# Project Protocol: Home rehabilitation for people with COVID-19: Implementing telehealth approaches to care

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| **Project Title:** **Home rehabilitation for people with COVID-19: Implementing telehealth approaches to care** |

**Project team roles and responsibilities of investigators and other key project team members.**

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| Name: **Professor Maria Crotty** | |
| Institutional affiliation: Flinders Medical Centre | |
| What is the position of this person on the research project? Principle Investigator | |
| What are the research activities this person will be responsible for: Oversight of all aspects of the research. | |
| Department and department address: Division of Rehabilitation, Aged and Palliative Care; Flinders Medical Centre, Flinders Dr, Bedford Park SA 5042 | |
| Contact details: a Health or University email address is preferred | Phone: 084042232  Email: Maria.Crotty@sa.gov.au |
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| Name: **Dr Miia Rahja** | |
| Institutional affiliation: Flinders University | |
| What is the position of this person on the research project? Investigator | |
| What are the research activities this person will be responsible for: Co-design and implementation of research methods and writing of research documents | |
| Department and department address: Flinders University College of Medicine and Public Health. Division of Rehabilitation, Aged and Palliative Care; Flinders Medical Centre, Flinders Dr, Bedford Park SA 5042 | |
| Contact details: a Health or University email address must be used  I am the contact person for this project | Phone: 7221 8344  Email: miia.rahja@flinders.edu.au |
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| Name: **A/Prof Kate Laver** | |
| Institutional affiliation: Flinders University | |
| What is the position of this person on the research project? Investigator | |
| What are the research activities this person will be responsible for: Co-design and implementation of research methods and writing of research documents | |
| Department and department address: Flinders University College of Medicine and Public Health. Division of Rehabilitation, Aged and Palliative Care; Flinders Medical Centre, Flinders Dr, Bedford Park SA 5042 | |
| Contact details: a Health or University email address must be used  I am the contact person for this project | Phone: 7221 8335  Email: kate.laver@flinders.edu.au |

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| Name: **Dr Kisani Manuel** | |
| Institutional affiliation: Flinders Medical Centre | |
| What is the position of this person on the research project? Investigator | |
| What are the research activities this person will be responsible for: Engaging division staff in research program, collecting and analysing data, writing research documents | |
| Department and department address: Division of Rehabilitation, Aged and Palliative Care; Flinders Medical Centre, Flinders Dr, Bedford Park SA 5042 | |
| Contact details: a Health or University email address must be used  I am the contact person for this project | Phone: 7221 8344  Email: kisani.manuel@sa.gov.au |

**Resources**

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| **What resources are necessary for the project to be conducted?**   * In kind support from the SALHN ambulatory rehabilitation services to assist with identifying patients who may be eligible and seeking verbal consent for them to be contacted by a researcher. * Research rehabilitation therapist who will provide the intervention to those allocated to the intervention group (funded with research funds) * Computer access to electronic inpatient records (ePAS/Sunrise, and Australasian Rehabilitation Outcomes Centre (AROC)). * Access to telehealth modalities such as webcam, microphone and/or headsets which are already available. * Tablets/iPads or smart mobile phones (for research therapist and if required by participants). The division currently has 14 to use for those in the intervention group. Those in the control group will use existing items owned by SALHN. * Online communication platform; WebEx is supported by SA Health. * Statistical software i.e. IBM SPSS, and/or Stata. * SALHN employed (research) staff to identify potential participants, consent to approach from research staff and share routinely collected data. * Document storage as per policy and act described in section ‘Data Management’ of this document. |
| **Please declare what funding support and amount is being sought or has been secured for this project:**  Nil although we have applied for a grant of approximately $50,000 through the Flinders Health and Medical Research Institute special funding round for COVID-19 research. |

