Pressure Ulcer Prevention at Home: Pressure ulcer prevention for people with long-term neurological conditions (LTNCs) who self-manage care and live at home. A participatory intervention development approach.

Pressure Ulcer Prevention at Home

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1. Background

1.1 Project development

This project has been collaboratively developed by service users, carers, researchers and healthcare professionals. This includes extensive input from the Pressure Ulcer Research Service User Network (PURSUN), a group of people with personal experience of pressure ulcers / pressure ulcer risk. As this is a participatory project, PURSUN members and other services users, carers and PAs will continue to be part of the research team. Throughout this document, we refer to university researchers (e.g. Staff employed in a research role) and peer researchers (e.g. service users, carers and PAs) to help differentiate between different roles within the project.

1.2 Pressure Ulcers

PUs are a considerable patient safety issue. They are localised areas of damage to skin and underlying tissue as a result of mechanical load in the form of pressure, shear and friction and classified from Category 1 to 4 with increasing severity [4]. Category 1 indicates non-blanchable erythema; Category 2 PUs have superficial blister/skin loss and are reportable to the National Reporting and Learning System [5] and; Category 3/4 PUs are severe cavity wounds exposing fat, muscle and bone and reportable as 'serious incidents' on the Strategic Executive Information System [6]. UK prevalence data identifies 7-14% of hospital patients [1, 2] and 0.51/1000 to 0.71/1000 of the community population [3, 4] as having PU(s). Primary risk factors for PUs are immobility, poor skin status and poor circulation [5], while susceptible skin sites are those exposed to pressure (e.g. buttocks and heels) where relieving pressure is difficult for those with poor mobility.

Our previous research and Patient and Public Involvement (PPI) identified that PUs are painful [7] and have a major impact on QOL, effecting people emotionally, physically and socially [8]. Where severe PUs develop, the often months/years of treatment includes prolonged bedrest, coping with pain/smell/exudate, frequent home/clinic dressing visits, possible hospital admission for surgery/severe infection and work/education absence/loss of employment [9, 10]. PUs also present significant financial burden to health care services [11-14] estimated at 4% of the NHS budget [15] and a mean 1 year community patient cost of £1400 for Category 1 and >£8500 for Category 4 PUs [16].

There have been successive initiatives to improve NHS PU monitoring, prevention and management [6, 7]. From a monitoring perspective Category 2 PUs are reportable by primary and secondary care organisations to the National Reporting Learning System and Category 3/4 PUs are reportable to NHS England's serious incident management system [8, 9]. From a prevention and management perspective quality indicators, guidelines, outcome frameworks and a national Wound Care Strategy Programme [7] all advocate the avoidance of PU development. In clinical practice much effort is afforded within in-patient services and community nursing services with standard preventative care including risk assessment, specialised mattresses and cushions, repositioning and skin health optimisation (although the underpinning evidence is largely from trials in acute care patient populations) [6, 10].

1.3 Long-term Neurological Conditions (LTNCs)

Long-term Neurological Conditions (LTNCs), including but not limited to, Multiple Sclerosis (MS), Spina Bifida (SB), Spinal Cord Injury (SCI) and Muscular Dystrophy carry significant burden to individuals, families and carers, the NHS, and society as a whole. The estimated

spend on people with LTNC is £3.5% of NHS (£3.3 billion, 2012-13) and 14% of social care budgets [11]. The need to transform services was recognised in the 5 Years Forward View [12] and associated strategic priorities [13]. A pillar of the plan is developing capacity and capability to support self-management and independence, particularly for those with complex needs.

Improved life expectancy, changes to health/social care organisation, societal changes in attitudes to living with disability and personalised care funding has led to increasing numbers of people with LTNCs living and working while managing complex health needs [11] as well as fulfilling other roles in the family and society at large. This population are at a lifetime risk of pressure ulcer development. They often self-manage their personal and care needs independently at home, with or without support from informal carers or Paid Personal Assistants (PPAs). By 'informal carer' we mean a friend/family member who is usually unpaid. By 'personal assistant' we mean a carer employed by an individual/family to provide support (see 'population' section). To clarify the characteristics of this population please find some short case studies, developed in collaboration with our PPI co-applicants (Appendix 1).

The self-management of personal and care needs often occurs with no or minimal input from health (e.g. community nursing) or social services (e.g. domiciliary care). Despite their life-time risk of PU development which leads to major QOL deficits, exposure to professionals with expertise in Pressure Ulcer (PU) prevention is lacking. Therefore **it is vital that service users and their informal carers or PPAs are able to recognise and react to changes in risk themselves and negotiate care escalation**. This application focusses on facilitating PU prevention in this specific and often hidden, high risk population.

1.4 PU Risk and People with LTNCs:

People with LTCNs often have mobility problems limiting their ability to adjust their position sufficiently, leading to increased PU risk. In addition, lack of sensory perception may reduce their ability to feel/react to skin pain/discomfort and changes to soft tissues, reducing tissue tolerance and increasing the risk of PU development further [14]. While limited data are available regarding PU prevalence in people with Long Term Neurological Conditions (LTNC) specifically, a systematic review and meta-analysis estimated a high overall pooled prevalence of 32.36% (95% CI 28.21-36.51) in people with Spinal Cord Injury [15].Given that many people with LTNCs have mobility limitations and/or skin sensation changes, both important risk factors for pressure ulcer (PU) risk [5], it is likely that their prevalence aligns closer to SCI populations, rather than general adult populations.

Another distinguishing factor of the LTNC population is the constant or fluctuation in PU risk they experience overlain with gradual and acute escalation of risk:

- Constant risk –someone living with Spina Bifida or Cerebral Palsy who is a full-time wheelchair user will have a constant level of risk.
- Fluctuating risk –someone with Multiple Sclerosis may experience fluctuations in their mobility related to fatigue and/or muscle weakness. Fluctuations may be hour to hour, day to day or week to week.
- Gradually increasing risk - in people with constant and fluctuating risk, ageing and disease progression impacting mobility and skin tolerance leads to a gradual increase in PU risk over months/years.

- Acute escalation –in people with constant and fluctuating risk, significant life events leading to changes in people's self-care routine (e.g. bereavement) and acute illness (e.g. flu) will exacerbate underlying risk if there is impact upon self-care, mobility or skin tolerance.

1.5 PU Prevention for people with LTNCs living at home

Risk assessment, monitoring PU risk and provision of prevention interventions for those with LTNCs living day to day in their own home and self-managing personal and care needs is ad-hoc and infrequent. Their risk is often overlooked during interactions with health services for chronic disease management and when they have an acute illness (such as chest infection) or 'minor' problem (such as minor surgery) which have a major impact upon their mobility/daily routines. Our research and PPI indicate that PUs may be severe before appropriate care is initiated with prevention opportunities missed [16]. There is also a need to raise awareness among those with LTNC who have experienced a PU, that they are at higher risk of future PU development [17].

As part of routine prevention practice hospital and community nurses use PU risk assessment instruments to identify those at risk. It is recommended that these assessments are undertaken in partnership with patients, to encourage shared decision-making [6]. Despite this, information about PU risk is rarely shared with patients/carers and they are not encouraged to monitor or report PU warning signs. Our research and PPI has identified that, when patients do raise concerns, they are not listened to, GP services are not equipped to initiate appropriate interventions and patients are blamed for PUs [16, 18].

