Effectiveness of nurse-led volunteer support and technology-driven pain assessment in improving the outcomes of hospitalised older adults: protocol for a cluster randomised controlled trial

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ABSTRACT

Introduction Hospitalised older adults are prone to functional deterioration, which is more evident in frail older patients and can be further exacerbated by pain. Two interventions that have the potential to prevent progression of frailty and improve patient outcomes in hospitalised older adults but have yet to be subject to clinical trials are nurse-led volunteer support and technology-driven pain assessment of pain.

Methods and analysis This single-centre, prospective, non-blinded, cluster randomised controlled trial will compare the efficacy of nurse-led volunteer support, technology-driven pain assessment and the combination of the two interventions to usual care for hospitalised older adults. Prior to commencing recruitment, the intervention and control conditions will be randomised across four wards. Recruitment will continue for 12 months. Data will be collected on admission, at discharge and at 30 days post discharge, with additional data collected during hospitalisation comprising records of pain assessment and volunteer support activity. The primary outcome of this study will be the change in frailty between both admission and discharge, and admission and 30 days, and secondary outcomes include length of stay, adverse events, discharge destination, quality of life, depression, cognitive function, functional independence, pain scores, pain management intervention (type and frequency) and unplanned 30-day readmissions. Stakeholder evaluation and an economic analysis of the interventions will also be conducted.

Ethics and dissemination Ethical approval has been granted by Human Research Ethics Committees at Ramsay Health Care WAISA (number: 2057) and Edith Cowan University (number: 2021-02210-SAUNDERS). The findings will be disseminated through conference presentations, peer-reviewed publications and social media.

Trial registration number ACTRN12620001173987.

STRENGTHS AND LIMITATIONS OF THIS STUDY

Randomised controlled trial design provides a rigorous test of the effectiveness of nurse-led volunteer support and technology-driven pain assessment versus usual care for hospitalised older adults.

Use of an electronic comprehensive assessment instrument will allow measurement of a Frailty Index at admission and discharge.

Interventions will be randomised at the level of the ward (ie, cluster randomisation) rather than the individual due to practical constraints of the hospital environment.

INTRODUCTION

Hospitalisation is associated with a high risk of iatrogenic harm. There is an urgent need to develop interventions that prevent functional decline among older people requiring acute care (AC). Older patients, particularly those who are frail, are at increased risk of adverse health-related outcomes including increased length of stay, increased risk of clinical incidents and postoperative complications, decreased functionality post discharge, readmission to hospital and death, all of which result in increased healthcare costs. Evidence suggests that outcomes for frail patients can be improved, with the Asia-Pacific Clinical Practice Guidelines for the Management of Frailty recommending effective interventions including validated frailty assessment, multicomponent interventions and frailty clinical pathways.

Pain and frailty are common in older adults; however, pain is often managed inadequately.
and can accelerate functional decline, leading to behavioural and psychosocial disturbances, such as agitation, aggression, depression, anxiety, delirium, impaired quality of life and poor clinical outcomes. Therefore, effective pain assessment is critical for older adults as part of the multicomponent interventions for managing frailty. Assessing pain usually begins with a person’s verbal or non-verbal self-report using pain assessment tools but this can be challenging in older patients, consequently, technology-driven pain assessments have been developed to improve pain assessment in these patients. One such application is PainChek Universal (www.painchek.com), which has sound psychometric validity and reliability and enables better assessment of pain at the point of care for patients whose ability to communicate fluctuates. PainChek Universal contains two scales: a Numeric Rating Scale for those who can self-report pain and the PainChek scale for those who cannot self-report pain. PainChek uses automated facial recognition and analysis to identify pain-related facial micro-expressions, together with a series of user completed checklists of pain behaviours to produce a pain score. PainChek has been implemented and evaluated in aged care settings; however, no previous studies have evaluated its effectiveness in an AC setting.

Multicomponent interventions involving volunteers for hospitalised older adults improve clinical outcomes, with a reduction in fall rates, incidences of delirium, pain and reduced length of stay. Volunteer programmes such as the Hospital Elder Life Program (HELP), which includes multicomponent physical, nutritional and cognitive strategies, have been implemented successfully around the world and have been shown to improve quality and effectiveness of care of hospitalised older adults; to maintain cognitive and physical functioning of high-risk older adults throughout hospitalisation; maximise independence at discharge; assist with the transition from hospital to home; and prevent unplanned hospital readmissions. The HELP goals were initially targeted for the prevention of delirium; however, this programme has been modified for use with frail older adults and has been found to be effective in supporting frail older people undergoing surgery. Other volunteer programmes to support patient care have been implemented and have shown a positive impact on health outcomes for older patients in hospital related to nutrition, falls and delirium. Nurse-led models of volunteer support that capitalise on the expertise and clinical skills of nurses are emerging but evaluation is limited and no rigorous clinical or cost-effectiveness analyses have been conducted. There is a knowledge gap in relation to the potential of technology-driven pain assessment, nurse-led volunteer support or a combination of the two interventions to reduce negative clinical outcomes for frail older patients in hospital.

The primary objective of the study is to evaluate the effectiveness of using nurse-led volunteer support interventions and a technology-driven pain assessment (PainChek Universal) tool compared with standard care, on changes in frailty and specific clinical outcomes of older adults during hospitalisation, at hospital discharge and at 30 days after discharge. The secondary objectives are to evaluate the stakeholder experiences (ie, staff, volunteers and family members) of nurse-led volunteer support interventions and technology-driven pain assessment (PainChek Universal); and to determine the cost-effectiveness of using nurse-led volunteer support interventions and a technology-driven pain assessment (PainChek Universal).

METHODS AND ANALYSIS

Study design and setting

This is a single-centre, prospective, non-blinded, cluster randomised controlled trial. The four intervention conditions are:

1. Standard care plus nurse-led volunteer support.  
2. Standard care plus technology-driven pain assessment (PainChek Universal).  
3. Standard care plus nurse-led volunteer support and technology-driven pain assessment (PainChek Universal).  

There will be four participating wards, and the interventions will be randomised by ward. Cluster randomisation at the level of the ward was chosen as randomisation at the level of the individual was not feasible for implementing the study interventions in the hospital setting. In the case of the technology-driven pain assessment, ward staff will conduct usual pain assessments using PainChek Universal. If patients receiving this intervention were scattered across different wards, this would be challenging to organise, require greater resources and likely result in reduced compliance. The control arm of this study will receive standard care. Given the aim is to determine whether the interventions can improve outcomes for hospitalised patients relative to current outcomes, standard care was chosen as the most appropriate control condition. A statistician not involved in recruitment or data collection will conduct the randomisation of the intervention group on three wards and the control group on one ward.

The primary outcome will be the change in frailty from admission to discharge as measured by the Frailty Index generated by the InterRAI Tool, and change in frailty from admission to 30 days post discharge as measured by the modified Reported Edmonton Frail Scale (mod-REFS), both tools have been validated for use in Australian hospitals. Secondary outcome measures include length of stay, adverse events (falls, death, delirium), activities of daily living, continence, discharge destination, quality of life, depression, cognitive function, functional independence, pain scores, pain management intervention (type and frequency including analgesic use) and unplanned 30-day readmissions.

This study will be conducted at the largest acute private hospital in Perth, Western Australia. The hospital has
over 800 licensed beds and provides a range of services including cardiology, gastroenterology, general medicine, general surgery, neurosurgery, oncology, orthopaedics, palliative care, psychiatry, rehabilitation and urology. The study will be conducted across 4 medical wards totalling 100 beds.

**Recruitment**

Participants will be recruited from those patients who are admitted to the four study wards according to the following criteria:

**Inclusion criteria:**
- Patients aged 65 years and over.
- Anticipated length of stay 48 hours or longer.

**Exclusion criteria:**
- Non-medical patients admitted to the medical ward.
- Severe intellectual disability.
- Patients who require isolation due to infection control precautions.

Eligible participants will be provided with verbal and written information about the study by the project nurse and will be required to provide written consent (see online supplemental material). Where a patient is unable to provide informed written consent due to cognitive impairment or inability to communicate verbally, written proxy consent will be sought from their guardian or next-of-kin following guidelines from the Western Australian Department of Health to adhere to the requirements of the Guardianship and Administration Act 1990 (WA).

Recruitment for the intervention will continue for 12 months (March 2021 to February 2022). The interventions will be provided for the duration of the patient’s hospital admission. The intervention will be discontinued if the patient is transferred off the intervention ward, becomes infectious or requests withdrawal from the study.

**Sample size calculation**

The lack of literature on interventions for frailty in hospitalised older adults precludes the calculation of a required sample size based on previous effect sizes. Based on an admission rate of five patients over 65 years per medical ward per weekday, 80% consent rate for screening, 50% frailty rate (The original proposal included a screening phase to invite only patients classified as frail on the mod-REFS into the intervention however this step was removed to reduce the burden on patients) and 50% consent rate for the intervention, a sample size of 180 participants per intervention group, and 720 participants total, is feasible over the 12-month recruitment phase. With this sample size, the study will have 95% power to detect an effect size of d=0.027 at an alpha level .05 for the comparison of frailty between admission and discharge in each group.

**Intervention**

For participants allocated to the nurse-led volunteer support intervention, an individualised volunteer support plan will be developed by a registered nurse at admission, based on patient admission assessments. The volunteers will then provide patient support as per the individualised volunteer support plan. Volunteer support activities are focused on orientation, mobility, nutrition, cognitive, sensory and other support (table 1). Participants will be provided with up to two 1-hour sessions with a volunteer per weekday. Processes will be put in place to ensure enough trained volunteers are available to deliver the intervention including an online volunteer management system. If due to unforeseen circumstances, volunteer support is not able to be provided this will be addressed in analysis.

For all four clusters, information about participants’ pain assessments will be recorded, including the scale used, whether assessment was at rest or on movement, and any action taken in response to the assessment (eg, medication, repositioning). This is part of usual care while in hospital and will be recorded by ward staff. For the intervention groups receiving technology-driven pain assessment, this information will be recorded in the PainChek Universal application. For the other groups,
this information will be recorded on a pain assessment chart, which will be kept in the patients’ room.