**Background**

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| **Hypothesis - What is the scientifically valid research question being asked?**  Is a telerehabilitation program focussed on enhancing participation in usual activities and delivered in a virtual group format more effective and efficient than a traditional telerehabilitation program which is focussed predominantly on improving physical function? |
| **Aims - What do the investigators intend to achieve with this research project?**  The primary aim of this study is to evaluate the efficacy and efficiency of two telerehabilitation interventions:  1) traditional model which is predominantly focuses on improving physical function and is currently offered as usual care by the home rehabilitation service:  2) a rehabilitation intervention which focuses more on participation in usual activities and is offered via a coaching model to a virtual group of people.  Both interventions are provided in a telehealth format as a response to the global pandemic, COVID-19. Table 1 below sets out the content of each intervention.  The purpose of this study is to determine whether the novel intervention is more effective as well as if it is more efficient (as it is offered in a virtual group format so the therapist is able to reach more people in the same amount of time).  Table 1 - Intervention characteristics   |  |  | | --- | --- | | **Standard care  Multidisciplinary telerehabilitation program** | **Experimental care  Participation focussed telerehabilitation program designed to offer evidence-based intervention to a larger number of people at one time** | | * Patient goals identified with therapist (1:1) * Input as required from physiotherapist, occupational therapist and allied health assistants * Telehealth consultations focussed on improving physical function through exercise and modifying activities of daily living to enhance independence | * Patient goals identified with therapist (1:1) * Virtual groups (4participants per session) with physiotherapist and occupational therapists which focus on increasing participation in life roles and usual activities. Groups adopt a coaching model and utilises motivational interviewing methods where the therapist talks about common challenges, facilitates discussion and sharing of experiences and ideas and the group brainstorm and plan next steps together. | |
| **Objectives** - **How will investigators achieve the aims of the research project?** The objectives of this study are:   * To test the efficacy of a novel telehealth intervention on the primary outcome of return to usual activities. * To identify the costs of providing each model of care as well as the economic outcomes |
| **Expected outcomes**  We expect to be able to describe the activity and participation outcomes of people receiving two different models of telerehabilitation for individuals confirmed with COVID-19 receiving home rehabilitation services. |
| **Rationale / justification**  Our health sector is under incredible pressure due to the COVID-19 pandemic (World Health Organization, 2020).The pandemic will create an increase in the number of people requiring acute care. People admitted to acute care during this time are expected to be discharged quickly. Even short illnesses can result in significant deconditioning and rehabilitation is recommended. People who are already frail are at great risk of experiencing long periods of reduced independence.  No one knows how long this pandemic will last and currently there are no vaccines or treatments for COVID-19. The environment in which we deliver health and rehabilitation services has changed. Infection control, people working from home and scarce resources, means there is a rapid move towards telehealth which is strongly supported by the Government. As a response, the Division of Rehabilitation, Aged and Palliative Care at Flinders Medical Centre is adapting home rehabilitation supports for individuals with confirmed COVID-19 via telehealth approaches. This study seeks to evaluate two telerehabilitation interventions that have been adjusted from standard care provision in response to the COVID-19 pandemic. |
