**STUDY PROTOCOL**

Use and non-use of Digital Health Technologies (DHT) in rehabilitation: an exploration of factors that influence implementation.

1. **BACKGROUND**

Digital Health Technologies (DHT) have significant potential to revolutionise patient care, transform processes, streamline services, deliver significant cost savings and improve individuals' health and wellness (Health Education England 2019; National Health Service 2019; Nolte 2018). DHT have been defined as “Apps, programmes and software used in the health and care system” (National Institute for Health and Care Excellence 2019). They include a broad range of applications including telehealth, wearable devices, and smart-phone, tablet and PC compatible applications (Monitor Deloitte 2015). In the last few years, the availability of DHT has increased exponentially and it is predicted that over 80% of the NHS workforce will use smart-phone applications (apps) within the next decade (Health Education England 2019). However, the NHS lacks a strong track record in embedding DHT into practice (The King's Fund 2018). Many technologies that were anticipated to transform services have failed to be adopted, were not sustained and/or could not spread beyond single sites (Greenhalgh et al. 2017). Clearly, if the promise of DHT to transform healthcare is to be realised, we must learn from these failures, and use an interdisciplinary approach to explore how DHT can be successfully designed, implemented, evaluated and sustained in routine and realistic clinical practice.

Rehabilitation has been defined as *“*a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment” (World Health Organization 2022). It has been estimated that 1 in 3 people globally are experiencing a health condition that would benefit from rehabilitation (Cieza et al. 2020). DHT present an opportunity to motivate and engage individuals in evidence-based rehabilitation to deliver additional rehabilitation within current staffing and time constraints. With focused and sustained research activity showing promising results with virtual/augmented reality technology (Cheng et al. 2019; Laver et al. 2017; Gustavsson et al. 2021), apps for smartphones and tablets (Scullin et al. 2022; Wallace et al. 2022; Lin et al. 2020; Pugliese et al. 2018) and telerehabilitation (Gutiérrez et al. 2013; Lavoie et al. 2021; Kessler, Anderson, and Dawson 2021), implementation of these technologies will be key to their success.

**2 RATIONALE**

Rehabilitation staff see clear value in using DHT to augment rehabilitation, and DHT provide sustained motivation for patients to complete repetitious activities (often over weeks/months) to improve function (Hamilton et al. 2019). In 2021, 88% of all adults in the UK had a smartphone, indicating a wide use of DHT in the population. Surprisingly, despite an apparent willingness to use DHT, and their increasing availability, it has been shown that DHT are not widely implemented in rehabilitation, highlighting the need to understand the factors that influence their integration into clinical practice (Langan et al. 2018).

Recent studies in general healthcare settings have concluded factors including the design of the DHT, behaviours of the users, and the wider organisational context, amongst others, are important in determining if a DHT is used (Greenhalgh et al. 2017). Despite its clear potential, no studies have sought to comprehensively understand the factors that influence the successful or unsuccessful implementation of DHT in rehabilitation.

Therefore, the aim of this project is to explore factors that influence use and non-use of DHT in rehabilitation in the United Kingdom (UK). This aim will be addressed by seeking individuals from a range of stakeholder groups and inviting these individuals to share their experiences of designing, implementing, and using DHT to develop a comprehensive understanding of implementation processes and outcomes. The study will ultimately provide evidence-based guidance to support the implementation of DHT into a healthcare setting.

**3****THEORETICAL FRAMEWORK**

Rehabilitation interventions have several interacting components and are defined as complex.   Normalisation Process Theory (NPT) enables exploration of the ‘normalisation’ of complex interventions into practice.  Normalisation is described as changes to “thinking, acting and organising” to facilitate the embedding of an innovation (May and Finch 2009, p.540).  This theory describes four components required for the implementation and operationalisation of complex interventions in healthcare (May 2006), which are:

* Coherence, - the meaning of the innovation to those involved
* Cognitive participation, -the ‘sign-up’ to and belief in the innovation and subsequent participation by those involved
* Collective action, - the actions that need to be, or are undertaken by those involved to work towards the goal
* Reflexive monitoring, - the processes that are in place to understand, appraise, evaluate and monitor the implementation of the innovation.

