings. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. Consent will be taken remotely for Work Package 2. If willing to proceed, the Informed Consent Form will read out to them by the researcher and the responses audio-recorded. This consent process will be carried out before entering the study and before any data is collected. Remote contact will be made by telephone or Microsoft Teams and recorded using a separate audio recorder, and then uploaded to a secure server, in line with security recommendations from Newcastle University and Northumbria University. No video or images will be recorded. Written consent will be taken for Work Package 3. The investigator or their nominee and the participant shall both sign and date the Informed Consent Form before the person can participate in the study. The participant will receive a copy of the signed and dated forms and the original will be retained in the Study Master File. A second copy will be given to the participant to retain for their records.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to re-consent using revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

DATA PROTECTION

The following refers to personal data. This therefore applies to Work Packages 2 and 3 since Work Package 1 does not intend to collect personal data.

All study staff and investigators will protect the rights of the study participants to privacy and informed consent, and will adhere to the General Data Protection Regulation (GDPR). The study will only collect the minimum required information for the purposes of the analysis. Access to the information will be limited to the study staff and investigators and relevant regulatory authorities (see above). Computer held data will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method). Data which contains personal and identifiable information (e.g. audio-recorded consent files) will be stored separately from anonymised data (e.g. interview transcripts) to ensure anonymity is protected.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Newcastle University as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and associated insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

STUDY CONDUCT

Study conduct may be subject to systems audit of the Study Master File for inclusion of essential documents; permissions to conduct the study; CVs of staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with Newcastle University and Northumbria University research procedures, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Study Master File and documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the Newcastle University and Northumbria University. This archive shall include all associated meta-data encryption codes.

STATEMENT OF CONFIDENTIALITY

Individual participant information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.
Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

In the feasibility study, if participants score ‘4’ or ‘5’ on the EQ-5D anxiety and depression item (indicating that they are ‘severely’ or ‘extremely’ anxious or depressed) then the research team will feed this information back to the usual care team involved in the double handed homecare review process. This information will be feedback via the lead practitioner at site, where possible, or by the social care duty point if the lead practitioner is not available. The research team will aim to report this information within 24 hours of the participant visit and no more than 48 hours. The usual care team will then act in accordance with their local policies and procedures had they received this information directly from the participant themselves.

PUBLICATION AND DISSEMINATION POLICY

We will produce the following outputs:

- The NIHR RfSC report within the agreed timescales
- The best practice recommendations (synthesised findings from all three work packages) in the format of a protocol for roll-out in either a further clinical and cost effectiveness evaluation or implementation study, subject to the findings of the survey
- Academic papers for the survey, qualitative interviews with stakeholders, and development of the recommendations in high impact journals which will be made freely available via open access or Newcastle University and Northumbria University repositories
- Presentations at a range of national and international conferences (likely to include Society for Research in Rehabilitation; Royal College of Occupational Therapists Annual Conference- Social Care Stream; European Conference for Social Work Research)
- A key findings 'infographic' for older and disabled people, their families and carers

- A plain English Policy & Practice Briefing explaining the findings to be widely disseminated through our extensive networks.

USER AND PUBLIC INVOLVEMENT

Public and Person Involvement (PPI) is integral throughout this application and woven through all stages of our research plan. Our PPI aim is to co-design and co-develop this project, from outline stage of project funding application to its successful completion, evaluation and further development. Our strategy for PPI is based on valuing and maximising the meaningful involvement, engagement and participation of lay experts as co-applicants whom we see as integral to the real world application of our research. We use the UK NIHR INVOLVE (www.invo.org.uk) definitions of Patient and Public Involvement, Engagement and Participation and the values and principles of public involvement in research. We recognise that all three elements are complimentary, and essential to maximising the relevance, quality and impact of our research. Our working group represents thorough and meaningful PPI and includes a range of stakeholder involvement throughout all stages of the research.

Our PPI co-applicant, Mrs Anne Raffle, represents Elder's Council (EC) and will act as a conduit between EC and the research team during the study. Anne Raffle will work collaboratively throughout the study with Drs Bailey and Whitehead to implement the UK NIHR INVOVLE ethos within the operation of the Working Group (WG) and the co-production of the project outputs. In particular they will ensure that the WG is embedded within and across the research study and its Work Packages. This is a core PPI role and responsibility at planned WG time points, in relation to survey design and piloting (WP1), planning and refining of stakeholder interviews (WP2) and taking a lead role in co-development and feasibility testing of 'best practice' recommendations (WP3) are inter-dependent. AR will report progress of and invite input to the research at EC's HSCCG bi-monthly meetings and will call on the expertise and experience of the group outside regular meetings. This will be particularly helpful to inform sampling, recruitment, data collection, analysis and dissemination of research findings.

STUDY FINANCES

Funding source

This study is funded by The National Institute for Health Research, Research for Social Care (NIHR RfSC).

Participant stipends and payments

Participants will not be paid to participate in the study. Homecare workers who participate in the interviews will be offered a gift voucher with a value of £25.00.

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