| **Literature review**  Public health emergencies, such as the outbreak of COVID-19, are stressful times for people and communities (Centers for Disease Control and Prevention, 2020). Health services are stretched, and healthcare workers worldwide are strained. There is pressure for healthcare workers from the burden of the illness (and other illnesses) that stresses the health system’s capacity. There is also the risk of infection on healthcare workers treating confirmed COVID-19 carriers. They (healthcare workers) are expected to implement appropriate infection control precautions when assessing and managing suspected and/or confirmed COVID-19 cases, as well as consider options that may reduce risk and harm.  Telehealth is the use of technology and telecommunication systems to deliver healthcare from a distance, and is accessible to healthcare providers and users (Meskó, Drobni, Bényei, Gergely, & Győrffy, 2017). In general, telehealth involves monitoring of disease-specific symptoms to prompt feedback on treatment and advice, providing treatment advice, providing education and/or advice on self-management, facilitating specialist consultations, and enabling consultations with healthcare professionals from a distance (Meskó et al., 2017). Approximately two thirds of studies that have examined telehealth interventions have found that these interventions were less costly and equally effective as non-telehealth alternatives (Wade, Karnon, Elshaug, & Hiller, 2010). Studies have also demonstrated the feasibility of delivering telehealth intervention to frail older people living at home (Banbury et al., 2014) as well as for people with limited digital literacy (Banbury, Nancarrow, Dart, Gray, & Parkinson, 2018). Advances in technology also means that videoconferencing can now be achieved using readily available smartphones, tablets and computers, and software. This may be used to complement other forms of communication such as email and telephone use. As such, telehealth has been well accepted and little concern has been raised over privacy issues (Banbury et al., 2018). Although with only a few studies, telehealth groups have also been found to result in similar treatment outcomes to in-person groups (Gentry, Lapid, Clark, & Rummans, 2019), and appear to improve mental health outcomes (Banbury et al., 2018).  The COVID-19 pandemic is expected to create an increase in the number of people requiring acute care. Following illness, people become deconditioned, and rehabilitation is recommended. However, new models of care are urgently required. Thus, as a response to the COVID-19 pandemic, and the need to provide rehabilitation services for people confirmed with COVID-19, the division of Rehabilitation, Aged and Palliative care at Flinders Medical Centre is trialling two models of home rehabilitation supports for individuals with confirmed COVID-19 via telehealth approaches. The first model is the traditional model (offered via telehealth) and the second model is focussed on return to activity and participation and also offered via telehealth with a focus on motivational interviewing and coaching from therapists and peer support. The format follows a standard multidisciplinary approach to rehabilitation and Table 2 below outlines the format in more detail.  Table 2 - Format of the experimental care intervention   |  |  | | --- | --- | | Session | Content | | 1 | Introduce participants to other peer members of the group (up to 4 people per group) and sharing of stories and what participants want to get out of the program  Occupational therapist shares information about recovering from illness and principles of rehabilitation (e.g. setting and working towards concrete goals, celebrating successes, gaining support from networks, weekly planning, recognising that recovery takes time, prioritising mental health and physical health) | | 2 | Physiotherapist provides information about recovering physically and how participants can gradually resume their normal activities and participation in life roles | | 3-8 | Motivational interviewing group sessions led by physiotherapist or occupational therapist  The focus of each session is on identifying progress and goals achieved, discussing new challenges and collaboratively determining strategies to overcome these challenges.  Goals for each participant will be reviewed and activities to work on between each session will occur. |   The purpose of this study is to determine whether the novel intervention is more effective as well as if it is more efficient than the standard rehabilitation intervention. |