NPT provides an evidence-based theory on which to build implementation research. The NPT is the predominant theory underpinning the sampling strategy, data collection and analysis.

**4 RESEARCH QUESTION/AIM(S)**

This study aims to explore factors that influence use and non-use of DHT in rehabilitation in the United Kingdom (UK) from a range of stakeholder perspectives.

**4.1** **Objectives**

* To identify and describe factors that influence use and non-use of DHT in rehabilitation across a broad range of stakeholders
* To explore the roles of stakeholders in the choice to, and processes of, implementing DHT as part of rehabilitation
* To identify key themes that influence DHT implementation in rehabilitation
* To utilise the findings to contribute to a framework that guides DHT implementation in healthcare rehabilitation

**4.2** **Outcome**

The outcome of this study will be a comprehensive understanding of the factors that impact implementation of a Digital Health Technology as part of rehabilitation. These findings will be used alongside reviews of behaviour change in rehabilitation and broader theoretical models of DHT implementation to generate a programme theory and practical framework to guide DHT implementation in healthcare practice.

**5 STUDY SETTING**

This study will be based in the UK. Participants will be sought from a wide geographical area to address the research aim and objectives. Due to the diverse nature of the participants a variety of methods will be utilised to identify and recruit potential participants. These methods are described in Section 6.3.

**6** **SAMPLE AND RECRUITMENT** (please note Appendices are numbered in relation to IRAS Form and may appear out of order in this protocol)

**6.1 Eligibility Criteria**

Our current work, with two Digital Health Technologies (Virtual Engagement Rehabilitation Assistant [VERA] and Neurorehabilitation On-Line [NROL]) and other literature (Greenhalgh et al. 2017) have indicated that there are a broad range of stakeholders who either influence or are directly involved in implementing Digital Health Technologies. The study population will include patients/service-users and their carers, clinical staff such as physiotherapists, occupational therapists, speech and language therapists and nurses, NHS/HSC service managers/leads, project leads, DHT developers, information technologists, those involved in procurement, and regulatory requirements at service, Trust and national level. These stakeholders have been grouped based on their relationship to the processes involved in DHT implementation (see Table 1) and were derived from our initial stakeholder work. To gain a comprehensive understanding of factors influencing implementation of DHT, individuals involved in successful, partially successful, and unsuccessful implementation of DHT will be sought.

Table 1: The Stakeholders

|  |  |
| --- | --- |
| STAKEHOLDER GROUP  | Includes:  |
| PEOPLE ENGAGING WITH NHS/HSC  | Patients Carers  |
| CLINICAL TEAM IN NHS/HSC  | Allied health professions Nursing staff Medical staff  |
| INFORMATION TECHNOLOGY  | NHS/HSC IT Electronic record integration  |
| GATEKEEPERS IN NHS/HSC  | Service leads/managers Procurement managers  |
| INNOVATION IN NHS/HSC  | Service improvement leads,  Commercialisation leads,  People positioned to lead project  |
| REGULATORY MANAGERS/LEADS  | Information governance leads Data protection leads  |
| PEOPLE INVOLVED IN INTRODUCTION OF NEW TECHNOLOGY  | Digital technology developers Research and innovation/knowledge transfer,  Medicines and Healthcare Products Regulatory Agency  |

**6.1.1** **Inclusion criteria**

Individuals will be included if they are 18 years of age or over, one of the stakeholders indicated in 6.1 and have been involved in implementing/using one or more Digital Health Technologies, irrespective of outcome, in an NHS/HSC adult rehabilitation healthcare setting within the last five years. This includes individuals with experience developing, using or facilitating adoption of a DHT in rehabilitation.

**6.1.2** **Exclusion criteria**

Individuals who have experience of implementing DHT outside an NHS/HSC setting only. Individuals who, despite support, are unable to understand or communicate their needs sufficiently to provide a valid consent.

**6.2 Sampling**

This section provides information about sampling, further detail about recruitment is provided in section 6.3.