Stakeholder evaluation

Stakeholder experiences (patients, family members of participants in the intervention group, clinical staff and volunteers) of nurse-led volunteer support interventions and technology-driven pain assessment (PainChek Universal) will also be evaluated. Prior to discharge, patients in the intervention conditions will be invited to complete a paper survey to evaluate their satisfaction with the interventions. Survey responses will be anonymous, patients will place completed surveys in an envelope to be returned to the project nurse. Surveys will take approximately 10 min to complete. Family members of participants in the intervention groups will be invited to complete a telephone survey after the patient is discharged, to evaluate their perceptions of the interventions.

Clinical staff working on the intervention wards including registered nurses, enrolled nurses, doctors, allied health professionals and allied health professional assistants will be invited to complete a preintervention survey to explore their perceptions of volunteer support and technology-driven pain assessment prior to the interventions, and then a postintervention survey at the end of the study. Each survey will take approximately 10 min to complete. Staff will also be invited to participate in a focus group post intervention to explore their experiences of nurse-led volunteer support and use of technology-driven pain assessment. Volunteers will be invited to complete a survey at the end of the study to explore their motivations for volunteering, satisfaction with volunteering and the organisational aspects of the volunteering programme. The survey will take approximately 10 min to complete. Volunteers will also be invited to participate in a focus group to explore their experiences of volunteering.

Economic evaluation

An economic analysis will be conducted to determine the cost-effectiveness of using volunteer support interventions and a technology-driven pain assessment (PainChek Universal). This will include health system resource use and cost including the cost of the interventions (staff time, staff training and implementation), length of stay and the cost of adverse events.

Data collection

All participants will be recruited within 24 hours of hospital admission where possible. The research nurse will complete an admission assessment with all participants, using the InterRAI AC and the mod-REFS Tool. The assessments will take up to 25 min to administer and data will be entered into the online databases via a laptop. The InterRAI AC assessment will also be completed on discharge. All participants will be followed up by telephone at 30 days post discharge, and information on hospital readmissions will be collected, and the frailty (mod-REFS) and Quality of Life (12-item AQoL-4D) tools will be administered. For patients for whom proxy consent was obtained, the hospital readmission questionnaire and mod-REFs will be completed by the proxy on behalf of the patient. Figure 1 presents a summary of the data collection and the details of the measurements for assessing the primary and secondary outcomes are summarised in table 2.

To ensure reliability of data collection, the research nurse will receive training to conduct assessments using the InterRAI AC. Data collectors conducting the telephone interviews will be provided with a script to follow. Nursing staff on the wards receiving the electronic pain assessment intervention will be provided with PainChek training and additional support will be provided by the research nurse.

Human Research Ethics Committee (HREC) approval did not require a data monitoring committee. Data monitoring will be undertaken by the research committee and reported to the HREC and funding bodies. Any adverse events will be reported as per the HREC guidelines.

Data reporting and analysis

All analyses will be conducted on an intention-to-treat basis. Descriptive statistics will be calculated using mean with SD, median and IQR and frequency for baseline characteristics. The primary outcomes, change in frailty during hospital admission and change in frailty between admission and 30 days post discharge, will be analysed using generalised linear mixed models, comparing the intervention wards with the control wards, adjusting the standard errors for clustering. Models will be adjusted for age, gender, Charlson Comorbidity Score and for clustering by ward. All quantitative analysis will be conducted in STATA. Qualitative data generated from the interviews and focus groups will be managed for emerging themes, and then discussed and organised using the NVivo software. A cost-benefit analysis from an Australian health perspective will be undertaken.

Data management

Data will be managed according to the Australian National Statement on Ethical Conduct in Human Research. Consent forms and hard copy data forms will be stored in locked filing cabinets accessible only by Edith Cowan University (ECU) research team members. Deidentified data and participant information will be stored securely on University servers only accessible by ECU research team members on password-protected computers. PainChek Universal data will be stored in a repository within the PainChek secure cloud database. Data will only be accessible by the research team members via a password-protected web administration portal. InterRAI data will be stored on a secure server at the University of Queensland accessible only by the research team via password. All data will be kept for a minimum of 7 years in line with the Statement on Ethical Conduct in Human Research.
with ECU guidelines. Ultimately, data will be destroyed by deletion of electronic files, and disposal of hard copy documents via secure confidential bins.

**Patient and public involvement**

A consumer representative from the study hospital’s consumer advisory committee is a coinvestigator on the research team and contributed to the study design. Research findings will be discussed with key groups at the study hospital including the consumer advisory committee. Findings will also be disseminated to participants who have requested them and will be published in the study hospital newsletter and national hospital group newsletter.

**ETHICS AND DISSEMINATION**

This study has ethical approval from both the Ramsay Health Care HREC for Western Australia and South Australia (reference: 2057) and the ECU HREC (reference: 2021-02210-SAUNDERS). Model participant information and consent forms are available in online supplemental material. Any changes to the protocol will be communicated to all relevant parties as per the HREC requirements.

The final dataset will be available from the first author on reasonable request. Results of this study will be disseminated across the international healthcare organisation, presented at conferences and published in relevant journals.
Table 2  Measurements used to assess primary and secondary outcomes

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Measurement</th>
<th>Details of the measurement</th>
<th>Completed by</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in frailty from admission to discharge</td>
<td>Frailty Index generated by the InterRAI AC23</td>
<td>A Frailty Index is derived from the outcome of the assessments in the InterRAI assessment system for AC23</td>
<td>Nurse researcher</td>
</tr>
<tr>
<td>Change in frailty from admission to 30 days post discharge</td>
<td>Modified Reported Edmonton Frail Scale (mod-REFS)24</td>
<td>The mod-REFS is a 13-item self-report questionnaire scored from 0 to 18, where a score of 8 and above is classified as frail. Severity classification: not frail (0–5), apparently vulnerable (6–7), mild frailty (8–9), moderate frailty (10–11) and severe frailty (12–18)24</td>
<td>Patient or proxy</td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of stay, activities of daily living, continence, discharge destination, quality of life, depression, cognitive function, functional independence</td>
<td>Scores collected by the InterRAI AC will be used to measure the outcomes32</td>
<td>The interRAI AC is a nursing assessment instrument consisting of 56 items that determine functional and psychosocial needs and includes diagnostic and risk screeners32</td>
<td>Nurse researcher</td>
</tr>
<tr>
<td>Adverse events (falls, death, delirium)</td>
<td>Frequency and type of incident</td>
<td>Obtained from clinical administrative database</td>
<td>Nursing staff</td>
</tr>
<tr>
<td>Pain scores, pain management intervention</td>
<td>Frequency of pain, pain levels, type of pain management intervention, types of analgesic use</td>
<td>Obtained from PainChek Universal database using both the Numerical Rating Score 0–10 or PainChek scores: no pain (0–6), mild (7–11), moderate (12–15) and severe (≥16)13-15</td>
<td>Nursing staff</td>
</tr>
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<td>AC, acute care.</td>
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</tbody>
</table>

publications plus shared through the media. Authorship of publications will be decided according to the International Committee of Medical Journal Editors guidelines.

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Contributors The study was designed by RS, MA, CB, MKB, CE-B, BE, OG, RMG, KG, K-HN, BO, KS, JH and SH. Chief investigators overseeing the trial were RS and CE-B. RS, KG, RMG and DS will be responsible for running the trial with support from SGMA, KG and KS drafted the manuscript and all authors have reviewed and approved the final manuscript. SH is a consumer representative from the study hospital.

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Disclaimer The funder has no role in or authority over study design, data analysis, publications or decisions to publish.

Competing interests KG is the director of clinical services at Hollywood Private Hospital. JH and MA are two of the originators of PainChek, which is marketed by PainChek. They both have share holdings in PainChek Ltd (ASX: PCK), which is a publicly listed company in the Australian Share Securities. They also have a granted patent entitled ‘A pain assessment method and system’ (PCT/AU2015/000501) in Australia, Japan, China and the USA, which was assigned to PainChek. JH holds the position of chief scientific officer of PainChek and is also an emeritus Professor at Curtin Medical School, Curtin University. MA previously held the position of a senior research scientist (October 2018 to May 2020) at PainChek and is currently serving the position of a Research and Practice Lead at The Dementia Centre, HammondCare, and is also an adjunct lecturer at Curtin Medical School, Curtin University.

Patient and public involvement Patients and/or the public were involved in the design, conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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References
29. StataCorp LLC. Stata statistical software: release 15. College Station, TX: StataCorp LLC, 2017.
Supplementary Material: Sample Consent Forms
Participant Information and Consent Form
(Intervention – Participant Ward 1)

Title: Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

Lead Researchers: Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

Introduction
You are invited to take part in this research study as you are currently a patient at Hollywood Private Hospital, aged 65 years or more, are likely to be staying at hospital for 48 hours or longer. This study is being conducted from March 2021 to March 2022 to investigate whether volunteer support and technology driven pain assessment (using the smart-device application PainChek Universal®) can improve levels of frailty and other clinical outcomes for frail older adult patients at Hollywood Private Hospital.

Your participation in this study is entirely voluntary. If you decide to participate in the study, you will be asked to provide written consent and you may keep this Participant Information Form and the Consent Form for your records.

What is the purpose of this study?
Health services want to understand how they can better provide care for older adults who are frail and/or have pain.

Intervention groups
If you consent, you will be participating in a cluster randomised controlled research project comparing four types of care known as ‘interventions’. Sometimes we do not know which intervention is best when caring for patients. To find out we need to compare different interventions. We put people into groups and give each group a different intervention. The results are compared to see if one is better. In a cluster randomised trial, groups of participants (in this case wards) are allocated an intervention by chance (random). Random allocation ensures the study is fair and robust.

In this study the interventions are: 1. Standard care plus nurse led volunteer support; 2. Standard care plus pain assessment using Universal®; 3. Standard care plus both nurse led volunteer support and pain assessment using PainChek Universal®; 4. Standard care. There are four wards in the hospital that are participating in the study. Each ward has been randomly allocated an intervention. You have been admitted to XXX Ward and will be receiving: 1. Standard care plus nurse led volunteer support.