**Project design**

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| **Research project setting -** The study will take place in the Southern Adelaide Local Health Service and link with the Home Rehabilitation Service provided by the Division of Rehabilitation, Aged and Palliative Care division.  Participants may be referred to the Home Rehabilitation Service from several different sources within the SALHN such as general medicine and respiratory care as well as new wards which may be established to meet the demand. |
| **Methodological approach - Rationale for choices of methods that are tied back to the aims/objectives:**  We will conduct a randomised controlled trial to answer our research questions about efficacy and efficiency.  The trial will use a Zelen single consent model to randomisation and recruitment. This approach is a variation of randomised controlled trials in that participants are pre-randomised to groups, that is, participants are assigned at random to an experimental treatment or to the best standard treatment. Those allocated to standard care group will automatically be included in research and an opt out consent will apply. Consent will be sought for those allocated to the experimental treatment. Those participants who are randomized to the experimental treatment group, but who do not consent to be in the treatment, receive the standard treatment (Zelen, 1979). Figure 1 depicts the process of single consent Zelen randomisation.    Figure 1 - Process of single consent Zelen randomisation  Given the state of urgency of the current pandemic, we chose this approach as we consider it the most ethical and appropriate approach for answering the research question. In a Zelen design, participants who are allocated to the experimental group are approached for consent will know that they can receive the new treatment. This is advantageous as the participants know which treatment will be given before providing consent (Zelen, 1979). The consent process is simplified, and the participants are more likely to have a better understanding of the intervention to which they are consenting. Full consent prior to randomization can run the risk of discouragement within the standard care group, potentially increasing the rate of noncompliance with rehabilitation. Hawthorne effects, that is, participants changing their behaviour as a result of knowing they are being observed, may also occur in conventional randomised trials (but is more avoidable using the Zelen approach). As such, the use of a Zelen design reduces biases and potential negative outcomes. It also allows for a trial that more closely replicates anticipated procedures in usual clinical practice. Thus, this approach can improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research in this urgent time.  ***Standard care arm*** For participants in the standard care arm (following randomisation), an opt -out consent process will apply.  As per National Statement 2.3.6: a) the study data collected is the combination of routine data, thus carrying no more risk to participants than standard care; b) the proposed study will better define rehabilitation-related issues during pandemics such as the COVID-19 and answer subsequent treatment questions; c) our ability to do so is improved with every extra person's information. However, the requirement for explicit consent would compromise the necessary level of participation; d) we will be using an opt-out consent process which provides all prospective participants with appropriate plain language information explaining the nature of the information to be collected, the purpose of collecting it, and the option to decline participation or withdraw from the research; e) & f) the study provides participants the mechanism to decline participation at any time; g) the study data is managed and maintained as per relevant SA Health security standards; h) the study is governed by the appropriate process specifying responsibility for the project and appropriate management of the data as per the SSA; and i) the opt-out approach is not prohibited for this purpose.  ***Experimental care arm***  Participants in the experimental care arm (following randomisation), will be asked for informed consent for the study. Participant Information and Consent Form attached to this application. |
| **What are your outcome measures?**  Primary outcome measure:   * The Reintegration to Normal Living Index (RNLI) - A 11-item questionnaire-based instrument that measures the degree to which individuals who have experienced traumatic or incapacitating illness achieve reintegration into normal social activities (such as recreation, movement in the community, and interaction in family or other relationships) (Wood-Dauphinee, Opzoomer, Williams, Marchand, & Spitzer, 1988). This can be administered over the phone.   Other outcome measures used:   * FRAIL scale –A five-question test that can increase the identification of frailty without a face-to-face examination (Morley, Malmstrom, & Miller, 2012). * EQ-5D – a five-dimensional questionnaire that is widely used for measuring health-related quality of life for the estimation of quality-adjusted life years within economic evaluations (Dolan, Gudex, Kind, & Williams, 1996) * Functional outcomes as measured using routinely collected data by the Australasian Rehabilitation Outcomes Centre (AROC) within the setting (i.e. Functional Independence Measure; FIM) * Average cost of services/intervention delivered per participant, calculated based on the purchase price of telehealth hardware and therapist time for each client (including set up time). * Adverse events * Readmissions   All data can be accessed via existing databases or over the phone |
| **Project duration:** Up to 18 months and depending on nature of the pandemic |