**NHS/HSC Staff**

Two types of non-probability sampling will be used in this study. Initially we will aim to recruit two participants from participating NHS/HSC Organisations, through purposive sampling (Kumar 1999, p. 162), from each stakeholder group (Table 1). This will be Phase 1 of the study.

These initial interviews will be transcribed and analysed using a constant comparison method. Based on the analysis of these Phase 1 interviews, gaps, and areas where clarification or further exploration is required will be identified. Phase 2 stakeholders will be sought based on this analysis.

In Phase 2, we will continue with purposive sampling. In addition, snowball sampling will be used to increase the breadth and size of the sample. Snowball sampling can be a useful technique where there is no list of potential participants, or where potential participants may be hard to reach. As both these challenges are anticipated in this study, we will employ an constant, with researchers making purposive decisions about which participants to recruit, based on the objectives of the study (Simkus 2022; Formplus 2022). Researchers will aim to recruit for maximum variation across the stakeholder groups, considering 1. the types of DHT that have been utilised; 2. the condition/s that the DHT seeks to impact; 3. people with different roles within each stakeholder group; 4. the types of organisations in which the DHT has been implemented. We will also aim to recruit stakeholders who were involved in DHT with variable outcomes to capture experiences of failed implementation, those who decided not to implement DHT in their service, immature and mature DHT implementation.

**Patients & carers**

Purposive sampling will be used to identify a range of potential patient participants. This purposive sampling will consider 1. the types of DHT that have been utilised; 2. the condition/s that the DHT sought to impact.

**People involved in introduction of new technology**

**Digital Health Technologies Developers:** Purposive sampling will be used to identify potential DHT developer participants with experience developing different types of DHT, for a range of settings/conditions within the NHS.

**Medicines and Healthcare Products Regulatory Agency:** it is not anticipated that there will be a large number of personnel from the MHRA who meet the inclusion criteria, so we will aim to include all who would like to participate.

**6.2.1 Size of sample**

Interviewing six people from each stakeholder category will lead to a total of 42 individuals. We anticipate that there will be some overlap in the codes and categories (themes) across the stakeholder groups, as this has been evident in previous studies (Brouns et al. 2018; Hochstenbach-Waelen and Seelen 2012; Yang, Waterson, and Eng 2021). We, therefore, estimate that this sample will provide sufficient data to reach an inductive thematic saturation, where no additional codes or  categories (themes) are being developed during the analysis (Saunders et al. 2018). The data collection and analysis methods (constant comparison) will allow for ongoing review of level of saturation. If further data collection is required, to reach an inductive thematic saturation, up to a maximum of 48 interviews will be undertaken.

**6.3****Recruitment**

This qualitative study will aim to collect a broad range of views. Researchers will, therefore, aim to reach a wide range of participants as described in 6.2.

**NHS/HSC Staff recruitment**

Following the identification of minimum six and maximum eight Trusts as described in 6.2, the Local Collaborator at each Trust will promote the study within their Trust. they will forward the details of the study to individuals and groups they feel may be interested, using the recruitment poster (Appendix 7), email (Appendix 8a) and verbal communications.

**NHS/HSC Staff participant recommendation (snowballing):** Each participant will be asked to consider if there is anyone else in their organisation, or whom they know, from any of the stakeholder groups that may be prepared to participate in the study, and where this is the case, to provide them with information about the study. Researchers may provide details about who they are purposively seeking (see section 6.2). For example, where all previous participants have experience of a DHT that was successfully implemented, researchers would ask previous participants to consider contacting individuals with experience of a DHT which was not implemented, or where implementation was partial.

The UCLan researcher will make it clear that finding others is not a requirement of participating in the study. This will be clearly articulated in the Participant Information Sheet and Consent Form Appendices 2 and 4a, b.

**Patient and carer recruitment**

We will list the study on the Be Part of Research (<https://bepartofresearch.nihr.ac.uk/>), Research for the Future (<https://www.researchforthefuture.org/>) and SHARE (The Scottish Health Research Register and Biobank - <https://www.registerforshare.org/>) registries (further information that Be Part of Research and Research for the Future requested be included in ethical approval process is provided in Appendices 18 to 21). The study will be promoted through the usual channels of these registries. We will also use social media such as Twitter to publicise the study and seek patient and carer participants.