What will participation in this research involve?
If you agree to participate, while you are in hospital and after you have given your written consent to participate in the study, the following steps will occur:

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
1) At the start of your hospital stay, the project nurse will collect routine admission data and clinical information about your frailty and overall health and enter the data into an Acute Care Assessment System called interRAI™. Some of the information will have been collected on admission by ward staff, in which case the project nurse will collect the information from your file. If certain information is not available from your file the project nurse will conduct an assessment. This information will include:

   a. Activities of Daily Living
   b. Cognitive Assessment
   c. Continence
   d. Depression
   e. Falls Risk
   f. Frailty
   g. Functional Independence
   h. Medication Use
   i. Mobility
   j. Nutrition & Body Mass Index
   k. Pain Assessment
   l. Physical Deconditioning
   m. Pressure Injury Risk
   n. Quality of Life

Where assessment is required this will involve the project nurse asking you questions and entering your responses into interRAI™ using an iPad. This will also require you to undertake (if able) a Timed Up and Go Test (TUG) to assess your mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

On the basis of your admission assessment the project nurse will develop a personalised "Volunteer Care Plan" (in consultation with ward staff and yourself) that will describe the volunteer support that you will receive. This might include assistance with walking, assistance with meals and/or companionship. During your hospital stay you will receive up to one hour volunteer support from a trained project volunteer up to two times a day. A record will be kept of the type and duration of volunteer support you receive. Your volunteer care plan and record of volunteer support will be added to your patient file.

As part of the admission assessment the researcher will also assess your frailty using the modified-Reported Edmonton Frail Scale, which involves asking you questions and entering your responses on an iPad. In addition to the assessment routine admission data: year of birth (not date-of-birth), gender, Aboriginal or Torres Strait Islander status, admission date, admission type (elective/acute), type of residence (home/age care facility), admitting diagnosis, and clinical information (active medical conditions) will be collected from your medical file.

2) During your hospital stay, when conducting a pain assessment ward staff will keep a record for this research project of your pain level and any actions taken in response to the pain assessment (e.g., medication given).

**Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)**
3) Near the end of your hospital stay, the project nurse will collect discharge data and clinical information about your frailty and overall health either from your patient file or by assessment and will enter the data into interRAI™. This information will include:

- Active Medical Conditions
- Activities of Daily Living
- Adverse Incidents
- Cognitive Assessment
- Continence
- Depression
- Discharge Destination
- Falls Risk
- Frailty
- Functional Independence
- Length of Stay
- Medication Use
- Mobility
- Nutrition & Body Mass Index
- Pain Assessment
- Physical Deconditioning
- Pressure Injury Risk
- Quality of Life

Where assessment is required this will involve the project nurse asking you questions and entering your responses into interRAI™ using an iPad. This will also require you to undertake (if able) a Timed Up and Go Test (TUG) to assess your mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

At the time of your discharge, the project nurse will also ask you to complete an evaluation survey which will take 5-10 minutes. Within 48 hours of discharge a researcher will also contact your nominated next-of-kin by telephone to conduct a verbal evaluation survey which will take 5-10 minutes. By providing written consent, you consent to the researchers contacting your nominated next-of-kin.

- Evaluation Survey

4) 30 days after you have been discharged from hospital, a research team member will contact you by telephone to conduct a final verbal questionnaire which will take approximately 15 minutes in total and includes 3 aspects:

- Frailty Assessment (mod-REFS)
- Hospital Readmission Questionnaire
- Australian Quality of Life Questionnaire (A-QoL-4D)

**Do I have to take part in this research project?**
Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide you don’t want to continue taking part you are free to

*Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)*
discontinue and withdraw from the project at any time, without providing an explanation unless you choose to. Your hospital care will not be jeopardised in any way by your non-participation.

What are the possible benefits of taking part?
We cannot guarantee or promise that you will receive any direct benefit from this research. You may get some satisfaction from knowing that you are assisting in contributing to better care delivery for patients who are frail and/or in pain.

What are the possible risks and disadvantages of taking part?
Other than the inconvenience of the time required to complete the additional assessments with the project nurse and the post-discharge telephone call with a researcher, there are no risks or disadvantages to participating in this study. By consenting to be part of this study you are agreeing to receive volunteer support.

What if I withdraw from this research project?
If at any time you decide you don’t want to continue taking part in the research project you are free to discontinue and withdraw from the project without prejudice. Choosing to withdraw from the project will not affect your current or future medical care. If you decide to withdraw from the project, please notify the project nurse or contact the lead researcher (contact details below). No further data will be collected from the date of withdrawal, although data and personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the researchers up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

What will happen to information about me?
By providing written consent you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Prior to analysis all data will be de-identified (i.e., names will be removed) and each participant will be allocated a unique code. Hard copy (paper) forms will be stored in locked filing cabinets accessible only by Edith Cowan University research team members. Data and participant information will be stored securely on University servers only accessible by Edith Cowan University research team members on password protected computers. The interRAI™ data will be stored on a secure server at the University of Queensland accessible only by the research team via password. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All data will be destroyed after seven years in line with University guidelines.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
permission. Given that all data will be de-identified prior to analysis identification to one single participant will be impossible.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

If you would like to receive copies of publications resulting from this research, please tick the box and provide your email or postal address:

☐ Yes, I would like to receive publications resulting from this research, via:

   Email: ______________________________________________________________________
   OR Post: _____________________________________________________________________

Who is organizing and funding the research?
This research project is being conducted by the School of Nursing and Midwifery at Edith Cowan University in collaboration with Hollywood Private Hospital. The project has been funded by the Ramsay Hospital Research Foundation.

Further information and who to contact
If you have any questions about the research, you can contact the following people:

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Associate Professor Christopher Etherton-Beer
Lead Researcher
Phone: (08) 9224 2750
Email: Christopher.Etherton-Beer@uwa.edu.au

Deb Scaini
Project Nurse
Phone: (08) 9346 6023
Email: scainid@ramsayhealth.com.au

Ethics Approval
This research project has been approved by the Ramsay Health Care WA/SA Human Research Ethics Committee (ref 2057) and the Edith Cowan University Human Research Ethics Committee (ref 2021-02210-SAUNDERS).

   Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

Executive Officer
WA/SA Human Research Ethics Committee
Ramsay Health Care
Phone: (08) 9400 9400 (ext. 6404)
Or: (08) 9400 9897
Email: RamsayHREC.WA-SA@ramsayhealth.com.au

Research Ethics Officer
Edith Cowan University
270 Joondalup Drive
Joondalup WA 6027
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Participant Consent Form (Intervention – Patient)

**Title:** Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

**Lead Researchers:** Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

**Study Site:** Hollywood Private Hospital, Gate 2/101 Monash Ave, Nedlands WA 6009

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

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**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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<th>Name of Researcher† (please print)</th>
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† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Participant Information and Consent Form  
(Intervention – Participant Ward 2)

**Title**: Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

**Lead Researchers**: Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

**Introduction**
You are invited to take part in this research study as you are currently a patient at Hollywood Private Hospital, aged 65 years or more, are likely to be staying at hospital for 48 hours or longer. This study is being conducted from March 2021 to March 2022 to investigate whether volunteer support and technology driven pain assessment (using the smart-device application PainChek Universal®) can improve levels of frailty and other clinical outcomes for frail older adult patients at Hollywood Private Hospital.

Your participation in this study is entirely voluntary. If you decide to participate in the study, you will be asked to provide written consent and you may keep this Participant Information Form and the Consent Form for your records.

**What is the purpose of this study?**
Health services want to understand how they can better provide care for older adults who are frail and/or have pain.

**Intervention groups**
If you consent, you will be participating in a cluster randomised controlled research project comparing four types of care known as 'interventions'. Sometimes we do not know which intervention is best when caring for patients. To find out we need to compare different interventions. We put people into groups and give each group a different intervention. The results are compared to see if one is better. In a cluster randomised trial, groups of participants (in this case wards) are allocated an intervention by chance (random). Random allocation ensures the study is fair and robust.

In this study the interventions are: 1. Standard care plus nurse led volunteer support; 2. Standard care plus pain assessment using Universal®; 3. Standard care plus both nurse led volunteer support and pain assessment using PainChek Universal®; 4. Standard care. There are four wards in the hospital that are participating in the study. Each ward has been randomly allocated an intervention. **You have been admitted to XXX Ward and will be receiving: 2. Standard care plus pain assessment using PainChek Universal®.**

**What will participation in this research involve?**
If you agree to participate, while you are in hospital and after you have given your written consent to participate in the study, the following steps will occur:

**Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)**
5) At the start of your hospital stay, the project nurse will collect routine admission data and clinical information about your frailty and overall health and enter the data into an Acute Care Assessment System called interRAI™. Some of the information will have been collected on admission by ward staff, in which case the project nurse will collect the information from your file. If certain information is not available from your file the project nurse will conduct an assessment. This information will include:

a. Activities of Daily Living  
b. Cognitive Assessment  
c. Continence  
d. Depression  
e. Falls Risk  
f. Frailty  
g. Functional Independence  
h. Medication Use  
i. Mobility  
j. Nutrition & Body Mass Index  
k. Pain Assessment  
l. Physical Deconditioning  
m. Pressure Injury Risk  
n. Quality of Life

Where assessment is required this will involve the project nurse asking you questions and entering your responses into interRAI™ using an iPad. This will also require you to undertake (if able) a Timed Up and Go Test (TUG) to assess your mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

As part of the admission assessment the researcher will also assess your frailty using the modified-Reported Edmonton Frail Scale, which involves asking you questions and entering your responses on an iPad. In addition to the assessment routine admission data: year of birth (not date-of-birth), gender, Aboriginal or Torres Strait Islander status, admission date, admission type (elective/acute), type of residence (home/age care facility), admitting diagnosis, and clinical information (active medical conditions) will be collected from your medical file.

During your hospital stay ward staff will assess your pain as part of routine care using PainChek Universal®. This involves asking you some questions and entering your responses on an iPad. PainChek Universal® is a secure medical device in the form of a smart device application where nurses will record your pain levels. The application adheres to strict medical privacy and confidentiality legislation (for more information you can visit https://painchek.com/). PainChek Universal® use and data, and the actions taken in response by the nurse performing the assessment (e.g., medication given), will be recorded for this research project. The PainChek Universal® data will be added to your patient file.