While PU prevention has received a lot of attention from a clinical, secondary care perspective, we have limited evidence about if/how people with LTNC self-manage their risk at home. There is a gap in research regarding interventions which help these high risk individuals, with the focus to date being on behavioural change of staff in hospitals and care home settings and patient/carer education, while interventions addressing system level inadequacies are lacking (see evidence section below). This is an important omission as our PPI work has suggested that appropriately accessing services for pressure ulcer prevention is difficult for people with LTNC who are self-managing at home. We also know little about the role of informal carers and PPAs, who are often in a position to support risk identification/modification, recognise early signs of skin damage and negotiate care escalation. However, this opportunity is often lost because the person with LTNC, their informal carers and/or PPAs do not have the necessary skills to facilitate this and have minimal exposure to health and social service professionals who might be able to help.

1.6 PU Prevention Self Care Interventions in LTNC

Service users and carers are often the only constant factor in a complex journey between health/social care professionals and settings [19]. They are uniquely positioned to facilitate preventative interventions, yet current service provision, particularly the lack of service user involvement/support, hampers this. In addition, the COVID-19 pandemic has highlighted the importance of effective self-care for people living at home who may need to shield during this and future pandemics.

PURSUN identified the need to increase our understanding of how people currently manage PU risk and what resources are needed to facilitate PU prevention, for those who self-care

with LTNCs at home. The group emphasised the need to go beyond patient education models and consider if / how PU prevention fits within existing self-care regimes, lifestyles and services. The importance of knowing how and when to escalate concerns and the need to build trust between service users, informal carers, personal assistants and health/social care professionals and services was also highlighted. This will require consideration from a broader systems perspective, to understand how health systems, contexts, and actors act, react and interact with each other to identify challenges and possible solutions. This will underpin a theory of change on which to base a multi-component intervention [20].

2. Overall Aim

To develop a Theory of Change (ToC) pathway to facilitate the development of a multi-component intervention package supporting PU risk identification and risk management, in partnership with people with LTNC who self-manage care and live at home, their informal carers and paid personal assistants.

2.1 Objectives

I. Explore and understand how people living with LTNC currently identify and self-manage PU risk.
II. Explore and understand the role of informal carers and paid personal assistants in supporting people with LTNC to manage PU risk.
III. Map factors that help/hinder people's ability to identify and manage PU risk (factors within the family, workplace, community and wider system).
IV. Explore the perspectives of professional and strategic partners on PU prevention at home, including the need for services to respond to informed, empowered service users, facilitating self-care and blame/stigma avoidance.
V. Identify and prioritise points in the system, which would most benefit from intervention.
VI. Develop a Theory of Change (ToC) pathway on which intervention development can be based.

3. Design

3.1 Overall design

We will use a partnership approach based in the participatory research paradigm, utilising cooperative inquiry [21], peer to peer interviews [22, 23] and participatory systems mapping [24, 25]. Participatory research aims for equal partnerships between those conducting the research and those whose lives are the focus of the research, with stakeholders involved *with* (not just participating *in*) every aspect of a study [26]. This recognises participation as a right [49]. Participatory research is characterised by commitment to collaboration; collective project ownership; empowerment; critical reflexivity; valuing different types of knowledge (including experiential knowledge); and democratic processes [27]. Participatory intervention development can increase sustainability and acceptability as it [26]:

- Is culturally and logistically appropriate
- Increases recruitment through the involvement of community representatives
- Develops capacity of all stakeholders
- Promotes productive discussions between stakeholders, which result in negotiation of useful resolutions
- Increases quality of outputs and outcomes over time

- Results in sustainability of interventions with less reliance on external funding
- Encourages system transformation and spin off projects

These outcomes are achieved through partnership synergy, which develops over time and results in increasing trust between partners [26, 28]. Increased trust reinforces partnership working, maintaining and sustaining the relationship and allowing space for spin off projects and unanticipated impacts. This has been termed the ripple effect [28]. Ripple effects may include increased confidence and empowerment of individual research partners, especially community partners, or new research or policy collaborations [29].

Good facilitation is vital [22]. Facilitators act as intermediaries between stakeholders, supporting research activities and individuals [27]. Each stage will be co-led by an experienced participatory facilitator (DM / JD) and qualitative researcher (SC / research fellow). The team have experience of training/support for peer to peer interviewers [30], creative facilitation techniques [31, 32] and collaborative data analysis/interpretation [31, 33]. We have extensive experience of facilitating PPI / participatory research around challenging, emotive health topics and across professional boundaries.

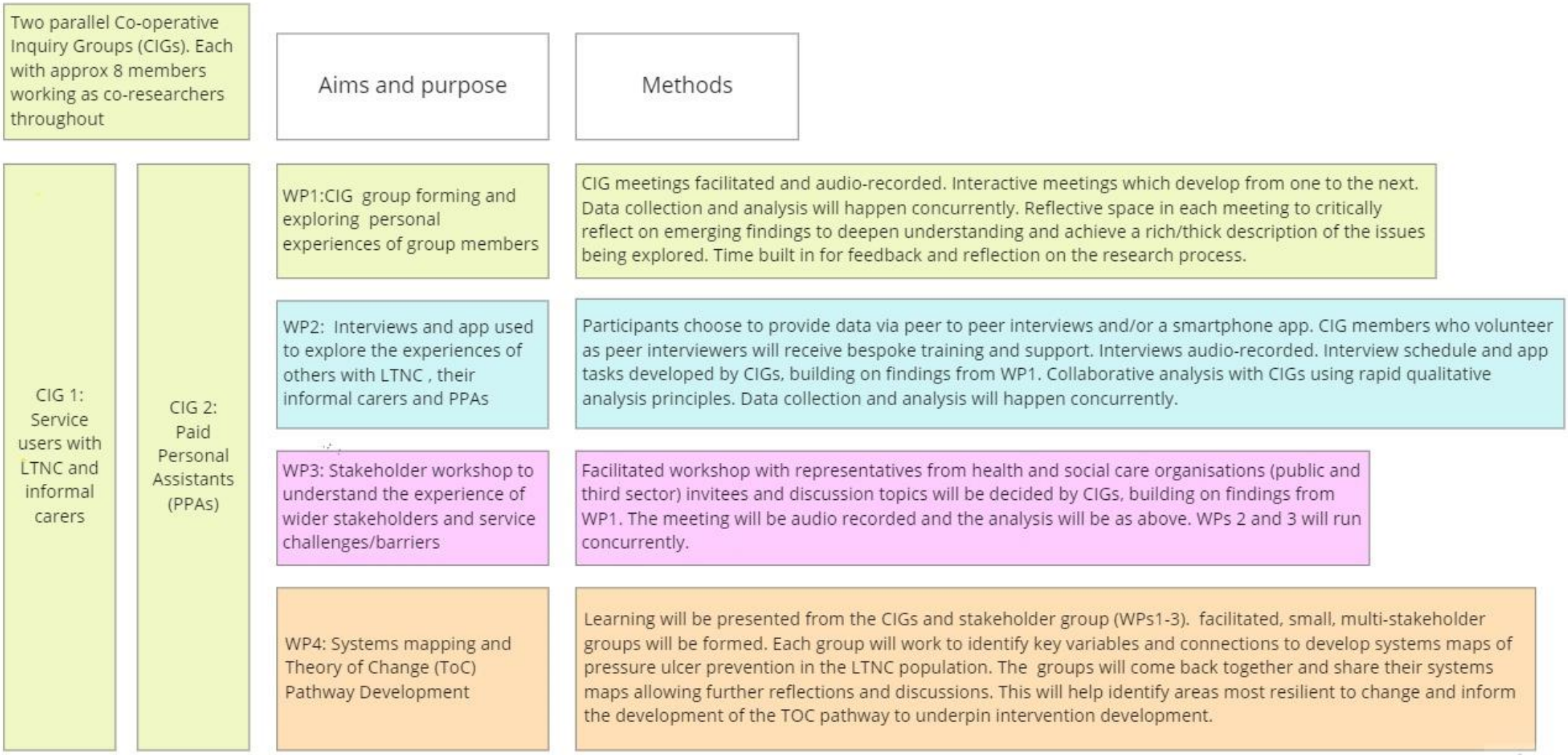
The participatory approach will be underpinned by the Theory of Change (TOC), a pragmatic framework to describe how change can be achieved clarifying the resources that need to be in place and how particular contextual factors influence change [34]. These are articulated as a ToC pathway with a pictorial representation (underpinned by narrative summary) of how components of an intervention can impact short, intermediate and long-term outcomes. It is a flexible approach that can be strengthened by integration of sociological and/or psychological theories to explain why particular links occur at key points [35] and helps to identify where the system may be resilient to change, informing intervention development. The flexible nature of ToC fits particularly well with our programme of work, which will iteratively draw together research evidence, actors in the context and sphere of influence and strategy.