We will use a range of resources to support this activity (Appendices 7 and 9).

**People involved in introduction of new technology**

**DHT developers:** professional contacts and social media such as Twitter and Linkedin will be utilised to publicise the study and seek DHT developer participants. We will use a range of resources to support this activity for example (Appendices 7, 8b and 9). As the study progresses, researchers may need to add details to these resources to indicate who they are purposively seeking to recruit to ensure a range of DHT developers are included in the study.

**Medicines and Healthcare Products Regulatory Agency:** we will be contact directly by email (Appendix 8c)

**Processes for all staff, patient and carer recruitment**

Individuals responding to the invitation to find out more about participating in the study will be contacted by a UCLan researcher. They will be sent an email (Appendix 10) (or letter if email is not available) inviting participation in the study and a Participant Information Sheet (Appendix 2). At this time, the researcher will ask the potential participant to confirm that they meet the eligibility criteria and provide an opportunity to ask questions. Where further information is sought by the potential participant, Additional Participant Information Sheet (Appendix 3) will be provided.

It is anticipated that this communication will take place by email, but if a potential participant requests a further / more detailed conversation, then this will be arranged via Microsoft Teams or by telephone based on potential participant’s preference. The individual will then be given at least 24 hours to decide if they would like to participate. A UCLan researcher will follow-up the invite by email or telephone within two weeks of the provision of this information.

It is possible that more people indicate an interest in participating than it is possible to recruit to the study, for example where a large number of people from one stakeholder group wish to participate. Where it is not possible to include an individual in the study they will be contacted by email (or post if email is not available) to thank them for their interest in the study and explain why they have not been contacted to be part of the study. An example of this correspondence is provided in Appendix 11.

It is anticipated that the majority of interviews and focus groups will take place either online (using MS Teams) or telephone. It is not anticipated that participants will incur personal financial costs by participating in this study. If a face-to-face interview is required, the interviewer will travel to the participant’s choice of venue for the interview, so that costs are incurred by the research team not the participant.

**6.3.2 Consent**

As indicated above, individuals indicating that they would like to participate will be provided with a written Participant Information Sheet (see Appendix 2), given an opportunity to ask questions and, if they choose to participate, asked to complete a consent process. The written Participant Information Sheet will be provided in an audio-format if this is more accessible to a participant.

To enable all individuals who want to participate to complete the consent process, theConsent Form (Appendices 4 a and b (all stakeholders except patients and carers) and 4c and d (patients and carers); appendices 4c and d include a required statement from Be Part of Research) may be completed online via a Microsoft Form. Alternatively, provision can be made to undertake and record consent procedures verbally through Microsoft Teams following UCLan’s Remote Research Guidelines (<https://www.uclan.ac.uk/students/support/research/ethics.php>). If required a consent form can be posted to a potential participant.

Consent for face-to-face interviews may be completed online, on paper or be audio-recorded on an encrypted digital recorder to suit the participant’s needs.

If verbal consent is being recorded, the researcher will read out the consent statements and ask the participants to verbalise their agreement to each, recording the names of both parties and the date. The consent recording will be kept separate from the main interview recording / transcript following the process outlined below for the interview recording and linked via participant PIN.

The researcher undertaking the consent process will have training and experience in this activity. They will ensure all participants understand what the research involves.

An accessible Participant Information Sheet and Consent Form are available (Appendices 12 and 13) to support those with a communication difficulty decide if they would like to participate in the study. These documents use images to reduce reliance on words. If a participant has difficulty expressing their consent, the consent will be witnessed by an individual of the participant’s choosing. Translators will be sought for individuals who require this support and wish to participate.

Potential participants will have responded to a request for study participants and chosen to engage with the researchers. Capacity to consent will be assumed in line with the five principles of the Mental Capacity Act (Department of Health 2005). If the research process indicates that an individual cannot understand information given to them; retain the information long enough to be able to make the decision; weigh up the information available to make the decision; or communicate their decision, a researcher will discuss their concerns with the individual. All efforts will be made to provide the support required to enable the individual to participate in the study if this is their wish. If this is not possible, the individual will be withdrawn from the study and the need to do this will be explained to the individual.