6) Near the end of your hospital stay, the project nurse will collect discharge data and clinical information about your frailty and overall health either from your patient file
or by assessment and will enter the data into interRAI™. This information will include:

a. Active Medical Conditions  
b. Activities of Daily Living  
c. Adverse Incidents  
d. Cognitive Assessment  
e. Continence  
f. Depression  
g. Discharge Destination  
h. Falls Risk  
i. Frailty  
j. Functional Independence  
k. Length of Stay  
l. Medication Use  
m. Mobility  
n. Nutrition & Body Mass Index  
o. Pain Assessment  
p. Physical Deconditioning  
q. Pressure Injury Risk  
r. Quality of Life

Where assessment is required this will involve the project nurse asking you questions and entering your responses into interRAI™ using an iPad. This will also require you to undertake (if able) a Timed Up and Go Test (TUG) to assess your mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

At the time of your discharge, the project nurse will also ask you to complete an evaluation survey which will take 5-10 minutes. Within 48 hours of discharge a researcher will also contact your nominated next-of-kin by telephone to conduct a verbal evaluation survey which will take 5-10 minutes. By providing written consent, you consent to the researchers contacting your nominated next-of-kin.

a. Evaluation Survey

7) 30 days after you have been discharged from hospital, a research team member will contact you by telephone to conduct a final verbal questionnaire which will take approximately 15 minutes in total and includes 3 aspects:

a. Frailty Assessment (mod-REFS)  
b. Hospital Readmission Questionnaire  
c. Australian Quality of Life Questionnaire (A-QoL-4D)

Do I have to take part in this research project?
Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide you don’t want to continue taking part you are free to discontinue and withdraw from the project at any time, without providing an
explanation unless you choose to. Your hospital care will not be jeopardised in any way by your non-participation.

**What are the possible benefits of taking part?**
We cannot guarantee or promise that you will receive any direct benefit from this research. You may get some satisfaction from knowing that you are assisting in contributing to better care delivery for patients who are frail and/or in pain.

**What are the possible risks and disadvantages of taking part?**
Other than some inconvenience regarding the time required to complete the additional assessments with the project nurse and the post-discharge telephone call with a researcher, there are no risks or disadvantages to participating in this study.

**What if I withdraw from this research project?**
If at any time you decide you don't want to continue taking part in the research project you are free to discontinue and withdraw from the project without prejudice. Choosing to withdraw from the project will not affect your current or future medical care. If you decide to withdraw from the project, please notify the project nurse or contact the lead researcher (contact details below). No further data will be collected from the date of withdrawal, although data and personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the researchers up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

**What will happen to information about me?**
By providing written consent you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Prior to analysis all data will be de-identified (i.e., names will be removed) and each participant will be allocated a unique code. Hard copy (paper) forms will be stored in locked filing cabinets accessible only by Edith Cowan University research team members. Data and participant information will be stored securely on University servers only accessible by Edith Cowan University research team members on password protected computers. The interRAI™ data will be stored on a secure server at the University of Queensland accessible only by the research team via password. PainChek Universal® data will be stored in a repository within the PainChek Universal® secure cloud database. PainChek Universal® data will only be accessible by the research team members via a password protected Web Administration Portal. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All data will be destroyed after seven years in line with University guidelines.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your

*Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)*

permission. Given that all data will be de-identified prior to analysis identification to one single participant will be impossible.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

If you would like to receive copies of publications resulting from this research, please tick the box and provide your email or postal address:

☐ Yes, I would like to receive publications resulting from this research, via:

Email: 
OR Post: 

Who is organizing and funding the research?
This research project is being conducted by the School of Nursing and Midwifery at Edith Cowan University in collaboration with Hollywood Private Hospital. The project has been funded by the Ramsay Hospital Research Foundation.

Further information and who to contact
If you have any questions about the research, you can contact the following people:

Dr Rosemary Saunders
Lead Researcher
Phone: (08) 6304 3513
Email: Rosemary.Saunders@ecu.edu.au

Associate Professor Christopher Etherton-Beer
Lead Researcher
Phone: (08) 9224 2750
Email: Christopher.Etherton-Beer@uwa.edu.au

Deb Scaini
Project Nurse
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Ethics Approval
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Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
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Research Ethics Officer
Edith Cowan University
270 Joondalup Drive
Joondalup WA 6027
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Participant Consent Form (Intervention – Patient)

**Title:** Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

**Lead Researchers:** Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

**Study Site:** Hollywood Private Hospital, Gate 2/101 Monash Ave, Nedlands WA 6009

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

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**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
**Participant Information and Consent Form**  
(Intervention – Participant Ward 3)

**Title:** Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

**Lead Researchers:** Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

**Introduction**  
You are invited to take part in this research study as you are currently a patient at Hollywood Private Hospital, aged 65 years or more, are likely to be staying at hospital for 48 hours or longer. This study is being conducted from March 2021 to March 2022 to investigate whether volunteer support and technology driven pain assessment (using the smart-device application PainChek Universal®) can improve levels of frailty and other clinical outcomes for frail older adult patients at Hollywood Private Hospital.  
Your participation in this study is entirely voluntary. If you decide to participate in the study, you will be asked to provide written consent and you may keep this Participant Information Form and the Consent Form for your records.

**What is the purpose of this study?**  
Health services want to understand how they can better provide care for older adults who are frail and/or have pain.

**Intervention groups**  
If you consent, you will be participating in a cluster randomised controlled research project comparing four types of care known as ‘interventions’. Sometimes we do not know which intervention is best when caring for patients. To find out we need to compare different interventions. We put people into groups and give each group a different intervention. The results are compared to see if one is better. In a cluster randomised trial, groups of participants (in this case wards) are allocated an intervention by chance (random). Random allocation ensures the study is fair and robust.

In this study the interventions are: 1. Standard care plus nurse led volunteer support; 2. Standard care plus pain assessment using PainChek Universal®; 3. Standard care plus both nurse led volunteer support and pain assessment using PainChek Universal®; 4. Standard care. There are four wards in the hospital that are participating in the study. Each ward has been randomly allocated an intervention. **You have been admitted to XXX Ward and will be receiving: 3. Standard care plus both nurse led volunteer support and pain assessment using PainChek Universal®.**

**What will participation in this research involve?**  
If you agree to participate, while you are in hospital and after you have given your written consent to participate in the study, the following steps will occur:

- **Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)**
8) At the start of your hospital stay, the project nurse will collect routine admission data and clinical information about your frailty and overall health and enter the data into an Acute Care Assessment System called interRAI™. Some of the information will have been collected on admission by ward staff, in which case the project nurse will collect the information from your file. If certain information is not available from your file the project nurse will conduct an assessment. This information will include:
   a. Activities of Daily Living
   b. Cognitive Assessment
   c. Continence
   d. Depression
   e. Falls Risk
   f. Frailty
   g. Functional Independence
   h. Medication Use
   i. Mobility
   j. Nutrition & Body Mass Index
   k. Pain Assessment
   l. Physical Deconditioning
   m. Pressure Injury Risk
   n. Quality of Life

Where assessment is required this will involve the project nurse asking you questions and entering your responses into interRAI™ using an iPad. This will also require you to undertake (if able) a Timed Up and Go Test (TUG) to assess your mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

As part of the admission assessment the researcher will also assess your frailty using the modified-Reported Edmonton Frail Scale, which involves asking you questions and entering your responses on an iPad. In addition to the assessment routine admission data: year of birth (not date-of-birth), gender, Aboriginal or Torres Strait Islander status, admission date, admission type (elective/acute), type of residence (home/age care facility), admitting diagnosis, and clinical information (active medical conditions) will be collected from your medical file.

On the basis of your admission assessment the project nurse will develop a personalised “Volunteer Care Plan” (in consultation with ward staff and yourself) that will describe the volunteer support that you will receive. This might include assistance with walking, assistance with meals and/or companionship. During your hospital stay you will receive up to one hour volunteer support from a trained project volunteer up to two times a day. A record will be kept of the type and duration of volunteer support you receive. Your volunteer care plan and record of volunteer support will be added to your patient file.

9) During your hospital stay ward staff will assess your pain as part of routine care using PainChek Universal®. This involves asking you some questions and entering your responses on an iPad. PainChek Universal® is a secure medical device in the

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
form of a smart device application where nurses will record your pain levels. The application adheres to strict medical privacy and confidentiality legislation (for more information you can visit https://painchek.com/). PainChek Universal® use and data, and the actions taken in response by the nurse performing the assessment (e.g., medication given), will be recorded for this research project. The PainChek Universal® data will be added to your patient file.

10) Near the end of your hospital stay, the project nurse will collect discharge data and clinical information about your frailty and overall health either from your patient file or by assessment and will enter the data into interRAI™. This information will include:

   a. Active Medical Conditions
   b. Activities of Daily Living
   c. Adverse Incidents
   d. Cognitive Assessment
   e. Continence
   f. Depression
   g. Discharge Destination
   h. Falls Risk
   i. Frailty
   j. Functional Independence
   k. Length of Stay
   l. Medication Use
   m. Mobility
   n. Nutrition & Body Mass Index
   o. Pain Assessment
   p. Physical Deconditioning
   q. Pressure Injury Risk
   r. Quality of Life

Where assessment is required this will involve the project nurse asking you questions and entering your responses into interRAI™ using an iPad. This will also require you to undertake (if able) a Timed Up and Go Test (TUG) to assess your mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

At the time of your discharge, the project nurse will also ask you to complete an evaluation survey which will take 5-10 minutes. Within 48 hours of discharge a researcher will also contact your nominated next-of-kin by telephone to conduct a verbal evaluation survey which will take 5-10 minutes. By providing written consent, you consent to the researchers contacting your nominated next-of-kin.

   a. Evaluation Survey

11) 30 days after you have been discharged from hospital, a research team member will contact you by telephone to conduct a final verbal questionnaire which will take approximately 15 minutes in total and includes 3 aspects:

   Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
a. Frailty Assessment (mod-REFS)
b. Hospital Readmission Questionnaire
c. Australian Quality of Life Questionnaire (A-QoL-4D)

Do I have to take part in this research project?
Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide you don’t want to continue taking part you are free to discontinue and withdraw from the project at any time, without providing an explanation unless you choose to. Your hospital care will not be jeopardised in any way by your non-participation.

What are the possible benefits of taking part?
We cannot guarantee or promise that you will receive any direct benefit from this research. You may get some satisfaction from knowing that you are assisting in contributing to better care delivery for patients who are frail and/or in pain.

What are the possible risks and disadvantages of taking part?
Other than some inconvenience regarding the time required to complete the additional assessments with the project nurse and the post-discharge telephone call with a researcher, there are no risks or disadvantages to participating in this study. By consenting to be part of this study you are agreeing to receive volunteer support.