**Participant selection and activities**

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| **How many participants will be selected for the study?**  Based on the Australian study published by Fairhall, Sherrington, Kurrle, Lord, and Cameron (2011) which reported data on 181 frail older people who completed the Reintegration to Normal Living Index (RNLI) we have calculated a sample size of 52 participants (26 per group). This is based on a mean of 22.2 and standard deviation of 4.31 in recently discharged frail older adults with alpha 0.05 and power at 80%. We will allow for 10% drop out and therefore ***we will recruit 58 participants.*** |
| **How will participants be recruited into the study?** The below outlines the recruitment and participant engagement procedures. Figure 1 (above) further depicts the recruitment process.   * A person is referred to the Division’s Home Rehabilitation Services and they have been confirmed with COVID-19 (shown in patient records). * The person is randomised to standard or experimental care using the approach described by Zelen (1979) * Participant has a phone meeting with the therapist who will discuss and create individualised rehabilitation goals as per usual practice.   Baseline data is collected:   * + RNLI, FRAIL scale, EQ-5D, Functional status (measured using the Functional Independence Measure (FIM) listed in AROC) * For participants who have been randomised to the experimental group, the therapist will also discuss the intervention with the participants and obtain consent to participate. * Participants will receive their assigned telerehabilitation intervention (for up to 4 weeks) as per the study/division protocol. * Follow up phone call is made at 3 months post baseline to all participants.   + RNLI, FRAIL scale, EQ-5D, Functional status (measured using the Functional Independence Measure (FIM) listed in AROC * Review of hospital records at 12 months to check for readmissions. * Analysis and evaluation   *Standard care:*  It will be the responsibility of the division of rehabilitation to ensure that opt-out consent information is provided to all patients assigned to the standard care arm as early as possible after their referral.  *Experimental care:*  It will be also the responsibility of the therapist to ensure that consent is received from patients assigned to the experimental group.  ***For participants with capacity to consent (likely majority of participants)*** *Standard care*: The participants are made aware at time of entering the home rehabilitation service that their detail will be included in the study unless they choose to opt-out. They will be provided with forms related to the study detail (attached to this application) and the forms will include all detail they will need to know about how to ask further questions, and opt-out, as well as how to lodge complaint through an independent complaints process.  *Experimental care:*  It will be the responsibility of the therapist to ensure that consent is received from patients assigned to the experimental group. They will speak with the potential participants and ask if they would be willing to take part in the study and receive the experimental intervention. If agreeable, the potential participant will be provided with the participant information sheet /consent form and go through all details of the form.  ***Participants with limited or without capacity to consent (likely minority of participants)*** *Standard care*: It is expected that participants without the capacity to consent will have their rehabilitation needs communicated with somebody, referred to as ‘person responsible’ or ‘authorised representative’. In such occasion, at time of entering the home rehabilitation service, the representative is made aware that the participant’s detail will be included in the study unless they choose to opt-out. they will be provided written detail about the study, and the forms will include all detail they (and the participant) will need to know about how to ask further questions, opt-out, as well as how to lodge complaint through an independent complaints process.  *Experimental care:* As above, it is expected that participants without the capacity to consent will have their rehabilitation needs communicated with somebody, referred to as ‘person responsible’ or ‘authorised representative’. In such occasion, the therapist will explain the nature of the study and answer any related questions to the prospective participant’s representative. The representative is made aware that the participant’s detail will be only be included in the study if they consent to the experimental intervention.  Consent (for experimental care) will also be documented in the participant’s electronic records as recommended by the Health Care Act 2008. Documentation will include the study title, researcher’s name, and contact details. The following statement will also be documented: “I have obtained consent from the potential participant to be involved in this research project”; followed by the researcher's signature and date.  **How are they identified as possible participants?**  Potential participants will be identified through an initial screen of referral that is completed by a SALHN employed staff who receive patient referrals for the Home Rehabilitation Service. This is typically the service manager. The initial screen by a SALHN employee will include going through EPAS/Sunrise to look at new home rehabilitation service referrals. The screen will include checking of participant age (to ensure over the age of 18), and level of cognition (to ensure potential participant is able to consent for self – or need for “person on behalf”), and to confirm COVID-19 diagnosis. |
| **What are the inclusion and exclusion criteria?**  **Inclusion:** Any person aged 18, confirmed with COVID-19 referred to home rehabilitation services through the division of rehabilitation, aged and palliative care will be included in this study.  **Exclusion:** Prospective participants are excluded from the study if they decline the offer to participate in the study experimental arm. |
| **Participant commitment**  As per standard care, the participants are asked to attend their rehabilitation sessions using telehealth modalities, (WebEx, zoom or skype). If a participant does not have devices to access these platforms, the research team will provide a tablet computer with a SIM card for internet access for the duration of their rehabilitation. Participants assigned to the experimental group will be attending twice per week group discussions with other participants using the same online platforms. The Home Rehabilitation Service has established methods for telehealth and a dedicated technology support worker.  The participants will be contacted for a 10-minute telephone interview related to the study at 3 months following their baseline assessment and the interview will include the re-administration of the RNLI, FRAIL scale and EQ-5D. No additional commitment is required from the participants. |
| **Participant follow up – how are participants monitored during the study?**  Participants will receive care as per the rehabilitation protocol within the Division and receive (1) standard predominantly physical based telerehabilitation support or (2) predominantly participation/psychosocial based support. Participants are followed up with a 10-minute telephone interview related to this study at 3 months following their initial baseline assessment. |