**7  STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS** (please note  Appendices are numbered in relation to IRAS Form and may appear out of order in this protocol)

**7.1 Study Design**

This study is a qualitative exploration of stakeholder experience and to develop our understanding of the factors that contribute to the use and non-use of DHT. The study is underpinned by a social constructionist perspective. The researchers recognise the importance of social interactions as the foundations of learning when deciding to implement and use DHT (Andrews 2012; Robson 2011, p.8). This stance has informed the recruitment strategy, sampling method, data collection and analysis methods, as the study aims to explore the participants constructed learning in relation to implementing DHT. Data collection has been shaped by the constructs within the Normalisation Process Theory, with questions that seek to collect data about how an DHT was normalised into practice, or where this did not happen, the barriers to this process.

Qualitative data will be collected from individual interviews or, where there are individuals within a single stakeholder group that are able to participate at the same time, a focus group.

**7.2 Data collection**

All participants will be invited to complete a Contextual Information Survey and to participate in one interview or focus group.

**7.2.1 Contextual Information Survey**

Participants will be sent a link and invited to complete a Qualtrics Survey data collection tool (Contextual Information Survey-Appendix 5) to collect the following information: 1. PIN; 2. age group; 3. gender; 4. ethnicity. This information will be used to describe the sample in this study. Participants will also be asked to record their perception of themselves as high/low users of technology? If a link is not accessible to a participant, a version can be emailed or posted, depending on the participant’s preference, or the responses can be audio-recorded using an encrypted digital recorder or through Microsoft Teams.

1. **Interview**

Interviews will last up to 60 minutes. The semi-structured schedule (Appendix 6) is underpinned by the NPT theory and will explore Digital Health Technologies in respect to coherence (sense-making); cognitive participation (engagement); collective action (work done to enable the intervention); and reflexive monitoring (appraisal of the intervention). This schedule will provide a framework for the interviews; it may be adapted in response to individuals and on-going data analysis. This interview schedule was piloted as part of an evaluation of a Digital Health Technology (Neurorehabilitation On-Line [NROL]).

The interviews will be undertaken by an UCLan researcher who will also be a registered allied health professional with experience of working with people with complex communication needs. If a participant’s speech has been affected, for example by stroke, strategies will be used to facilitate communication, as guided by the participant. This may include using supporting equipment, alternate methods, or support from another person.

It is anticipated that these interviews will be conducted securely online through Microsoft Teams, using either audio and video, or just audio, depending on participant preference. The consent process and interviews will be conducted in accordance with UCLan’s Remote Research Guidelines (<https://www.uclan.ac.uk/students/support/research/ethics.php>).

Face-to-face interviews will be considered if there is a reason to believe that this will lead to a more effective or efficient data collection process and infection control measures allow this approach. Face-to-face interviews will be recorded on an encrypted digital recorder supplied by UCLan and transferred and stored as described in section 7.2.4. The interviewer will travel to the participant’s choice of venue for the interview, so that costs are incurred by the research team not the participant.

Recordings, along with any field notes made during the interviews, will be stored as described in section 7.2.4.

With consent, the interviewer will be able to see the participant during the interview and know the participant’s first / chosen name. Any identifiers will be removed from the data at the first possible opportunity. The data will be stored in a pseudonymised form and the files with identifiers will be permanently deleted.

1. **Focus group**

Where there are a group of stakeholders a focus group discussion may be offered. This will last no more than 90 minutes. It will be co-facilitated by two UCLan researchers. The facilitator will use the piloted semi-structured schedule described in 7.2.1 (Appendix 6). This schedule will provide a framework for the focus groups; it may be adapted in response to individuals involved in the group and on-going data analysis.

If infection control measures and research partner protocols for COVID-19 enable face-to-face focus groups, these will be considered if there is a reason to believe that this will lead to a more effective or efficient data collection process. They will be recorded on an encrypted digital recorder supplied by UCLan and transferred and stored as in section 7.2.4.