What if I withdraw from this research project?
If at any time you decide you don’t want to continue taking part in the research project you are free to discontinue and withdraw from the project without prejudice. Choosing to withdraw from the project will not affect your current or future medical care. If you decide to withdraw from the project, please notify the project nurse or contact the lead researcher (contact details below). No further data will be collected from the date of withdrawal, although data and personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the researchers up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

What will happen to information about me?
By providing written consent you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Prior to analysis all data will be de-identified (i.e., names will be removed) and each participant will be allocated a unique code. Hard copy (paper) forms will be stored in locked filing cabinets accessible only by Edith Cowan University research team members. Data and participant information will be stored securely on University servers only accessible by Edith Cowan University research team members on password protected computers. The interRAI™ data will be stored on a secure server at the University of Queensland accessible only by the research team via password. PainChek Universal® data will be stored in a repository within the PainChek

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)

Universal® secure cloud database. PainChek Universal® data will only be accessible by the research team members via a password protected Web Administration Portal. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All data will be destroyed after seven years in line with University guidelines.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Given that all data will be de-identified prior to analysis identification to one single participant will be impossible.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

If you would like to receive copies of publications resulting from this research, please tick the box below and provide your email or postal address:

☐ Yes, I would like to receive publications resulting from this research, via:

   Email: ________________________________

   OR Post: ________________________________

   ________________________________

Who is organizing and funding the research?
This research project is being conducted by the School of Nursing and Midwifery at Edith Cowan University in collaboration with Hollywood Private Hospital. The project has been funded by the Ramsay Hospital Research Foundation.

Further information and who to contact
If you have any questions about the research, you can contact the following people:

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Lead Researcher
Phone: (08) 6304 3513
Email: Rosemary.Saunders@ecu.edu.au

Associate Professor Christopher Etherton-Beer
Lead Researcher
Phone: (08) 9224 2750
Email: Christopher.Etherton-Beer@uwa.edu.au

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Deb Scaini  
Project Nurse  
Phone: (08) 9346 6023  
Email: scainid@ramsayhealth.com.au

**Ethics Approval**

This research project has been approved by the Ramsay Health Care WA/SA Human Research Ethics Committee (ref 2057) and the Edith Cowan University Human Research Ethics Committee (ref 2021-02210-SAUNDERS).

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WA/SA Human Research Ethics Committee  
Ramsay Health Care  
Phone: (08) 9400 9400 (ext. 6404)  
Or: (08) 9400 9897  
Email: RamsayHREC.WA-SA@ramsayhealth.com.au

**Research Ethics Officer**
Edith Cowan University  
270 Joondalup Drive  
Joondalup WA 6027  
Phone: (08) 6304 2170  
Email: research.ethics@ecu.edu.au

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Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Participant Consent Form (Intervention – Patient)

Title: Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

Lead Researchers: Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

Study Site: Hollywood Private Hospital, Gate 2/101 Monash Ave, Nedlands WA 6009

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project. I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____________________________
Signature _____________________________ Date ________________

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____________________________
Signature _____________________________ Date ________________

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.
Participant Information and Consent Form
(Intervention – Participant Ward 4)

Title: Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

Lead Researchers: Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

Introduction
You are invited to take part in this research study as you are currently a patient at Hollywood Private Hospital, aged 65 years or more, are likely to be staying at hospital for 48 hours or longer. This study is being conducted from March 2021 to March 2022 to investigate whether volunteer support and technology driven pain assessment (using the smart-device application PainChek Universal®) can improve levels of frailty and other clinical outcomes for frail older adult patients at Hollywood Private Hospital.

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Health services want to understand how they can better provide care for older adults who are frail and/or have pain.

Intervention groups
If you consent, you will be participating in a cluster randomised controlled research project comparing four types of care known as 'interventions'. Sometimes we do not know which intervention is best when caring for patients. To find out we need to compare different interventions. We put people into groups and give each group a different intervention. The results are compared to see if one is better. In a cluster randomised trial, groups of participants (in this case wards) are allocated an intervention by chance (random). Random allocation ensures the study is fair and robust.

In this study the interventions are: 1. Standard care plus nurse led volunteer support; 2. Standard care plus pain assessment using Universal®; 3. Standard care plus both nurse led volunteer support and pain assessment using PainChek Universal®; 4. Standard care. There are four wards in the hospital that are participating in the study. Each ward has been randomly allocated an intervention. You have been admitted to XXX Ward and will be receiving: 4. Standard care.

What will participation in this research involve?
If you agree to participate, while you are in hospital and after you have given your written consent to participate in the study, the following steps will occur:

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
12) At the start of your hospital stay, the project nurse will collect routine admission data and clinical information about your frailty and overall health and enter the data into an Acute Care Assessment System called interRAI™. Some of the information will have been collected on admission by ward staff, in which case the project nurse will collect the information from your file. If certain information is not available from your file the project nurse will conduct an assessment. This information will include:

   a. Activities of Daily Living
   b. Cognitive Assessment
   c. Continence
   d. Depression
   e. Falls Risk
   f. Frailty
   g. Functional Independence
   h. Medication Use
   i. Mobility
   j. Nutrition & Body Mass Index
   k. Pain Assessment
   l. Physical Deconditioning
   m. Pressure Injury Risk
   n. Quality of Life

   Where assessment is required this will involve the project nurse asking you questions and entering your responses into interRAI™ using an iPad. This will also require you to undertake (if able) a Timed Up and Go Test (TUG) to assess your mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

   As part of the admission assessment the researcher will also assess your frailty using the modified-Reported Edmonton Frail Scale, which involves asking you questions and entering your responses on an iPad. In addition to the assessment routine admission data: year of birth (not date-of-birth), gender, Aboriginal or Torres Strait Islander status, admission date, admission type (elective/acute), type of residence (home/age care facility), admitting diagnosis, and clinical information (active medical conditions) will be collected from your medical file.

13) During your hospital stay, when conducting a pain assessment ward staff will keep a record for this research project of your pain level and any actions taken in response to the pain assessment (e.g., medication given).

14) Near the end of your hospital stay, the project nurse will collect discharge data and clinical information about your frailty and overall health either from your patient file or by assessment and will enter the data into interRAI™. This information will include:

   a. Active Medical Conditions
   b. Activities of Daily Living
   c. Adverse Incidents
   d. Cognitive Assessment

   Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
e. Continence  
f. Depression  
g. Discharge Destination  
h. Falls Risk  
i. Frailty  
j. Functional Independence  
k. Length of Stay  
l. Medication Use  
m. Mobility  
n. Nutrition & Body Mass Index  
o. Pain Assessment  
p. Physical Deconditioning  
q. Pressure Injury Risk  
r. Quality of Life

Where assessment is required this will involve the project nurse asking you questions and entering your responses into interRAI™ using an iPad. This will also require you to undertake (if able) a Timed Up and Go Test (TUG) to assess your mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

15/30 days after you have been discharged from hospital, a research team member will contact you by telephone to conduct a final verbal questionnaire which will take approximately 15 minutes in total and includes 3 aspects:

a. Frailty Assessment (mod-REFS)  
b. Hospital Readmission Questionnaire  
c. Australian Quality of Life Questionnaire (A-QoL-4D)

Do I have to take part in this research project?  
Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide you don’t want to continue taking part you are free to discontinue and withdraw from the project at any time, without providing an explanation unless you choose to. Your hospital care will not be jeopardised in any way by your non-participation.

What are the possible benefits of taking part?  
We cannot guarantee or promise that you will receive any direct benefit from this research. You may get some satisfaction from knowing that you are assisting in contributing to better care delivery for patients who are frail and/or in pain.

What are the possible risks and disadvantages of taking part?  
Other than some inconvenience regarding the time required to complete the additional assessments with the project nurse and the post-discharge telephone call with a researcher, there are no risks or disadvantages to participating in this study.

What if I withdraw from this research project?

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
If at any time you decide you don’t want to continue taking part in the research project you are free to discontinue and withdraw from the project without prejudice. Choosing to withdraw from the project will not affect your current or future medical care. If you decide to withdraw from the project, please notify the project nurse or contact the lead researcher (contact details below). No further data will be collected from the date of withdrawal, although data and personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the researchers up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

What will happen to information about me?

By providing written consent you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Prior to analysis all data will be de-identified (i.e., names will be removed) and each participant will be allocated a unique code. Hard copy (paper) forms will be stored in locked filing cabinets accessible only by Edith Cowan University research team members. Data and participant information will be stored securely on University servers only accessible by Edith Cowan University research team members on password protected computers. The interRAI™ data will be stored on a secure server at the University of Queensland accessible only by the research team via password. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All data will be destroyed after seven years in line with University guidelines.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Given that all data will be de-identified prior to analysis identification to one single participant will be impossible.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

If you would like to receive copies of publications resulting from this research, please tick the box below and provide your email or postal address:

☐ Yes, I would like to receive publications resulting from this research, via:

Email: __________________________________________

OR Post: _________________________________________

__________________________

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Who is organizing and funding the research?
This research project is being conducted by the School of Nursing and Midwifery at Edith Cowan University in collaboration with Hollywood Private Hospital. The project has been funded by the Ramsay Hospital Research Foundation.

Further information and who to contact
If you have any questions about the research, you can contact the following people:

Dr Rosemary Saunders
Lead Researcher
Phone: (08) 6304 3513
Email: Rosemary.Saunders@ecu.edu.au

Associate Professor Christopher Etherton-Beer
Lead Researcher
Phone: (08) 9224 2750
Email: Christopher.Etherton-Beer@uwa.edu.au

Deb Scaini
Project Nurse
Phone: (08) 9346 6023
Email: scainid@ramsayhealth.com.au

Ethics Approval
This research project has been approved by the Ramsay Health Care WA/SA Human Research Ethics Committee (ref 2057) and the Edith Cowan University Human Research Ethics Committee (ref 2021-02210-SAUNDERS).