**Consent**

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| **How you will be obtaining consent and/or what alternatives you will be using**:  The person completing the initial screen (SALHN employed) will randomise the person referred to the rehabilitation service to either the standard care arm or experimental arm.  Participants who were randomised for the standard care arm (1) are enrolled via an opt-out consent process in order to avoid sampling biases of the population of interest. We have developed a Standard Operating Procedure regarding the opt-out consent to be obtained at the earliest possible point during a participant’s referral to the home rehabilitation services and before the prospective participant’s data is incorporated into the study database. All staff in the relevant clinical area are authorised to present and discuss the opt-out consent and are delegated this duty as representatives of their key investigators. The investigators or their divisional representative(s) will explain the nature of the study and answer all questions regarding the study to the prospective participant or, for prospective participants without the capacity to consent (e.g. a cognitive impairment, an intellectual disability, or a mental illness) their legally authorized representative (defined as the person’s guardian or any person or organization authorized by law, usually the person’s relative or carer).  The opt-out consent form contains details on how to opt-out of the study via phone or email, what the participant is opting out of, as well as the role and the phone number of the person to notify and the contact details of the research team, including chief investigator. Reassurance is provided that the participants are able to opt-out at a later date and that the decision not to participate in the study will not affect their medical treatment or their relationship with the staff that are caring for them. Participants will also be given the opportunity to confirm ongoing participation or withdrawal during their rehabilitation sessions. They are also given details on how to lodge a complaint through an independent complaints process.  For patients who lack the competence to provide consent, or where the patient is from a Non-English speaking background and has limited command of English hospital staff will approach a person with lawful authority on behalf of that patient (this is usually the next of kin or carer) with the opt-out information sheet for the study.  Written consent will be sought from prospective participants allocated to the experimental arm (2). The person completing the initial screen (SALHN employed) will seek verbal consent from the people randomised to the experimental arm for a member of the research team to contact them and discuss the study in more detail. They will be provided with the participant information & consent form and a member of the research team will go through the form together with the participants. The participants may consent after reading the explanation and having questions answered. Alternatively, they may take explanation and consent and be contacted again at a later time. They will also be encouraged to discuss involvement with their family.   The signed consent form will be photocopied and a copy provided to the participant. Consent will also be documented in the participant’s electronic records as recommended by the Health Care Act 2008. Documentation will include the study title, researcher’s name, and contact details. The following statement will also be documented: “I have obtained consent from the potential participant to be involved in this research project”; followed by the researcher's signature and date. Obtaining consent is further illustrated in Figure 2.    Figure 2 - Obtaining consent procedure |
| **Which investigators will issue the information sheets and consent forms**:  Study investigators, therapists, and the divisional representatives are responsible for distributing the opt-out consent forms to members of the Home Rehabilitation Service for providing to clients of the service upon admission to the service. |
| **How much time will participants have to consider participation**:  Prospective participants in the standard care arm (1) can opt-out consent at any time following their referral to the home rehabilitation service. In addition, a four-week (28 day) “lag” is applied to allow prospective participants to initially opt-out before their data is incorporated into the study database.  The potential participants in the experimental care arm (2) may consent after reading the participant information and having questions answered. Alternatively, they may take the information provided and be approached again after around 48-72 hours. |
| **Please specify which investigators will obtain consent from participants**:  The study investigators, research therapist, or the divisional representative(s) will explain the nature of the study and answer any related questions. The patients are made aware at the time of their initial contact with the home rehabilitation service that their detail will be included in the study unless they choose to opt-out (standard care), or consent to participate in the study (experimental care). When follow-up contact is made with participants (as per the study protocol) the researcher making contact with the participant will seek verbal consent prior to commencing these questions. |
| **Will there be an opportunity to confirm or renegotiate consent during the research project?**  All prospective participants (and/ or their authorised representatives) are able to renegotiate their consent at any point during the research. They will be provided with detail they will need to know about how to opt-out consent. Prospective participants are also provided with an option to renegotiate their consent during / prior to any telephone contact made. |
| **Who will be confirming or renegotiating consent with participants and what process will be undertaken?** The study investigators, research therapist, or divisional representative(s) will explain the nature of the study and answer any related questions to the prospective participants. The patients are made aware at time of form provision that their detail will be included in the study unless they choose to opt-out, and that the form will include all detail they will need to know about how to ask further questions, and how to opt-out.  At the time of the telephone contact, a member of the research team will ask the participant (or their legal representative) if they still wish to participate and they may decline at this time. |