However, it is anticipated that the focus groups will be conducted online through Microsoft Teams, using video recording, in accordance with UCLan’s Remote Research Guidelines (<https://www.uclan.ac.uk/students/support/research/ethics.php>). Video recording will be used to capture non-verbal communication within the focus group to allow reflection on possible effects such as conformity and censoring which may occur in a focus group (Asbury 1995; Sim and Wright 2000, p.58).

The recordings will be stored along with any field notes made during the focus group, pseudonymised by using PINs, as described in section 7.2.4.

The facilitator and co-facilitator will see the participants and know the participants’ first / chosen names during the focus group. Any identifiers will be removed from the data at the first possible opportunity. The data will be stored in a pseudonymised form and the files with identifiers permanently deleted.



Figure 1 – Srotocol summary

1. **Anonymisation, transfer, storage and destruction**

To enable pseudonymisation of the data files, following consent, participants will be allocated a personal identification number (PIN). This will be allocated by the University of Central Lancashire (UCLan) researcher for use in all relevant file names. The ‘key’ document containing the participant’s name, contact details (email and/or phone number) and PIN (Appendix 14) will be stored in a password protected file which will be stored separately to all other data collection files. This ‘key’ document will be stored on the UCLan Office 365 OneDrive.

The ‘key’ will only be accessible to the UCLan researchers involved in the study, to enable de-anonymisation if necessary.

All data collected will be identified only by the participant’s PIN.

The interview data collected through Microsoft Teams (interview/focus group audio/video recordings) will be downloaded immediately to the secure Office 365 OneDrive storage of a named member of the UCLan DARE research team, and deleted from Microsoft Stream and Microsoft Teams.

Where the data has been collected using an encrypted portable audio-recording device or video camera, the recording will be deleted from the recording device as soon as this data has been transferred to the UCLan Office 365 OneDrive server.

Where data has been collected using the Qualtrics Survey Platform (Contextual Information Survey), the pseudonymised data is stored within Qualtrics Survey Platform. This is a GDPR compliant, UCLan approved, web-based survey platform (<https://www.qualtrics.com/support/survey-platform/getting-started/data-protection-privacy/>). Data is held in a UCLan account, only accessible to specified members of the UCLan DARE research team via password. This data will be analysed in the Qualtrics Survey Platform initially and then transferred to Office 365 OneDrive. Once the data and analysis has been moved to Office 365 OneDrive, they will be deleted from the Qualtrics Survey Platform.

Data collected on through Microsoft Forms (e.g. Staff consent forms) will be downloaded immediately to the secure Office 365 OneDrive storage of a named member of the UCLan DARE research team.

Once data has been analysed and anonymised, the subsequent anonymised reports and analyses will, additionally, be stored on the Faculty of Health & Care dedicated shared drive on the University network for research staff. Each project has a dedicated and individualized folder on the shared drive, which is only accessible, via UCLan password login, to the named research staff on that project. Changes to access must be approved and actioned by named senior research administrators for added security.

Using Office 365 OneDrive will reduce the need for data transfer. However, if there is a need to transfer any data this will be completed through a secure, password protected file transfer.

In line with UCLan policy all the data collected for this study will be kept for seven years (unless specified otherwise), after which they will be securely and permanently deleted.

1. **Data Analysis**

All analyses and associated documents will be held on the secure UCLan Office 365 OneDrive server. In line with UCLan data protection policy, the analyses and associated documents will be stored for seven years after the end of the study (31st October 2023), after which they will be securely and permanently deleted.

**7.3.1 Contextual Information Survey**

Data from Contextual Information Survey will be nominal and ordinal. Descriptive analysis will be undertaken by the UCLan DARE research team.

**7.3.2 Interviews and focus groups**

The interviews and focus groups will be transcribed verbatim. Where interviews have been undertaken using Microsoft Teams, the transcription within the programme will be checked and amended to ensure an accurate transcription. Audio-recordings and video-recordings from face-to-face interviews and focus groups will be transcribed by members of the UCLan research team supported by in-house automated transcription service.