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

Executive Officer
WA/SA Human Research Ethics Committee
Ramsay Health Care
Phone: (08) 9400 9400 (ext. 6404)
Or: (08) 9400 9897
Email: RamsayHREC.WA-SA@ramsayhealth.com.au

Research Ethics Officer
Edith Cowan University
270 Joondalup Drive
Joondalup WA 6027
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Participant Consent Form (Intervention – Patient)

**Title:** Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

**Lead Researchers:** Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

**Study Site:** Hollywood Private Hospital, Gate 2/101 Monash Ave, Nedlands WA 6009

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

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<th>Name of Participant (please print)</th>
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<td>Signature</td>
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**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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<th>Name of Researcher† (please print)</th>
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<td>Signature</td>
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† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

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**Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)**

Participant Information and Consent Form
(Intervention – Proxy Ward 1)

Title: Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

Lead Researchers: Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

Introduction
You and your family member (the patient) are invited to take part in this research study as your family member is currently a patient at Hollywood Private Hospital, they are aged 65 years or more, they are likely staying at hospital for 48 hours or longer. You are being asked to consent as the Research Decision Maker on behalf of the patient, as the patient cannot consent for themselves due to cognitive impairment. An independent medical practitioner has confirmed in writing that the patient is unlikely to regain the capacity to consent to the research within the timeframe of the project and that the research activity is not adverse to the patient’s interests.

This study is being conducted from March 2021 to March 2022 to investigate whether volunteer support and technology driven pain assessment (using the smart-device application PainChek Universal®) can improve levels of frailty and other clinical outcomes for frail older adult patients at Hollywood Private Hospital.

Your participation and the patient’s participation in this study are entirely voluntary. If you decide to participate, you will be asked to provide written consent on behalf of both yourself and the patient and you may keep this Participant Information Sheet and the Consent Form for your records.

What is the purpose of this study?
Health services want to understand how they can better provide care for older adults who are frail and/or have pain.

Intervention groups
If you consent, the patient will be participating in a cluster randomised controlled research project comparing four types of care known as ‘interventions’. Sometimes we do not know which intervention is best when caring for patients. To find out we need to compare different interventions. We put people into groups and give each group a different intervention. The results are compared to see if one is better. In a cluster randomised trial groups of participants, in this case wards, are allocated an intervention by chance (random). Random allocation ensures the study is fair and robust.

In this study the interventions are: 1. Standard care plus nurse led volunteer support; 2. Standard care plus pain assessment using PainChek Universal®; 3. Standard care plus both nurse led volunteer support and pain assessment using PainChek Universal®; 4. Standard care. There are four wards in the hospital that are participating in the...
study. Each ward has been randomly allocated an intervention. The patient has been admitted to XXX Ward and will be receiving: 1. Standard care plus nurse led volunteer support.

What will participation in this research involve?
If you agree to yourself and the patient participating, while the patient is in hospital and after you have given your written consent on behalf of yourself and the patient to participate in the study, the following steps will occur:

16) At the start of the patient’s hospital stay, the project nurse will collect routine admission data and clinical information about their frailty and overall health and enter the data into an Acute Care Assessment System called interRAI™. Some of the information will have been collected on admission by ward staff, in which case the project nurse will collect the information from the patient’s file. If certain information is not available from the file the project nurse will conduct an assessment. This information will include:

   a. Activities of Daily Living
   b. Cognitive Assessment
   c. Continence
   d. Depression
   e. Falls Risk
   f. Frailty
   g. Functional Independence
   h. Medication Use
   i. Mobility
   j. Nutrition & Body Mass Index
   k. Pain Assessment
   l. Physical Deconditioning
   m. Pressure Injury Risk
   n. Quality of Life

Where assessment is required this will involve the project nurse asking you questions about the patient and entering your responses into interRAI™ using an iPad. This will also require the patient to undertake (if able) a Timed Up and Go Test (TUG) to assess their mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

On the basis of the admission assessment the project nurse will develop a personalised “Volunteer Care Plan” (in consultation with ward staff and yourself) that will describe the volunteer support that the patient will receive. This might include assistance with walking, assistance with meals and/or companionship. During the patient’s hospital stay he/she will receive up to one hour volunteer support from a trained project volunteer up to two times a day. A record will be kept of the type and duration of volunteer support the patient receives. The volunteer care plan and record of volunteer support will be added to the patient’s file.
As part of the admission assessment the researcher will also assess the patient's frailty using the modified-Reported Edmonton Frail Scale, which involves asking you questions and entering your responses on an iPad. In addition to the assessment routine admission data: year of birth (not date-of-birth), gender, Aboriginal or Torres Strait Islander status, admission date, admission type (elective/acute), type of residence (home/age care facility), admitting diagnosis, and clinical information (active medical conditions) will be collected from the patient medical file.

17) During the patient's hospital stay, when conducting a pain assessment ward staff will keep a record for this research project of the patient's pain level and any actions taken in response to the pain assessment (e.g., medication given).

18) Near the end of the patient's hospital stay, the project nurse will collect discharge data and clinical information about their frailty and overall health either from the patient file or by assessment and will enter the data into interRAI™. This information will include:

   a. Active Medical Conditions
   b. Activities of Daily Living
   c. Adverse Incidents
   d. Cognitive Assessment
   e. Continence
   f. Depression
   g. Discharge Destination
   h. Falls Risk
   i. Frailty
   j. Functional Independence
   k. Length of Stay
   l. Medication Use
   m. Mobility
   n. Nutrition & Body Mass Index
   o. Pain Assessment
   p. Physical Deconditioning
   q. Pressure Injury Risk
   r. Quality of Life

   Where assessment is required this will involve the project nurse asking you questions about the patient and entering your responses into interRAI™ using an iPad. This will also require the patient to undertake (if able) a Timed Up and Go Test (TUG) to assess their mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

19) Within 48 hours of discharge a researcher will contact you by telephone to conduct a verbal evaluation survey which will take 5-10 minutes:
   b. Evaluation Survey
20) 30 days after the patient has been discharged from hospital, a research team member will contact you by telephone to conduct a final verbal questionnaire which will take approximately 10 minutes in total and includes 2 aspects:

a. Frailty Assessment (mod-REFS)
b. Hospital Readmission Questionnaire

Do the patient and I have to take part in this pre-screening?
Participation in any research is voluntary. If you do not wish to take part or you do not wish the patient to take part, you do not have to give consent. If you decide you don’t want to continue taking part you are free to discontinue and withdraw the patient from the project at any time, without providing an explanation unless you choose to. The patient’s hospital care will not be jeopardised in any way by non-participation.

What are the possible benefits of taking part?
We cannot guarantee or promise that you or the patient will receive any direct benefit from this research. You may get some satisfaction from knowing that you and the patient are assisting in contributing to better care delivery for patients who are frail and/or in pain.

What are the possible risks and disadvantages of taking part?
Other than some inconvenience regarding the time required to complete the additional assessments with the project nurse and the post-discharge telephone call with a researcher, there are no risks or disadvantages to participating in this study. By consenting to be part of this study you are agreeing to the patient receiving volunteer support.

What if I withdraw the patient from the research project?
If at any time you decide you don’t want the patient to continue taking part in the research project you are free to discontinue and withdraw them from the project without prejudice. Choosing to withdraw from the project will not affect the patient’s current or future medical care. If you decide to withdraw the patient from the project, please notify the project nurse or contact the lead researcher (contact details below). No further data will be collected from the date of withdrawal, although data and personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the researchers up to the time you withdraw the patient will form part of the research project results. If you do not want the patient’s data to be included, you must tell the researchers when you withdraw from the research project.

What will happen to information about the patient?
By providing written consent you consent to the relevant research staff collecting and using personal information about the patient for the research project. Any information obtained in connection with this research project that can identify you and the patient will remain confidential. Prior to analysis all data will be de-identified (i.e., names will be removed) and each participant will be allocated a unique code. Hard copy (paper) forms will be stored in locked filing cabinets accessible only by Edith Cowan University.

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
research team members. Data and participant information will be stored securely on University servers only accessible by Edith Cowan University research team members on password protected computers. The interRAI™ data will be stored on a secure server at the University of Queensland accessible only by the research team via password. Patient information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All data will be destroyed after seven years in line with University guidelines.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the patient cannot be identified, except with your permission. Given that all data will be de-identified prior to analysis identification to one single participant will be impossible.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the patient’s information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

If you would like to receive copies of publications resulting from this research, please tick the box below and provide your email or postal address:

☐ Yes, I would like to receive publications resulting from this research, via:

   Email: _____________________________________________
   OR Post: _____________________________________________
   _____________________________________________

Who is organizing and funding the research?
This research project is being conducted by the School of Nursing and Midwifery at Edith Cowan University in collaboration with Hollywood Private Hospital. The project has been funded by the Ramsay Hospital Research Foundation.

Further information and who to contact
If you have any questions about the research, you can contact the following people:

Dr Rosemary Saunders
Phone: (08) 6304 3513
Email: Rosemary.Saunders@ecu.edu.au

Associate Professor Christopher Etherton-Beer
Lead Researcher
Phone: (08) 9224 2750
Email: Christopher.Etherton-Beer@uwa.edu.au

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Ethics Approval
This research project has been approved by the Ramsay Health Care WA/SA Human Research Ethics Committee (ref 2057) and the Edith Cowan University Human Research Ethics Committee (ref 2021-02210-SAUNDERS).

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

Executive Officer
WA/SA Human Research Ethics Committee
Ramsay Health Care
Phone: (08) 9400 9400 (ext. 6404)
Or: (08) 9400 9897
Email: RamsayHREC.WA-SA@ramsayhealth.com.au

Research Ethics Officer
Edith Cowan University
270 Joondalup Drive
Joondalup WA 6027
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Participant Consent Form (Intervention – Family Proxy)

**Title:** Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

**Lead Researchers:** Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia

**Study Site:** Hollywood Private Hospital, Gate 2/101 Monash Ave, Nedlands WA 6009

**Declaration by Person Responsible**
I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to both myself (the 'Family-Participant' & 'Person Responsible') and the patient (the 'Patient-Participant') taking part in this research project as described and understand that I am free to withdraw myself or them at any time during the project without affecting their future care.

I understand that I will be given a signed copy of this document to keep.

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<th>Name of Patient-Participant (please print)</th>
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<td>Name of Family-Participant and Person Responsible for Patient-Participant (please print)</td>
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<td>Relationship of Person Responsible to Patient-Participant</td>
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<td>Signature of Family-Participant and Person Responsible</td>
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**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible for the participant has understood that explanation.