The project consists of 4 interlinked Work Packages (WPs):

- WP1 – Development of two co-operative Inquiry Groups (CIGs)
- WP2 - Peer to peer Interviews and/or app participation
- WP3– Professional stakeholder engagement
- WP4– Participatory systems mapping and Theory of Change (ToC) pathway development

Each package is described in detail in subsequent sections and in Figure 1 – Study Overview

Figure 1: Study Overview



3.2 Population

Throughout WPs 1, 2 and 4 we will be working with:

A. People with LTNCs which impact mobility, who self-manage health and care and live at home: PU Risk can be constant or fluctuating, with gradually increasing risk and acute escalations.

B: Carers: Many people living with LTNC will receive support from carers. Some individuals experience cognitive impairments which impact ability to self-care and reliance on support. We will focus on 2 carer groups:

- Informal carers: Defined by the NHS as someone who provides support for a family member/friend who would not otherwise be able to cope [36]. Informal care is usually 'unpaid', although state benefits may support living costs.
- Paid Personal Assistants (PPA): PPAs provide support and their role is determined by the needs/wishes of that individual (e.g. personal care, domestic support, travel, leisure/social activities and workplace support) with a focus on maintaining dignity and independence. PPAs can be employed/paid through a number of mechanisms including Access to Work schemes, Personal Independence Payments, Continuing Care Funding or by the disabled person themselves.

The social care landscape is complex and we recognise other types of social care exist, including formal domiciliary care services and other regulated providers. We have chosen to focus on informal carers and PPAs due to the longer term (often life-time), more holistic nature of the care they provide and the recognised lack of support they receive, with few opportunities for peer learning or networking and an absence of regulation.

During WP 3 we will engage wider professional and strategic partners with relevant experience of PU prevention for people with LTNC. This will include (but is not limited to) district, practice and tissue viability nurses; occupational therapists; physiotherapists; GPs; representatives from relevant charities and wheelchair services.

All participants will be asked to complete an anonymous demographics survey (via a digital version of the form that can be emailed back to the researcher, verbally over a call, or on paper). This will enable us to monitor and describe the diversity of our population and seek perspectives which are missing.

4. WP1 Two Co-operative Inquiry Groups (CIGs)

4.1 Aims

I. To establish two co-operative inquiry groups (CIGs) to underpin and support the design, management, data collection and conclusions of the study
II. To explore CIG members' experience of identifying and self-managing PU risk or supporting others to self-manage.

4.2 Method

We will establish 2 parallel groups: one including people with LTNCs and informal carers; a second comprising PPAs. Co-operative inquiry is a person-centred, participatory inquiry where people (in this case those with LTNC, their informal carers and PPAs) research a

topic through the lens of their own experience, taking on participant and co-researcher roles at different points [21]. In doing so they contribute to the generation of ideas, design, management, data collection and study conclusions, while simultaneously being co-subjects and participating in the research. An advantage of the approach is that their involvement throughout the research process will facilitate deep, rich understanding about the challenges they experience in preventing PUs (including system level and professional barriers) and outputs which are practical, user friendly and therefore amenable to implementation.

The two CIGs will meet separately at first, to facilitate open discussion about their own experience of PU risk. For example, living with risk; successfully preventing PUs; seeking help to manage risk; patient pathways and entry points into health / social care systems; and integrating PU risk management into wider self-care routines. Our PPI suggests that employment relationships can impact PPAs willingness/ability to challenge the health behaviours of people with LTNC. To enable people to honestly discuss this dynamic, we will form 2 separate yet parallel groups. With the permission of all members, the groups will come together later in the project, to further explore issues and share their learning. We will discuss facilitation and support with both groups to ensure this is done in a safe environment, where people feel able to contribute.

4.3 Sampling of Co-operative Inquiry Group Members (CIGs)

Participatory research is strengthened through partnership synergy and trust [26, 28], therefore we intend to recruit CIG participants from existing PURSUN members. This allows us to build on existing relationships within the group and between the group and the university. We will also extend membership, actively seeking people with different backgrounds and experiences to maximise diversity in terms of gender, ethnicity, socioeconomic status, LTNC, and PU experience. This approach aims to maximise the trusting relationships that we have with existing PURSUN members, whilst also allowing us to maximise the diversity of experiences within the group to facilitate information power [36]. In line with UK Public Involvement Standards [37], we will collectively appraise group diversity, and this will inform WP2 sampling.

Based on our previous experience with similar work, we anticipate each group will have approximately 8 participants. This is likely to fluctuate over time and we will aim to over-recruit to anticipate some natural drop out. DM, SC and the Research Fellow will also be members of the CIGs, providing facilitation and support, and working *with* the other group members.

4.4 Initial Service User (people with LTNC) Informal Carer and PPA Recruitment

We have provided detailed descriptions of the recruitment strategy for each work package, in the corresponding sections of this document (Sections 4.5, 5.4, 6.4, 7.4). Figure 2 (page 25) provides an overview of recruitment across the study as a whole.

We will begin with an initial outreach period, aiming to identify potential participants for all work packages. During the outreach period, the project coordinating group will send appropriate charities (e.g SHINE, the MS society) and PPA organisations (e.g. independent living centres) an electronic message with an attached summary of the study. Organisations will be invited to forward information to their membership via their usual communication channels (i.e. email, newsletter, social media). Organisations will also be able to request

paper versions (posters and / or leaflets) for use at face-to-face events or to be displayed within their buildings. In addition to our study summary leaflet, we will create social media adverts, text which is suitable for organisations' newsletters / websites, and a short video version of the study outline, which will be housed on the University's YouTube channel.

The study summary will include details of the different ways in which people can become involved in the study:

1. CIG membership
2. Interview / app participation
3. Joining an email mailing list to hear about study outputs and future pressure ulcer research opportunities

Potential participants will be invited to express an interest via a study email address or phone number, indicating which aspect(s) of the study they are interested in. If they have expressed an interest in options 1 or 2 (see above) a researcher will contact them to discuss in more detail (see section 4.5, 5.4 and 6.4 for specific areas of participation and subsequent recruitment sections). If they have only indicated an interest in option 3, they will be added to a mailing list, held on a secure server at the university of Leeds. They will be sent an email to confirm this, which will include a link to our GDPR policy.