Constant comparison is a data analysis method that enables researchers to analyse and reflect on the initial data they have collected (in Phase 1) and utilise this analysis to identify areas that require further exploration.

As there are a range of stakeholders in our study and the aim is to develop a comprehensive understanding of the factors influencing the use and implementation of DHT, the constant comparison method will enable the building of a detailed picture of this topic and ensure that a range of stakeholder settings and experiences are captured.

As established in section 6.2, the aim in Phase 1 will be to recruit two individuals from each of the seven groups identified in Table 1. Each interview discussion will be analysed sequentially. With consent as described in 6.3.2, the data collected during the pilot of the interview schedule, collected as part of an evaluation of a DHT (Neurorehabilitation On-Line [ NROL]) and meeting governance requirements for that evaluation, will be included in Phase 1.

Researchers will familiarise themselves with the data using the audio recordings, and transcriptions. Two researchers will independently analyse each of the Phase 1 interviews. For the first interview, codes will be developed and these organised into categories (themes). These will then be discussed and agreed. Data from each subsequent interview will be independently coded and compared to the previous categories (themes). Following discussion, codes and categories will be integrated with the previously identified codes and categories.

Once the Phase 1 interviews and analysis are complete, the research team will meet to reflect on the emerging findings. Areas that require further exploration will be agreed and efforts will be made to recruit participants to inform a comprehensive exploration. The aim of this study is not to develop a theory, so the sampling method could not be described as theoretical sampling where the focus would be to ensure the theory is ‘complete’ (Draucker et al. 2007), instead the aim is to gain a comprehensive understanding of the factors that influence use and implementation of DHT. The sampling strategy will enable the researchers to recruit stakeholders who may be able to provide a deeper understanding of the aspects that warrant further exploration.

The codes and categories agreed in Phase 1 will be used by one researcher to code, categorise and integrate data from the interviews in Phase 2 through an ongoing constant comparison.

Researchers will keep an anonymised reflexive journal, field notes and an audit trail of decisions. NVivo qualitative data analysis software will support management, analysis, and retrieval of the data.

**8 ETHICAL AND REGULATORY CONSIDERATIONS**

**Dignity of participants:**

Dignity will be preserved throughout the data collection process. Interviews will be within the control and at a time that is convenient to the participant. Where a focus group discussion is planned, researchers will aim to arrange this at a time convenient to all participants.

During interviews and focus group discussions, participants will be invited to describe their experience and perceptions of implementing DHT into rehabilitation. The researchers collecting the data will be trained in interviewing and conducting focus group discussions and will use high-level communication skills e.g. active listening, reflection and reframing to facilitate the discussion and enable the participants to articulate their thoughts.

**8.1** **Assessment and management of risk**

**Vulnerable participants**

The majority of participants would not be considered vulnerable, but where a patient or carer participant prefers to be accompanied by someone of their choice for the interview or focus group this will be arranged.

**Risks to security of data stored on DARE**

There is risk of loss of data, stolen data, breach of data from UCLan One Drive, Qualtrics Survey Platform where the study data will be stored. To reduce this risk, PIN numbers allocated to participants staff will be used on all data collection documents, thereby pseudonymising data. The data will be available only to the UCLan DARE research team. Usernames and Passwords will ensure controlled access. Access will only be permitted to trained staff.

**Risk of low recruitment**

There is a risk that recruitment will be low. This has been addressed by a range of recruitment strategies that give variety in approaches to support recruitment. If the planned number of participants are not recruited the study will continue to be of value due to the qualitative nature of that data being collected. Insights into the implementation of DHT will be gained even if the participant number is lower than expected.

**Time**

There is the risk that the interview/focus group may take time that participants would otherwise spend undertaking other duties. Interviews will be within the control and at a time that is convenient to the participant. Where a focus group discussion is planned, researchers will aim to arrange this at a time convenient to all participants.

**Identification of a service user or staff participant in reports/publications**

As there will be a small number of participants from each stakeholder group, particular care will be taken in publications or presentations to maintain the anonymity of all participants. In addition to anonymisation of a participant’s personal information, consideration will be given to whether concealment of the specifics of the DHT, and the role of the participant are also necessary to avoid identification.