**Data management**

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| **Who will collect the study data / information?** The patient specific data is routinely collected by SALHNstaff during the patient’s treatment at the division. The data will be extracted by a SALHN employed data officer (for example a case mix officer) and sent to the research team in a non-identifiable format. Data from the RNLI, FRAIL scale and EQ-5D will be collected by the research therapist. The research team is responsible for collating the study data in one data base. |
| **What format will the data or information be stored?** The electronic data will be stored in a password protected folder hosted by SALHN and is only accessible for the research staff. |
| **Please provide details regarding training of the research team on maintaining the integrity and security of the data** Anyone employed by SALHN will have undertaken mandatory training for safe and confidential handling of patient information as part of commencing employment in the organisation. Any research staff that is employed outside of SALHN (e.g. Flinders University), will be asked to familiarise themselves with Section 93 of the Health Care Act 2008; Code of Ethics for the South Australian Public Sector and Research and Governance Policy Directives that discuss procedures governing confidentiality and release of client information. These staff will also be asked to sign confidentiality deed poll with SALHN. |
| **What conditions can the data be accessed or granted to others?** Only staff nominated in this research proposal and granted access to the drive and folder where the study data is stored. This will be password protected via SA Health computer log on. Personal identifying information will not be available at data analysis and only group level results will be published/disseminated. |
| **How will the research data be stored and what security measures are in place to protect it?**  The data will be stored in the SA Health network drive which is password protected and secure for storing sensitive information. |
| **How will you provide access to, disclose, use/re-use or transfer the data?**  Any data that is presented at conferences, journal articles or other industry events will be non-identifiable. |
| **How long will the data be retained for?**  15 years |
| **What plans are in place to store / archive the study data once the research is completed?** The data will be stored electronically for 15 years then destroyed as per the storage and retention of data recommendations for public health institutions |
| **How will the study data be destroyed?** Electronicdeletion |
| **Matching and sampling strategies:**  All individuals who meet the inclusion criteria are included in the study. The Zelen single consent randomised controlled trial approach (Zelen, 1979) will be used and potential participants will be randomised using an online randomisation schedule generator. As earlier stated, the Zelen approach is a variation in randomised controlled trials in that participants are pre-randomised to groups, that is, participants are assigned at random to an experimental treatment or to the standard treatment. |
| **Accounting for potential bias, confounding factors and missing information:**  An opt-out consent is used order to reduce sampling bias that can come with research. A researcher who was not involved in the participant’s clinical care will conduct follow up telephone calls with participants in order to help address possible bias related to patients feeling they will need to provide positive feedback about the care that they have received. In addition, recall bias can potentially influence of the results of this project. To attend to recall bias and to ensure that we can compare the participant reported detail regarding their rehabilitation processes and outcomes, we will confirm some process and outcome details pertaining to participants through checking of their electronic inpatient records. These details are: age, gender, post code, amount of telerehabilitation sessions attended, rehabilitation outcome (which include FIM efficiency score, FIM score at admission and at discharge). We also plan to look at the participants’ record to see whether they have come back to hospital over the 12 months after their discharge. However, no contact is made with the participant at that time. |
| **Sample size and statistical or power issues**  Based on the Australian study published by Fairhall et al which reported data on 181 frail older people who completed the Reintegration to Normal Living Index we have calculated a sample size of 52 participants (26 per group). This is based on a mean of 22.2 and standard deviation of 4.31 in recently discharged frail older adults with alpha 0.05 and power at 80%. We will allow for 10% drop out and therefore **recruit 58 participants**. |
| **How will you measure, manipulate and/or analyse the information collected?**  We will report standard descriptive statistics such as mean and SD or median and range for continuous variables and proportions for categorical variables. We will compare means and proportions using t-tests, chi-square tests or fishers exact test as appropriate. We will also use regression analyses where the independent variable will be the allocated condition, and the dependent variable will be the outcomes following intervention (such as FIM score).  Recruitment data will be reported descriptively. Attendance (in rehabilitation sessions) data will be analysed descriptively in order to explore the number of sessions attended by participants. Characteristics of participants will be presented in a table. Process information (such as intervention processes), information about the telehealth equipment used and the need for technical support) will be presented narratively.  Costs will be calculated based on the costs of telehealth hardware for each person and the costs of providing the intervention for each participant. We will calculate staff time based on the time spent with each client and costs and hourly therapist wages. This information is not intended to provide a definitive cost of providing the intervention but will inform the larger planned study. |
| **Data linkage – what linkages are planned or anticipated?**  Nil. |
| **What impact will a participant withdrawing have on the data and how will this be responded to?**  Prospective participants will be made aware that they are under no obligation to participate and that they can opt-out consent at any time without the jeopardising their existing relationship with the hospital and their treating staff, or treatment. Participants will be made aware that data collected about them until the time point they choose to opt-out will kept and may be used in this research. However, no additional data will be collected, nor additional contact related to this study will be made. |

**Results, reporting, outcomes and future plans**

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| **Please detail your plans for the return of the research results to the participants**: Participants will not be offered direct access to research results (or their summaries). |
| **What are your plans for dissemination and publication of project outcomes**:  We will disseminate the results in academic journals, presentation at scientific conferences and local forums. |
| **Please detail other potential uses of the data at the end of the project**:  On top of using the data to inform division specific processes, other uses include using the data as a quality improvement benchmark and indicator within the division (and hospital) and we will seek to disseminate these finding within SALHN as well as other SA health networks. |
| **What are your plans for sharing and/or future use of data and/or follow-up research?** **i.e. anticipated secondary use of data:**  Results gained from this project may be used to assist in plan of intervention as well as quality improvement studies. |
| **What is the project closure process?**:  A final report will need to be submitted to the HREC |

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