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<th>Name of Researcher† (please print)</th>
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<td>Signature</td>
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† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)**
# Medical Research involving Research Decision-Maker

**Research Study Title**
Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: A cluster randomised control trial

**Short Title**
Nurse Led Volunteer Support and PainChek®: Frailty Trial (VP-Frailty)

**Protocol Number**
ACTRN12620001173987p

**Lead Researcher** *(must be a medical practitioner)*
Dr Christopher Etherton-Beer

**Study Site**
Hollywood Private Hospital

## Declaration by Research Decision Maker
- I am the Research Decision Maker who may consent or refuse consent for ____________________________ [Participant’s Name] (the Participant) to participate in Medical Research.
- I am over 18 years of age.
- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I have received and considered the determinations of an independent medical practitioner, Dr ____________________________ [Name of Independent Medical Practitioner] regarding the best interests and risk to the Participant with regards to their participation in this Medical Research.
- I believe that the participation of the participant in this study is in their best interests or not adverse to their interests. Specifically as I understand it, the research that the Participant will participate in:
  - will only involve observing the candidate or carrying out another non-invasive examination, treatment or procedure; or
  - will not involve any known substantial risks to the candidate; or
  - will not involve any known substantial risks to the candidate greater than the risks associated with the existing treatment available to the Participant; or
  - will not involve substantial risks to the candidate greater than if the candidate did not participate in the research.
- I have made a decision to allow the participant to participate in this research project as described and understand that I am free to revoke this decision at any time during the research project without affecting the Participants future health care.
- If the Participant attains the ability to consent in the timeframe for this research (as approved by the RHC WA(SA HREC)), then my ability to make a decision regarding the Participants participation in this research study will cease and their participation will also cease and not be recommenced unless the Participant provides their own.
- I am not aware of any advance health directive relating to the Participant that would prevent their participation in this Medical Research.

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**Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)**
I understand that I will be given a signed copy of this document to keep on behalf of the Participant.

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*Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness* to informed consent is required*

<p>| Name of Witness* to |
| Research Decision Maker’s Signature |</p>
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* Witness is *not* to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may *not* act as a witness to the consent process. Witness must be 18 years or older.

**Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)**
Participant Information and Consent Form
(Intervention – Proxy Ward 3)

Title: Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

Lead Researchers: Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

Introduction
You and your family member (the patient) are invited to take part in this research study as your family member is currently a patient at Hollywood Private Hospital, they are aged 65 years or more, they are likely staying at hospital for 48 hours or longer. You are being asked to consent as the Research Decision Maker on behalf of the patient, as the patient cannot consent for themselves due to cognitive impairment. An independent medical practitioner has confirmed in writing that the patient is unlikely to regain the capacity to consent to the research within the timeframe of the project and that the research activity is not adverse to the patient’s interests.

This study is being conducted from March 2021 to March 2022 to investigate whether volunteer support and technology driven pain assessment (using the smart-device application PainChek Universal®) can improve levels of frailty and other clinical outcomes for frail older adult patients at Hollywood Private Hospital.

Your participation and the patient’s participation in this study are entirely voluntary. If you decide to participate, you will be asked to provide written consent on behalf of both yourself and the patient and you may keep this Participant Information Sheet and the Consent Form for your records.

What is the purpose of this study?
Health services want to understand how they can better provide care for older adults who are frail and/or have pain.

Intervention groups
If you consent, the patient will be participating in a cluster randomised controlled research project comparing four types of care known as ‘interventions’. Sometimes we do not know which intervention is best when caring for patients. To find out we need to compare different interventions. We put people into groups and give each group a different intervention. The results are compared to see if one is better. In a cluster randomised trial groups of participants, in this case wards, are allocated an intervention by chance (random). Random allocation ensures the study is fair and robust.

In this study the interventions are: 1. Standard care plus nurse led volunteer support; 2. Standard care plus pain assessment using PainChek Universal®; 3. Standard care plus both nurse led volunteer support and pain assessment using PainChek Universal®; 4. Standard care. There are four wards in the hospital that are participating

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
in the study. Each ward has been randomly allocated an intervention. The patient has been admitted to XXX Ward and will be receiving: 3. Standard care plus both nurse led volunteer support and pain assessment using PainChek Universal®.

What will participation in this research involve?
If you agree to yourself and the patient participating, while the patient is in hospital and after you have given your written consent on behalf of yourself and the patient to participate in the study, the following steps will occur:

21) At the start of the patient’s hospital stay, the project nurse will collect routine admission data and clinical information about their frailty and overall health and enter the data into an Acute Care Assessment System called interRAI™. Some of the information will have been collected on admission by ward staff, in which case the project nurse will collect the information from the patient’s file. If certain information is not available from the file the project nurse will conduct an assessment. This information will include:
   a. Activities of Daily Living
   b. Cognitive Assessment
   c. Continence
   d. Depression
   e. Falls Risk
   f. Frailty
   g. Functional Independence
   h. Medication Use
   i. Mobility
   j. Nutrition & Body Mass Index
   k. Pain Assessment
   l. Physical Deconditioning
   m. Pressure Injury Risk
   n. Quality of Life

Where assessment is required this will involve the project nurse asking you questions about the patient and entering your responses into interRAI™ using an iPad. This will also require the patient to undertake (if able) a Timed Up and Go Test (TUG) to assess their mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

On the basis of the admission assessment the project nurse will develop a personalised “Volunteer Care Plan” (in consultation with ward staff and yourself) that will describe the volunteer support that the patient will receive. This might include assistance with walking, assistance with meals and/or companionship. During the patient’s hospital stay he/she will receive up to one hour volunteer support from a trained project volunteer up to two times a day. A record will be kept of the type and duration of volunteer support the patient receives. The volunteer care plan and record of volunteer support will be added to the patient’s file.

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
As part of the admission assessment the researcher will also assess the patient’s frailty using the modified-Reported Edmonton Frail Scale, which involves asking you questions and entering your responses on an iPad. In addition to the assessment routine admission data: year of birth (not date-of-birth), gender, Aboriginal or Torres Strait Islander status, admission date, admission type (elective/acute), type of residence (home/age care facility), admitting diagnosis, and clinical information (active medical conditions) will be collected from the patient medical file.

22) During the patient’s hospital stay nurses will assess the patient’s pain as part of routine care using PainChek Universal® on an iPad. PainChek Universal® is a secure medical device in the form of a smart device application, which uses artificial intelligence to assess and score pain levels in real time. The application has been validated and is used for assessing pain in people who cannot verbalise their pain in other settings. PainChek Universal® works by using facial recognition technology using the devices camera function to detect pain through facial muscle movements, together with other pain cues such as vocalisation to identify and quantify pain. The application does not store any images of the patient and it adheres to strict medical privacy and confidentiality legislation (for more information you can visit https://painchek.com/). PainChek Universal® use and data, and the actions taken in response by the nurse performing the assessment (e.g., medication given) will be recorded for this research project. The PainChek Universal® data will be added to the patient’s file.

23) Near the end of the patient’s hospital stay, the project nurse will collect discharge data and clinical information about their frailty and overall health either from the patient file or by assessment and will enter the data into interRAI™. This information will include:

   a. Active Medical Conditions
   b. Activities of Daily Living
   c. Adverse Incidents
   d. Cognitive Assessment
   e. Continence
   f. Depression
   g. Discharge Destination
   h. Falls Risk
   i. Frailty
   j. Functional Independence
   k. Length of Stay
   l. Medication Use
   m. Mobility
   n. Nutrition & Body Mass Index
   o. Pain Assessment
   p. Physical Deconditioning
   q. Pressure Injury Risk

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
r. Quality of Life

Where assessment is required this will involve the project nurse asking you questions about the patient and entering your responses into interRAI™ using an iPad. This will also require the patient to undertake (if able) a Timed Up and Go Test (TUG) to assess their mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

24) Within 48 hours of discharge a researcher will contact you by telephone to conduct a verbal evaluation survey which will take 5-10 minutes:

a. Evaluation Survey

25) 30 days after the patient has been discharged from hospital, a research team member will contact you by telephone to conduct a final verbal questionnaire which will take approximately 10 minutes in total and includes 2 aspects:

a. Frailty Assessment (mod-REFS)

b. Hospital Readmission Questionnaire

Do the patient and I have to take part in this pre-screening?

Participation in any research is voluntary. If you do not wish to take part or you do not wish the patient to take part, you do not have to give consent. If you decide you don’t want to continue taking part you are free to discontinue and withdraw the patient from the project at any time, without providing an explanation unless you choose to. The patient’s hospital care will not be jeopardised in any way by non-participation.

What are the possible benefits of taking part?

We cannot guarantee or promise that you or the patient will receive any direct benefit from this research. You may get some satisfaction from knowing that you and the patient are assisting in contributing to better care delivery for patients who are frail and/or in pain.

What are the possible risks and disadvantages of taking part?

Other than some inconvenience regarding the time required to complete the additional assessments with the project nurse and the post-discharge telephone call with a researcher, there are no risks or disadvantages to participating in this study. By consenting to be part of this study you are agreeing to the patient receiving volunteer support.

What if I withdraw the patient from the research project?

If at any time you decide you don’t want the patient to continue taking part in the research project you are free to discontinue and withdraw them from the project without prejudice. Choosing to withdraw from the project will not affect the patient’s current or future medical care. If you decide to withdraw the patient from the project, please notify the project nurse or contact the lead researcher (contact details below). No further data will be collected from the date of withdrawal, although data and personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
aware that data collected by the researchers up to the time you withdraw the patient will form part of the research project results. If you do not want the patient's data to be included, you must tell the researchers when you withdraw from the research project.

**What will happen to information about the patient?**

By providing written consent you consent to the relevant research staff collecting and using personal information about the patient for the research project. Any information obtained in connection with this research project that can identify you and the patient will remain confidential. Prior to analysis all data will be de-identified (i.e., names will be removed) and each participant will be allocated a unique code. Hard copy (paper) forms will be stored in locked filing cabinets accessible only by Edith Cowan University research team members. Data and participant information will be stored securely on University servers only accessible by Edith Cowan University research team members on password protected computers. The interRAI™ data will be stored on a secure server at the University of Queensland accessible only by the research team via password. PainChek Universal® data will be stored in a repository within the PainChek Universal® secure cloud database. PainChek Universal® data will only be accessible by the research team members via a password protected Web Administration Portal. Patient information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All data will be destroyed after seven years in line with University guidelines.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the patient cannot be identified, except with your permission. Given that all data will be de-identified prior to analysis identification to one single participant will be impossible.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the patient’s information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

If you would like to receive copies of publications resulting from this research, please tick the box below and provide your email or postal address:

- [ ] Yes, I would like to receive publications resulting from this research, via:

  - Email: ________________________________
  - OR Post: ________________________________

  __________________________________________________________________________

__Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)__

Who is organizing and funding the research?
This research project is being conducted by the School of Nursing and Midwifery at Edith Cowan University in collaboration with Hollywood Private Hospital. The project has been funded by the Ramsay Hospital Research Foundation.