4.5 CIG Recruitment

A university researcher will arrange a convenient time to call or meet the potential participant, to discuss becoming a member of the CIG. The researcher will give a verbal explanation of the study, discuss the personal implications of the study, and answer any questions. The researcher will also ask about any adaptions, support or access considerations. A detailed Participant Information Sheet (PIS) will confirm that participation is completely voluntary, and the researcher will ensure that no individual feels pressurised to take part in the study. This will include emphasising the right of the individual to refuse consent, without giving reasons. Individuals are free to withdraw consent at any point up to, during or following participation, without giving reasons, and their personal data will be deleted. Fieldwork data (including recordings/transcripts of activities they have taken part in) collected up to the point of their withdrawal will be retained. This is because they are taking part in a group process, and it will not be possible to remove the contribution of one person. Their personal data will be deleted, unless they wish to stay informed about project or have their contribution recognised in project outputs (e.g. publications), in which case this will be negotiated with the individual.

Potential participants will have as much time as they need to discuss the study with their family, advocate, carers and/or healthcare providers. If required, the researcher will arrange another date and time to re-contact them. If they agree to participate, they will be asked to give their written or verbal (audio-recorded) informed consent. Verbal consent will be given via Microsoft teams or telephone, on an encrypted device. Once the university researcher has started to record the conversation, they will ask the participant to state their name. The researcher will them read out each consent statement and ask the potential participant to state 'I agree' after each one. Consent can also be collected via an electronic form that can be emailed to the potential participant, where it can be completed and returned to the researcher via email. Written consent will only be given during a face-to-face meeting with

the researcher. Consent recordings / forms will be stored securely at CTRU and separately to other fieldwork data.

4.6 Data collection

The two CIGs will meet regularly (approximately monthly for 4 months and then bi-monthly thereafter) over the course of the study using a combination of in-person, virtual and hybrid meetings. The format, location and timings of meetings will be negotiated with group members, taking into consideration their needs, wishes and the specific focus at each stage of the project. We have already discussed the pros and cons of different meeting formats during our PPI activities. PURSUN members indicated that, over the course of the COVID pandemic, they had had increasingly positive experiences of virtual / hybrid meetings. Given the vulnerable nature of some CIG participants, and ongoing pandemic uncertainties, the need to have a virtual meeting option was agreed. It was noted that effective organisation, facilitation, agreed ground rules and access/support for IT equipment was imperative to success and would be carefully managed by the university research team. Any in-person meetings will be held in accessible and comfortable venues with refreshments available throughout. Participants who are unable to attend meetings, or prefer to provide information in writing, can do so by email.

Each CIG will collaboratively develop a set of shared values and a partnership agreement, which will shape how they work together. The research team have experience of developing partnership agreements based on international guidelines, outlining the ethical principles of participatory research [38] and covering key issues, including but not limited to confidentiality, ownership, payment, respect and authorship.

Following clarification of the aims of the work and agreement of the real world impact we want to achieve, each group will go through an adapted version of Heron's partial form co-operative inquiry methodology [21] (also see Figure 1):

i. **Group forming** – Getting to know each other and creating safe, communicative spaces, where people can engage in meaningful dialogue. This will include development of partnership agreements.

ii. **Self and group reflection** –participants will be invited to share personal experiences of managing PU risk and identify common themes. Participants will be offered different exercises to help them express their stories in a way which is accessible/meaningful to them [51]. Meeting regularly with the same group will allow depth of discussion and understanding.

iii. **Reviewing existing evidence –**The co-applicant team will be responsible for identifying and summarising existing evidence including risk assessment (e.g. PURPOSE T, a clinical pressure ulcer risk assessment tool) and self-management interventions (e.g. from spinal injuries). The CIGs will review and discuss this evidence to see if there is any transferable learning for prevention at home.

iv. **Preparation and training for WP2 peer to peer interviews –** The CIGs will design the WP2 interview schedule and agree the sampling strategy (see below). We will seek volunteers from each group to undertake interviews. Based on past projects, we

do not anticipate that all group members will want to undertake interviews. Training and support will be provided for the volunteers. Preparation will be tailored to each individual following detailed discussions about their confidence levels and needs.

v. **CIG Continued Immersion** - the CIGs will continue to meet regularly throughout WP1-4, moving between participant and peer researcher roles at different points in the project. Meetings will include discussions around study progress and planning; rapid qualitative analysis of preceding work (from WP1-4) and triangulation between work packages in an iterative process; co-designing topic guides for WP3 and WP4; and dissemination planning. CIG members will also participate in the stakeholder meeting and systems mapping and ToC workshop (as detailed below).

4.7 Analysis

With the consent of all present, CIG meetings will be audio-recorded. If we do not obtain permission to record, then we will take detailed notes. During meetings, facilitators will encourage participants to identify and record common themes emerging from discussions. We will draw on a selection of participatory methods to aid that process (for example flexible brainstorming, commentary charts, card sorts and direct ranking). These methods can be used to create a visual representation of discussions, which can then be photographed to form part of meeting summaries / data [39-41].

Towards the end of each meeting the group will collectively complete a Rapid Assessment Procedure (RAP) sheet. RAP sheets are a tool used in rapid qualitative research to summarise emerging findings and share these with other team members and stakeholders. They aim to highlight key discussions and ideas which can then be explored in more depth at a later point. University researchers will also make post meeting field notes, highlighting key events, discussions and emerging themes. These will be shared with the CIGs at subsequent meetings resulting in an iterative generation of rich discussion and data. Audio recordings of selected key discussions, agreed with the CIGs, will be transcribed (not all data will be transcribed). This data will be entered into NVivo and analysed with data from other WPs allowing the triangulation of data (see WP2 and WP4 Analysis sections for further details).

Each meeting will end with a reflective debrief, where people will be invited to consider and discuss how they are working together. This will be used and to improve and develop our collaborative processes as we progress through the project.

5. WP2 Peer to peer Interviews and/or Smartphone App Participation

WPs 2 and 3 will run concurrently

5.1 Aim

To explore PU prevention/risk management with people with LTNCs, informal carers and PPAs.

5.2 Method

Participants will be invited to take part in semi- structured interviews (face to face or online) and/or complete tasks via a smart-phone app. Our flexible approach to data generation aims to be inclusive and accessible to a diverse range of people.

Trained members of the CIGs will undertake semi-structured, peer to peer interviews with other people who have LTNCs, informal carers and PPAs. Peer to peer interviews have the potential to facilitate access to underserved communities and create greater depth, openness and trust for participants **[22, 42]**.

Completion of tasks via a digital smartphone app will enable the collection of data on day-to-day PU prevention behaviour and actions, as reported by them. This can facilitate a more detailed understanding and fuller immersion into lived experiences. One potential benefit of this approach, is that participants are likely to carry a phone wherever they are, making it easier to record thoughts and feelings as they happen [43]. The app allows information to be recorded via text, audio, photos and / or video. We will invite participants to respond to tasks in the format which is most accessible and meaningful for them. We will undertake user testing of the app within our CIGs before it is used more widely.

5.3 Sampling

We will appraise the diversity of the CIGs and actively seek interviewees with perspectives which are currently missing / underrepresented. Using a flexible, yet pragmatic approach and in keeping with the sampling of the CIG groups, we will purposively sample participants from varying backgrounds and experiences to maximise diversity in terms of gender, ethnicity, socioeconomic status, LTNC, and PU experience.

5.4 Recruitment

The University research team will re-contact potential participants identified during the initial outreach phase of recruitment (see section 4.4 and figure 2 for more information), to further discuss interview and / or app participation. Potential participants will be contacted via their preferred method and will be provided with a detailed Participant Information Sheet (PIS). We will provide a verbal explanation of interview and / or diary participation, followed by discussion of the personal implications of the study, answering any questions the potential participant may have.

The PIS will confirm that their participation is completely voluntary and can involve a semi-structured interview, diary tasks or both. The researcher will ensure that no individual feels pressurised to take part in the study. This will include emphasising the right of the individual to refuse consent without giving reasons and that individuals are free to withdraw consent at any point up to, during or following participation. If participants withdraw, their personal information will be deleted. Fieldwork data (interview recordings, transcripts and app tasks) will be kept, to protect the integrity of the study data.