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

Before the start of the study, a favourable opinion will be required from the UCLan Research Ethics Service.

The following will be adhered to:

* Substantial amendments that require review by UCLan REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
* All correspondence with the UCLan REC will be retained.
* It is the Chief Investigator’s responsibility to produce the annual reports as required.
* The Chief Investigator will notify the REC of the end of the study (completion of all data collection and analysis)
* An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
* If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
* Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications / abstracts, to the REC.

**Regulatory Review & Compliance**

The Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place prior to the recruitment of any participants. This study will require both Health Research Authority and UClan Research Ethics Service approval.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will agree whether the amendment is substantial or non-substantial and submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS/HSC sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as [amended](http://www.hra.nhs.uk/resources/after-you-apply/amendments/).

**Amendments**

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor’s responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments will be communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site.

Once agreed the amended documents will be held in the study file with the new version clearly stated. All members of the DARE research team will be advised of the changes.

**8.3 Peer review**

The protocol has been reviewed by members of the RUAG group and will be scrutinised by internal reviewers as part of the University Sponsorship processes.

**8.4 Patient & Public Involvement**

A Rehabilitation-user Advisory group (RUAG) was formed to develop the protocol for this research.

Initially to consider the acceptability and importance of this study. Subsequently to shape the design of the study. A member of the RUAG will be a member of the Study Steering Group. This will ensure that there is PPIE oversight of the management of the study throughout the full project timeline.

The RUAG group will have opportunity to:

* Engage with UCLan researchers in discussions about the study aims and objectives and the approach to ensure their achievement.
* Identify stakeholder groups for the study
* Be involved in developing tool/s to collect the views of stakeholders in order to meet the study aim and objectives.
* Review the study protocol and providing guidance to develop this document

**8.5** **Protocol compliance**

All efforts will be made to ensure protocol compliance through training and mentoring. It is recognised that accidental protocol deviations can happen at any time. If there are deviations from the protocol, these will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor for appropriate response.

**8.6** **Data protection and patient confidentiality**

The arrangements to address service user confidentiality and the appropriate management (collection, storage, processing and disclosure) of personal information will meet the General Data Protection Regulation (2018).

All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2018) in regard to the collection, storage, processing and disclosure of personal information and will uphold the Guidelines’ core principles

These processes have been described in detail in sections 6 and 7 of the protocol.

The data custodian is: RStockley1@uclan.ac.uk

**8.7 Indemnity**

Insurance / indemnity from Sponsor will cover:

1. The potential legal liability of the sponsor for harm to participants arising from the management of the research
2. The potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research

The NHS indemnity scheme will provide cover in respect to:

1. The potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research.

**8.8** **Access to the final study dataset**

The research team at UCLan will have access to the final study dataset. The Study Steering Committee will also have access to anonymised and analysed data.

**9 DISSEMINIATION POLICY**

**9.1 Dissemination policy**

The responsibility for the data collected from this study will lie with UCLan. On completion of the study, the data will be analysed, and a Final Study Report prepared. All efforts will be made to publish the findings from this study, which will ensure the report is available in a peer-reviewed journal. It will be possible to access the Executive Summary of the full study report by contacting the Chief Investigator. It will also be stored on the University of Central Lancashire Online Knowledge (CLoK) web-pages, to enable open access.

Funders, and others supporting the study will be acknowledged in any reports.

At debrief, at the participant’s ‘end of the study’ (i.e. following completion of the interview/focus group), participants will be advised how they can access the Executive Summary of the final report (Appendix 15).

**9.2 Authorship eligibility guidelines and any intended use of professional writers**

Authorship of any publications arising from the Research Project will be decided in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines on the authorship of medical publications (International Committee of Medical Journal Editors 2021). In line with these International Author Guidelines, authorship will be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work an author has undertaken themselves, an author will be able to identify which co-authors are responsible for specific other parts of the work. Each author will have confidence in the integrity of the contributions of their co-authors.

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