Potential participants will have as much time as they need to discuss the study with their family, advocate, carers and healthcare providers. If required, the researcher will arrange for another date and time to re-contact them for further discussions. If they agree to participate, they will be asked whether they would like to take part in an interview, use the app, or both.

Participants who choose to take part in app tasks (with or without an interview) will be invited to give their consent at the end of the call with the university researcher. Consent will be obtained via one of the following options: completion of a digital version of the form which is emailed back to the research team; verbally (which will be audio-recorded) or on paper. An electronic version of the consent form will be emailed to the potential participant, where it can be completed and returned to the researcher via email. If the potential participant would

prefer to provide their consent verbally, they will be asked to give their verbal, audio-recorded informed consent via Microsoft teams or telephone on an encrypted device. Once the university researcher has started to record the conversation, they will ask the participant to state their name. The researcher will then read out each consent statement and ask the potential participant to state 'I agree' after each one. Completed consent forms and consent recordings will be stored securely at CTRU and separately to other fieldwork data.

Participants who choose to only take part in an interview will be allocated an interviewer (a trained member of the CIGs) who will contact them to arrange a convenient time and place for the interview. Interview participants will be invited to give their verbal, audio recorded consent or written consent at the start of the interview. Peer interviewers will all receive training around informed consent and University researchers will be available to support that process, if needed.

5.4.1 Targeted Recruitment via the NHS / social care

If existing recruitment indicates a lack of diversity, we may recruit via clinical members of our Project Coordinating Group (PCG). This will allow us to target people with particular characteristics (e.g. age, gender, ethnicity, LTNC condition, pressure ulcer status), which are missing or underrepresented in our current study population. Recruitment via NHS and/or social care services will only be utilised if we fail to recruit a diverse sample during other recruitment activities. If required, clinical PCG members will screen service users for key characteristics via their workplace. This may happen during routine appointments or via conversations with colleagues. For example, our rehab physio will look for suitable potential participants via her routine clinical practice / clinical colleagues within neuro outpatients' physio in Leeds Teaching Hospitals Trust.

Clinical PCG members (or their immediate NHS / social care colleagues) will identify participants who they think may be suitable for the study, via their routine practice (those under their direct care). They will provide potential participants with a verbal explanation of the study, the study overview and a link to an online version of an 'agree to researcher contact form'. This information will either be given at the end of a routine appointment, or by email, phone or post. Where no appointment is scheduled in the near future, a member of the patient's existing clinical care team may access patient records to obtain contact details. Records will only be viewed by staff members who routinely have access to those records as part of their clinical practice. It will be made clear to participants that their treatment / support will not be affected if they decline participation.

Potential participants will be invited to express an interest via an 'agree to researcher contact form', which can be completed online. PCG members or other members of a clinical care team will offer to support individuals in completing the form online, by sitting with them during this process or completing the form on their behalf where this would be helpful to the potential participant (e.g.: straight after a routine appointment or after a telephone discussion). On receipt of the completed form, a university researcher will follow the recruitment process detailed in 5.4.

We anticipate the number of people recruited via this route will be very low. However, this recruitment strategy gives us the opportunity to actively seek participants with particular characteristics, which can be challenging when recruiting via third sector organisations, as

they may not hold the necessary demographic information. In addition, it allows us to seek the important perspective of people who are not already engaged with charities or other support organisations.

5.5 Data collection

Once consented to the study, all participants will be asked to complete an anonymous demographics survey (via a digital version of the form that can be emailed back to the researcher, verbally over a call, or on paper). This will enable us to monitor and describe the diversity of our population and seek perspectives which are missing.

Interviews - Peer to peer, semi-structured interviews will be conducted in a flexible manner to take account of both interviewer and interviewee needs. The process will be closely supported by the university research team. Interviews will be conducted either face-to-face, at a location accessible and convenient to both parties (with refreshments available throughout), or virtually via Microsoft Teams or Zoom. If desired by the interviewer or interviewee, some interviews may be conducted in pairs, with either DM, SC, the Research Fellow or another CIG member present, to support the interview process and facilitate feedback to the interviewer. Conducting interviews in pairs has been shown to increase the quality of peer interviewing [44]. Where participants have an informal carer they will be offered the option of doing a joint interview with their carer. The interviews will last approximately 45mins.

Virtual interviews will take place via a recorded video call using Microsoft Teams or Zoom. Recordings will be saved on a secure server at the University of Leeds.

Face to face interviews will be audio recorded using an encrypted device, provided by the University of Leeds. Interviewers will send audio files to the university via our secure file transfer service. They will be sent to our dedicated study email, moved to a secure server and then deleted from the device. University researchers will be available to guide peer interviewers through this process, if needed.

Smartphone app - Participants will be sent a link to download the app on their own smartphones. We will also send simple guidance. Guidance will include, technical support; tips for ease of use; safety when taking photographs (e.g. not taking photos of other people without permission); and signposting to additional support (e.g. clinical services and charities). A university researcher will contact participants to check they have downloaded the app and to run through any technical issues. Tasks will be set as ‘blocks’ of work, including a number of questions that will be immediately visible on the app when opened. The initial task will be very simple (e.g. please introduce yourself) to allow people to familiarise themselves with the technology. Tasks will be sent out across a period of 2 – 3 weeks. It will be made clear to participants that completion of tasks is voluntary. If neither the interview or smartphone app are accessible to participants, then they will be offered the option of answering questions via email.

University researchers will back up data stored in the app once a month (minimum). Back up data will be downloaded and transferred to a secure server at the University of Leeds.

Interview topic guides and app tasks will be co-developed with CIG members and informed

by emerging findings from WP1. We anticipate they will cover topics such as, home / work life, self-care routines, thoughts on PU prevention, PU prevention activities, awareness / use of services, sources of health information / support.

There will be a total of approximately 24-30 interviews overall. Over the course of the CIGs (WP1, n=16) and peer to peer interviews and diary participation (WP2, n=24-30) we will gain insight from the views of approximately 40-46 people with LTNC, their informal carers or PPAs.

5.5.1 Peer Interviewers

We estimate approximately 6-8 CIG members will be interested in, and have the time to conduct, interviews. We will work with people to identify what training and support they need and how much time they are able to commit to interviews. Our previous experience from similar work suggests that it is acceptable to ask peer researchers to complete 3-5 interviews each. More than one allows people to develop as interviewers, more than 5 would be a considerable time commitment for volunteers. Ultimately this will be negotiated with the CIG members.

A bespoke training and support package will be offered, based on the needs and wishes of the peer researchers. We anticipate it will include:

- Information on informed consent
- Rights and wellbeing of interview participants
- Interviewing skills (including role playing)
- Personal safety and wellbeing of interviewers
- Confidentiality
- Data security
- Completion of RAP sheets (see section 5.6 for more information)
- Technical support (e.g. recording interviews and using the secure transfer service)
- Opportunities for feedback and reflection
- Opportunities to interview in pairs (with either a university researcher or fellow peer researcher) for additional support

We will complete a risk assessment for face-to-face interviews and develop a lone working protocol, if needed. University researchers will keep a log of when all interviews are scheduled and check in with interviewees after each one.

5.6 Analysis

Data analysis of the semi-structured interviews and app tasks will be informed by key principles of rapid qualitative research [45]. This is appropriate as the study will be conducted over a relatively short time period (months) and there are multiple data sources (WP1-4 will all generate qualitative data), which will be triangulated during analysis. Data collection and analysis will be conducted collaboratively by the CIGs and university researchers. The research is iterative with data collection and analysis happening in parallel and early findings shaping future data collection. We will combine this with a framework analysis, which has been used successfully in participatory research [46, 47]. This involves a sequential process of familiarisation with the data, identifying themes, developing an

analytical framework and interpretation.

Interviewers will be asked to complete a reflective RAP sheet immediately after each interview. RAP sheets generate rapid data driven findings which can be used iteratively to inform later interviews and analysis. RAP sheets can also be used to help team members work together and familiarise themselves with large amounts of data quickly. They help to capture multiple perspectives by encouraging individual and then team critical reflection on the data [48]. Peer interviewers will be offered a meeting with a university researcher after each interview to debrief and support completion of the RAP sheets, if needed.

We will facilitate collaborative data analysis workshops with each CIG. Interviewers will be invited to present themes emerging from their interviews, guided by their RAP sheets. A similar process will be followed with app entries and data from WP3 (which will happen concurrently with WP2). For app entries, CIG members will be asked to familiarise themselves with one participant's app data (text, audio, images or short videos) prior to analysis workshops. They will then complete a RAP sheet for the participant and present to the rest of the CIG. A university researcher will also present a RAP sheet generated during the WP3 stakeholder workshop (see section 6 for more info). Through facilitated discussions, the group will then identify factors which help / hinder pressure ulcer prevention at home, across multiple data sources (interviews, app entries, WP3 stakeholder workshop). Analysis workshops will be recorded and detailed notes taken.

A university researcher will refine and organise emerging findings from the analysis workshops and develop an analytical framework derived from triangulated data from WPs 1 - 3 [46]. University researchers, and volunteers from each CIG, will then be invited to review data to looking for confirming / disconfirming quotes. During this process people will have access to interview recordings / transcripts, app data and recordings / transcripts from WP3.

Our previous experience of participatory analysis has demonstrated that audio-recordings are easier for some peer researchers to engage with (comparted to transcripts) and give a more nuanced account of the interview. However, transcripts will also be available. Emerging interpretations, especially any disconfirming data, will be shared with both CIGs at subsequent meetings to sense check the findings. Key findings will be taken forward to discuss further in WP4. The transcripts, RAP sheets and diary entries will be stored and managed in NVivo. Our team has experience of supporting collaborative analysis and will also follow emerging best practice [47]. It will be made explicit to participants in WP2 and 3 that recordings will be available to CIGs as part of the analysis process.

6. WP3– Professional Stakeholder Engagement

6.1 Aim

To explore the perspectives of professional and strategic partners on PU prevention at home.

6.2 Method

A stakeholder engagement focus group will be undertaken [49].

6.3 Sampling

Utilising existing clinical and research networks from our previous work we will purposively sample a group of approximately 12-14 professional and strategic partners incorporating health and social care professionals with relevant experience of PU prevention for people with LTNC [17]. The exact composition of the group will be driven by emerging findings from WP1. Participants are likely to include, district, practice and tissue viability nurses; nurses who provide specialised support for LTNC; occupational therapists; physiotherapists; mental health nurses; GPs; representatives from relevant charities; spinal Injury liaison staff and wheelchair services.

6.4 Recruitment

We will recruit professional and strategic partners via the established links of our PCG and CIGs and social media. We will send potential participants an introductory email with a summary of the study, a participant information sheet (detailing the rationale, design, and personal implications of the study) and a consent form. The email will ask them to respond by return if they are interested in participating. All potential participants will be offered a call with a university researcher to further discuss the study. The information sheet will confirm that their participation is completely voluntary and the researcher will ensure that no individual feels pressurised to take part in the study. This will include emphasising the right of the individual to refuse consent, without giving reasons. Individuals are free to withdraw consent at any point up to, during or following participation, without giving reasons, and their personal data will be deleted. Fieldwork (including recordings/transcripts of activities they have taken part in) collected up to the point of their withdrawal will be retained. This is because they are taking part in a group process, and it will not be possible to remove the contribution of one person. Their personal data will be deleted, unless they wish to stay informed about project or have their contribution recognised in project outputs (e.g. publications), in which case this will be negotiated with the individual.

Participants will be informed that the focus group will be audio-recorded and that sections of that recording may be shared with CIG members as part of analysis. If they are content to participate, they will be asked to complete the electronic consent form and return via email to the researcher. A copy of the consent form will be kept by the researcher and filed securely at the University of Leeds, separately from fieldwork data.

6.5 Data collection

The group will be guided by a topic guide co-designed by the CIG, informed by emerging findings from WP1. We anticipate it will include topics such the need for services to respond to informed, empowered service users, facilitating self-care and blame/stigma avoidance. A university researcher (SC) will facilitate the group, supported by DM, the post-doc researcher and a volunteer from each CIG. This will be an interactive meeting and will facilitate discussion/exploration of services and professional issues associated with supporting this currently underserved population. The group will be audio-recorded and conducted in an accessible and comfortable Leeds venue (or online if needed to meet COVID restrictions). It will last approximately 2 hours in total with refreshments available throughout.

6.6 Analysis

Data from the meeting will be analysed with the CIGs in keeping with key principles of rapid qualitative research and as detailed for WP1 and 2.

7. WP4– Participatory Systems Mapping and Theory of Change (ToC) Pathway

7.1 Aims

I. To develop systems maps to provide a visual representation of the systems associated PU prevention from the perspective of those living with LTNC, their informal carers, PPAs and health and social care professionals.
II. To develop a ToC pathway to underpin intervention development.

7.2 Methods

Systems mapping is a collaborative technique used to understand and present complex health problems/capacities within a system of contributory factors. It draws on systems thinking to provide a holistic approach [50] which considers individual and wider community variables and how they impact on outcomes. Systems mapping is an appropriate method for this work as our PPI and previous research [51] have shown that many inter-related factors help/hinder an individual's ability to manage PU risk. It is also recognised as a very useful method to elucidate areas within the system which are most resilient to change, contributing to a more comprehensive ToC pathway, which more effectively represents the characteristics and requirements of a complex adaptive system, identifying [52]:

- External contextual influences that might impact (enhance or impede) the path from action to outcome.
- Areas where policy may have positive/negative impacts in areas not immediately related to its intended outcomes.
- Feedback between outcomes or other factors, along a pathway that can increase or impede outcomes and negative consequences
- Levers that can be used to enhance outcomes

This more comprehensive ToC will inform and facilitate agreement of intervention component requirements.

7.3 Sampling

Participants from WP1 and WP3 will be invited to participate in the larger systems mapping workshop. This will be approximately 28-30 people.

7.4 Recruitment

We will invite existing participants from WP1 and WP3.

7.5 Data collection

The CIGs (WP1) will come together with wider stakeholder partners (WP3) for a face-to-face systems mapping workshop that will be held in a comfortable, accessible venue. The workshop will last approximately 3 hours with regular refreshment breaks. A researcher will provide a user-friendly explanation of systems thinking (eg: the analogy of a car that works because of all of its components – the car travelling is the outcome of all of these elements. However, it ceases to function once one of these is removed, such as if the clutch becoming faulty), provide an example systems map, outline the scope of the workshop and answer any questions.

Supported by experienced facilitators, and drawing on participatory methods, participants from the CIGS will present their learning so far from WP1-3 to the other participants of the

meeting. They will then split into two or three multi-stakeholder groups with at least one service user, carer, PPA, and professional in each group. A facilitator will lead discussions around a topic guide co-designed with the CIGs, in light of preceding work. Participants will be encouraged to share their opinions regarding key variables and the connections between them which impact pressure ulcer prevention in this population. They will construct a causal map made up of ‘factors’ (represented as nodes on the map) and their causal connections (positive, negative, unclear, complex) [52].

Following this, the groups will come back together and each present their systems map, facilitating further reflections and discussion about the key variables and connections between them (including negative and positive feedback loops) in order to identify and prioritise areas for intervention and to develop the ToC pathway. These discussions will also be audio-recorded to allow further analysis and reflection. Facilitators and researchers will complete RAP sheets regarding the individual group discussion and collective group discussion.

7.6 Analysis

A summary report of the meeting will be generated. The report will be compared to the maps developed during the meeting and further refinement will be made using STICKE mapping software. We will ask for volunteers from the CIGs to refine the systems map and TOC pathway, which will then be shared with the wider CIGs for review. Audio recordings of the workshop will be available to support this process.

8. Project Management

The University of Leeds will host the research and take on research sponsorship responsibilities. Each WP has a designated lead and the project team, comprising the joint CIs (SC and DM) and Post-Doctoral Research Fellow will meet at least once a fortnight to ensure day to day oversight/coordination between the WPs.

A Programme Co-ordinating Group (PCG) (Chair: SC) comprising the joint CIs, all co-applicants and the Research Fellow will meet once a month for the first 4 months and then 6 times for the remaining 20 months of the project. The group combines participatory (DM, JD), clinical academic (SC, JN, JD), specialist nurse (NS, HS), specialist neurological physiotherapist (C), social care (YB) and qualitative methods (SC, YB, DM, JD) expertise, and personal experience of living with a PU/PU risk, patient advocacy and caring for someone with a LTNC (AM,YR).

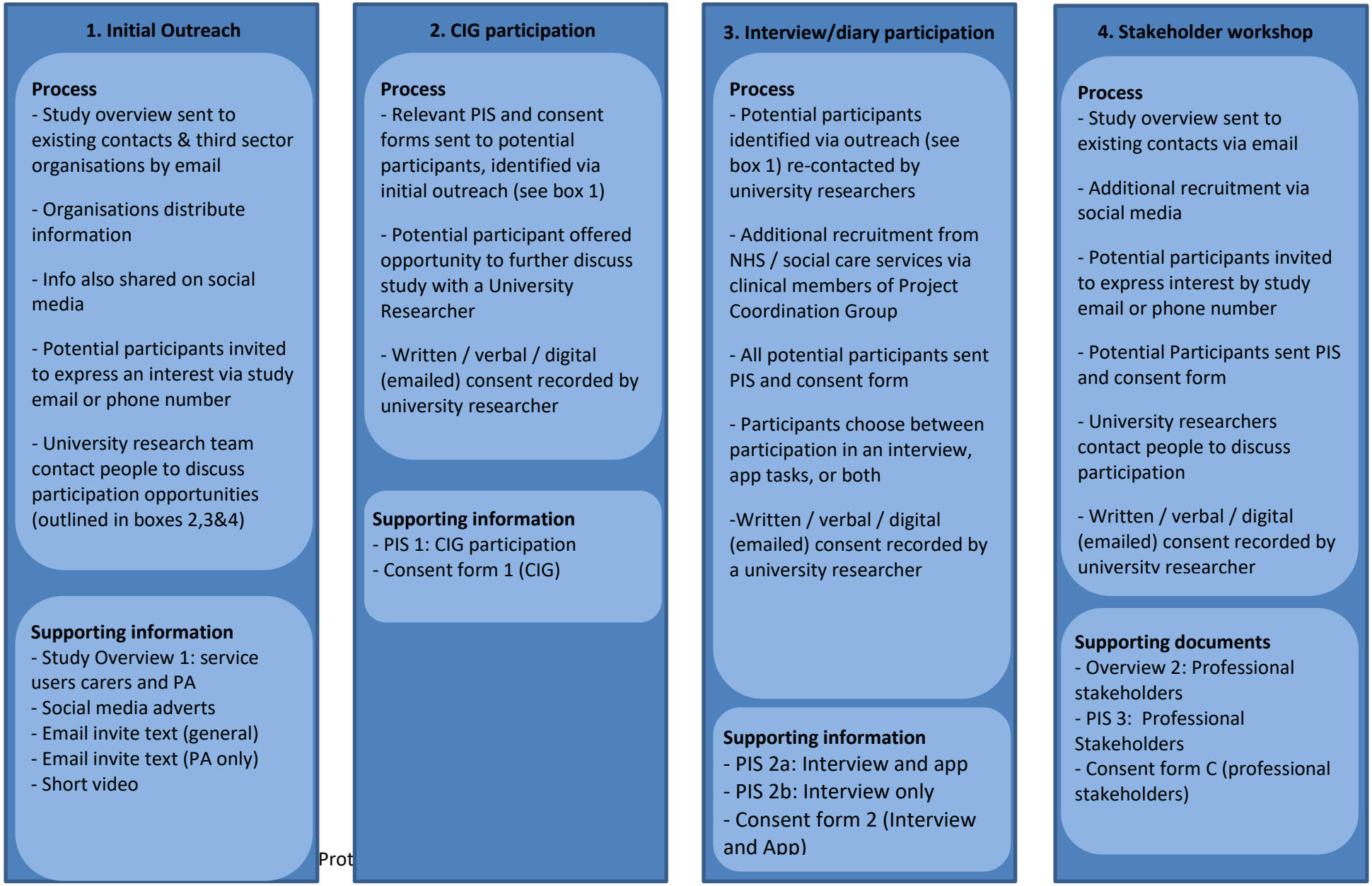
In line with participatory practice, the CIG members will also be a key part of project management. They will take a lead role on WP1 and 2, supported closely by the project team. The PCG will use their extensive expertise to support and guide the CIGs and provide oversite of the whole programme of work. AM and YR (public co-applicants) will act as a link between the CIGs and programme management group.

In addition, a Programme Steering Committee with 3 independent members from the social care/NHS sectors and a member of the public, will be established to oversee research conduct and progress against objectives. The committee will meet annually and will be led by 2 independent co-chairs (a service users and a participatory researcher). The joint CIs (SC and DM), and Post-Doctoral Research Fellow and the 2 public co-applicants will attend the Programme Steering Committee and report progress including issues which may be of strategic importance to the NHS and Social Care.

9. Clinical Governance and Issues

The University of Leeds will host the research and take on research sponsorship responsibilities. The study will be conducted in accordance with the principles of Good Clinical Practice (1998), the NHS Research Governance Framework (*and Scottish Executive Health Department Research Governance Framework for Health and Social Care 2006 for studies conducted in Scotland)* and through adherence to the University of Leeds, CTRU Standard Operating Procedures (SOPs).

Figure 2: Recruitment overview



10. Ethical Considerations

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, [1996]. Informed written or audio recorded verbal consent will be obtained from the participants prior to registration into the study. The right of a participant to refuse participation or withdraw from the study at any time, without giving reasons, will be respected.

Ethical approval will be sought through the University of Leeds ethics committee and for targeted NHS recruitment via the National Research Ethics Service (NRES) using the Integrated Research Administration System/Health Research Authority submission process. The project team will collaboratively develop detailed information resources for potential participants (see figure 2), to support informed consent. The CTRU will provide NRES with a copy of the final protocol, participant information, consent forms and all other relevant study documentation Any emerging ethical considerations will be discussed with CIG members, the PCG and / or the steering committee, as appropriate.

This project includes the discussion of potentially emotive health topics (e.g. during CIGs and interviews) as participants will be asked to draw on their experience of living with long term conditions. University staff, with experience of facilitating PPI and qualitative research in this field, will be available to provide support and signpost to appropriate clinical / support services, if needed. The cooperative inquiry methodology also creates opportunities for peer support.

There are particular ethical considerations associated with participatory practice. We will use the ‘community-based participatory research guide to ethical principles and practice’ [53] to steer our approach. The guide outlines 7 ethical principles. Below, we have summarised how we are addressing each principle.

1. **Mutual Respect**: developing relationships based on mutual trust.
    - Developing shared values, ground rules and partnership agreements with each CIG.
    - Financial reimbursement.
    - Building on an existing, longstanding relationship between the University and PURSUN members.
    - Longitudinal consent i.e. CIG members will be contributing to the project over a long period, moving between participant and researcher roles throughout the study. In addition to recording written / verbal informed consent at the start of the project, we will continually check whether participants have any concerns and are happy to continue.
    - Seeking informal permission to record conversations at the start of each session.
    - Acknowledgement of CIG members in all study outputs (with permission).

2. **Equality and Inclusion**: Enabling people from a range of backgrounds and identities to contribute.

- Using a range of data collection approaches (e.g. group sessions, app, interviews, online and face to face activities). In addition, participants are able to provide contributions in multiple formats (e.g. voice or film recordings in the app, visual facilitation techniques within group CIG sessions). This aims to make processes accessible and engaging to a broad range of people.
- Holding face-to-face activities in fully accessible locations.
- Providing tablets and IT support to CIG participants.
- Collectively appraising the diversity of our CIGs and actively seeking perspectives which are missing / underrepresented in WP2.

3. **Democratic Participation**: Enabling participants to contribute meaningfully to decision making and research conduct.

- CIG members playing a key role in research management.
- Our diverse PCG includes representation from service users, carers, healthcare professionals and methodologists.
- Our research management structure has been discussed and developed in a collaborative way.
- We are committed to acknowledging and discussing power dynamics within the research, to facilitate open, honest contributions. For example, providing separate spaces for PAs, service users and professionals to share their experiences, before coming together later in the project.
- We recognise it may be challenging for new members to join existing, experienced PURSUN members within the CIGs. PURSUN has an existing induction process, which we will utilise for new CIG members.

4. **Active Learning**: Research processes are an opportunity to learn with and from each other.

- Time built in for reflection and feedback.
- Collaborative analysis process.
- CIG members and university researchers share responsibility for interpreting findings and their wider implications.
- Bespoke training and development for interviewers.

5. **Making a difference**: Promoting research that creates positive changes

- This research has been designed collaboratively. That process included in depth discussions about unmet need within our populations. We will continue to explore what positive change looks like throughout the research e.g. during interviews and mapping.
- Systems mapping process will identify and priorities areas which will most benefit from intervention.
- Building positive impact throughout each stage of the study. E.g. the CIG process aims to provide needed peer support and development for PPAs.

6. Collective action: individuals and groups working together to achieve change

- This is a collaborative project which brings together different forms of expertise e.g. service user, carer, health / social care professionals, PPAs, research.

- Systems mapping process will bring together the perspective of different groups.

7. Personal integrity: Everyone involved behaving reliably, honestly and in a trustworthy fashion

- CIG shared values, ground rules and partnership agreements.
- Interview training will explore appropriate behaviour and personal safety.
- Opportunities for both group and individual feedback and reflection.

11. Confidentiality

All information collected during the course of the study will be kept strictly confidential. Information will be held securely on paper and electronically at the Clinical Trials Research Unit (CTRU). Any information which would allow individual participants to be identified will not be shared outside of the study team, unless the participant has given their explicit permission (E.g. if a CIG member chooses to become a co-author on a project publication).

Information collected during the course of the study will be anonymised and participants will be assigned a study ID number with linkage to the consent form / recoding only (held securely at CTRU). Some data will be collected via group interactions (CIG and stakeholder group and systems mapping workshops), therefore anonymity will have limitations. In groups settings, participants will be able to see who is taking part in the study and hear their contributions. The CTRU will comply with all aspects of the 2018 Data Protection Act, operationally this will include:

- Consent from participants to record personal details including age, gender, ethnicity , occupation, postal and email address and telephone number, role (professional stakeholders), type long-term neurological condition (LTNC), PU history (CIG, interview and smartphone app participants).
- Consent from participants for the CTRU to receive their consent form / recording (which includes their name) by either hard postal copy, emailed completed form or verbal digital copy. Consent from CIG participants to share their name and email address with Field Notes app for setting up an account to allow them to use the app.
- Consent from all participants to allow their study data to be looked at by responsible individuals from the research team and CIGs, this includes anonymised transcripts and non-anonymised data (recordings of transcripts and app entries)
- Consent for CIG participants to be acknowledged in presentations, publications and reports relating to the study.
- Consent from participants to allow their audio data to be transferred to a third-party transcription service, following the company signing a None Disclosure Agreement and in accordance with CTRU data transfer standard operating procedure to ensure secure data transfer. The data would be deleted from the third party's secure, DPA compliant system once the transcription work is completed.
- Consent from all participants that information gathered during the interviews, smartphone app exchanges, meetings or workshops, including direct quotes (anonymised), may appear in publications relating to the study and be used for training purposes for new research.
- Consent from all participants for their data (text, audio, photo, video) to be stored for the duration of the study by the Field Notes Community App provider. This data will

be hosted on a password protected website and transferred in an anonymised format to the CTRU server on a monthly basis (minimum). At the end of the study all data will be deleted from Field Notes. Individual data will be coded with a study number and participant initials. Group meetings (will be coded with a study number).

- Appropriate storage, restricted access and disposal arrangements for participant personal information.
- If a participant withdraws consent from further involvement, their personal details will be deleted. Fieldwork data will remain on file and will be included in the final study analysis.
- CIG members will be provided with training on data protection and security.

12. Archiving

At the end of the study (which is defined as the end of the funding period: 31st March 2024), data will be securely archived in line with the Sponsor's procedures for a minimum of 5 years. Data held by the CTRU will be archived in the Leeds Sponsor archive facility. Following authorisation from the Sponsor, arrangements for confidential destruction will then be made.

13. Publication Policy

The success of the study depends upon the collaboration of all participants. For this reason, credit for results will be given to all those who have collaborated in the study. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- Conception and design, or acquisition of data, or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content
- Final approval of the version to be published
- All these conditions must be met (www.icmje.org).

In light of this, members of the CIGs will be named as authors in publications (with their permission). In addition, all collaborators will be listed as contributors for the main study publication, giving details of roles in planning, conducting and reporting the study (again with permission).

To maintain the scientific integrity of the study, data will not be released prior to the first publication of the analysis, either for study publication or oral presentation purposes, without the permission of the Steering committee.

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Appendix 1 - Timelines

Study	Feb	March	Apr-22												Apr-23												
	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Oversight																										
Project Team																										
Programme Management Team																										
Steering Committee																										
Preparatory Work																										
Protocol Development WP1-3																										
Ethics and governance approvals WP1-3																										
WP1 Cooperative Inquiry																										
Recruitment of group members																										
Data collections - Meetings																										
Analysis																										
Evaluation of participatory approaches																										
Interview training of group participants																										
WP2 Peer to Peer Interviews																										
Recruitment of interview participants																										
Data collections - interviews																										
Analysis (to link with WP1)																										
WP 3 Stakeholder Engagement																										
Recruitment of participants																										
Data collection - focus group meeting																										
Analysis (to link with WP1)																										
WP4 Systems Mapping																										
Recruitment of participants																										
Data collection systems mapping and TOC workshop																										
Analysis (to link with WP1)																										
Dissemination and future Work																										
Develop dissemination stratgey (to link with WP1)																										
Grant application for intervention development																										
Final Report and Publications																										