Further information and who to contact
If you have any questions about the research, you can contact the following people:

Dr Rosemary Saunders
Phone: (08) 6304 3513
Email: Rosemary.Saunders@ecu.edu.au

Associate Professor Christopher Etherton-Beer
Lead Researcher
Phone: (08) 9224 2750
Email: Christopher.Etherton-Beer@uwa.edu.au

Ethics Approval
This research project has been approved by the Ramsay Health Care WA/SA Human Research Ethics Committee (ref 2057) and the Edith Cowan University Human Research Ethics Committee (ref 2021-02210-SAUNDERS).

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

Executive Officer
WA/SA Human Research Ethics Committee
Ramsay Health Care
Phone: (08) 9400 9400 (ext. 6404)
Or: (08) 9400 9897
Email: RamsayHREC.WA-SA@ramsayhealth.com.au

Research Ethics Officer
Edith Cowan University
270 Joondalup Drive
Joondalup WA 6027
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
# Participant Consent Form (Intervention – Family Proxy)

**Title:** Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

**Lead Researchers:** Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia

**Study Site:** Hollywood Private Hospital, Gate 2/101 Monash Ave, Nedlands WA 6009

**Declaration by Person Responsible**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to both myself (the ‘Family-Participant’ & ‘Person Responsible’) and the patient (the ‘Patient-Participant’) taking part in this research project as described and understand that I am free to withdraw myself or them at any time during the project without affecting their future care.

I understand that I will be given a signed copy of this document to keep.

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<th>Name of Patient-Participant (please print)</th>
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<tr>
<td>Name of Family-Participant and Person Responsible for Patient-Participant (please print)</td>
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<td>Relationship of Person Responsible to Patient-Participant</td>
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<tr>
<td>Signature of Family-Participant and Person Responsible</td>
<td>Date</td>
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**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible for the participant has understood that explanation.

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<th>Name of Researcher† (please print)</th>
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<td>Signature</td>
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† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

* Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
# Medical Research involving Research Decision-Maker

**Research Study Title**

Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: A cluster randomised control trial

**Short Title**

Nurse Led Volunteer Support and PainChek®: Frailty Trial (VP-Frailty)

**Protocol Number**

ACTRN12620001173987p

**Lead Researcher** (must be a medical practitioner)

Dr Christopher Etherton-Beer

**Study Site**

Hollywood Private Hospital

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**Declaration by Research Decision Maker**

- I am the Research Decision Maker who may consent or refuse consent for ____________________________ [(Participant's Name)] (the Participant) to participate in Medical Research.
- I am over 18 years of age.
- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I have received and considered the determinations of an independent medical practitioner, Dr ____________________________ [(Name of Independent Medical Practitioner)] regarding the best interests and risk to the Participant with regards to their participation in this Medical Research.
- I believe that the participation of the participant in this study is in their best interests or not adverse to their interests. Specifically as I understand it, the research that the Participant will participate in:
  - will only involve observing the candidate or carrying out another non-invasive examination, treatment or procedure; or
  - will not involve any known substantial risks to the candidate; or
  - will not involve any known substantial risks to the candidate greater than the risks associated with the existing treatment available to the Participant; or
  - will not involve substantial risks to the candidate greater than if the candidate did not participate in the research.
- I have made a decision to allow the participant to participate in this research project as described and understand that I am free to revoke this decision at any time during the research project without affecting the Participants future health care.
- If the Participant attains the ability to consent in the timeframe for this research (as approved by the RHC WAISA HREC), then my ability to make a decision regarding the Participants participation in this research study will cease and their participation will also cease and not be recommenced unless the Participant provides their own.
- I am not aware of any advance health directive relating to the Participant that would prevent their participation in this Medical Research.

_Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)_
- I understand that I will be given a signed copy of this document to keep on behalf of the Participant.

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<th>Name of Participant (please print)</th>
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<td>Name of Research Decision Maker (please)</td>
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<td>Relationship of Research Decision Maker to Participant</td>
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<td>Signature of Research Decision</td>
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*Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness* to informed consent is required

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<th>Name of Witness* to Research Decision Maker’s Signature (please print)</th>
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* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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*Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)*
Participant Information and Consent Form
(Intervention – Proxy Ward 4)

Title: Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

Lead Researchers: Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia.

Introduction
You and your family member (the patient) are invited to take part in this research study as your family member is currently a patient at Hollywood Private Hospital, they are aged 65 years or more, they are likely staying at hospital for 48 hours or longer. You are being asked to consent as the Research Decision Maker on behalf of the patient, as the patient cannot consent for themselves due to cognitive impairment. An independent medical practitioner has confirmed in writing that the patient is unlikely to regain the capacity to consent to the research within the timeframe of the project and that the research activity is not adverse to the patient’s interests.

This study is being conducted from March 2021 to March 2022 to investigate whether volunteer support and technology driven pain assessment (using the smart-device application PainChek Universal®) can improve levels of frailty and other clinical outcomes for frail older adult patients at Hollywood Private Hospital.

Your participation and the patient’s participation in this study are entirely voluntary. If you decide to participate, you will be asked to provide written consent on behalf of both yourself and the patient and you may keep this Participant Information Sheet and the Consent Form for your records.

What is the purpose of this study?
Health services want to understand how they can better provide care for older adults who are frail and/or have pain.

Intervention groups
If you consent, the patient will be participating in a cluster randomised controlled research project comparing four types of care known as ‘interventions’. Sometimes we do not know which intervention is best when caring for patients. To find out we need to compare different interventions. We put people into groups and give each group a different intervention. The results are compared to see if one is better. In a cluster randomised trial groups of participants, in this case wards, are allocated an intervention by chance (random). Random allocation ensures the study is fair and robust.

In this study the interventions are: 1. Standard care plus nurse led volunteer support; 2. Standard care plus pain assessment using PainChek Universal®; 3. Standard care plus both nurse led volunteer support and pain assessment using PainChek Universal®; 4. Standard care. There are four wards in the hospital that are participating in this study.

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
in the study. Each ward has been randomly allocated an intervention. The patient has been admitted to XXX Ward and will be receiving: 4. Standard care.

What will participation in this research involve?
If you agree to yourself and the patient participating, while the patient is in hospital and after you have given your written consent on behalf of yourself and the patient to participate in the study, the following steps will occur:

26) At the start of the patient's hospital stay, the project nurse will collect routine admission data and clinical information about their frailty and overall health and enter the data into an Acute Care Assessment System called interRAI™. Some of the information will have been collected on admission by ward staff, in which case the project nurse will collect the information from the patient's file. If certain information is not available from the file the project nurse will conduct an assessment. This information will include:

a. Activities of Daily Living
b. Cognitive Assessment
c. Continence
d. Depression
e. Falls Risk
f. Frailty
g. Functional Independence
h. Medication Use
   i. Mobility
   j. Nutrition & Body Mass Index
   k. Pain Assessment
   l. Physical Deconditioning
   m. Pressure Injury Risk
   n. Quality of Life

Where assessment is required this will involve the project nurse asking you questions about the patient and entering your responses into interRAI™ using an iPad. This will also require the patient to undertake (if able) a Timed Up and Go Test (TUG) to assess their mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

As part of the admission assessment the researcher will also assess the patient's frailty using the modified-Reported Edmonton Frail Scale, which involves asking you questions and entering your responses on an iPad. In addition to the assessment routine admission data: year of birth (not date-of-birth), gender, Aboriginal or Torres Strait Islander status, admission date, admission type (elective/acute), type of residence (home/age care facility), admitting diagnosis, and clinical information (active medical conditions) will be collected from the patient medical file.
27) During the patient's hospital stay, when conducting a pain assessment ward staff will keep a record for this research project of the patient's pain level and any actions taken in response to the pain assessment (e.g., medication given).

28) Near the end of the patient's hospital stay, the project nurse will collect discharge data and clinical information about their frailty and overall health either from the patient file or by assessment and will enter the data into interRAI™. This information will include:

- Active Medical Conditions
- Activities of Daily Living
- Adverse Incidents
- Cognitive Assessment
- Continence
- Depression
- Discharge Destination
- Falls Risk
- Frailty
- Functional Independence
- Length of Stay
- Medication Use
- Mobility
- Nutrition & Body Mass Index
- Pain Assessment
- Physical Deconditioning
- Pressure Injury Risk
- Quality of Life

Where assessment is required this will involve the project nurse asking you questions about the patient and entering your responses into interRAI™ using an iPad. This will also require the patient to undertake (if able) a Timed Up and Go Test (TUG) to assess their mobility, balance, and walking ability (unless already completed by a physiotherapist). The assessments will take around 20 minutes.

29) 30 days after the patient has been discharged from hospital, a research team member will contact you by telephone to conduct a final verbal questionnaire which will take approximately 10 minutes in total and includes 2 aspects:

- Frailty Assessment (mod-REFS)
- Hospital Readmission Questionnaire

**Do the patient and I have to take part in this pre-screening?**

Participation in any research is voluntary. If you do not wish to take part or you do not wish the patient to take part, you do not have to give consent. If you decide you don’t want to continue taking part you are free to discontinue and withdraw the patient from the project at any time, without providing an explanation unless you choose to. The patient’s hospital care will not be jeopardised in any way by non-participation.
What are the possible benefits of taking part?
We cannot guarantee or promise that you or the patient will receive any direct benefit from this research. You may get some satisfaction from knowing that you and the patient are assisting in contributing to better care delivery for patients who are frail and/or in pain.

What are the possible risks and disadvantages of taking part?
Other than some inconvenience regarding the time required to complete the additional assessments with the project nurse and the post-discharge telephone call with a researcher, there are no risks or disadvantages to participating in this study.

What if I withdraw the patient from the research project?
If at any time you decide you don't want the patient to continue taking part in the research project you are free to discontinue and withdraw them from the project without prejudice. Choosing to withdraw from the project will not affect the patient's current or future medical care. If you decide to withdraw the patient from the project, please notify the project nurse or contact the lead researcher (contact details below). No further data will be collected from the date of withdrawal, although data and personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the researchers up to the time you withdraw the patient will form part of the research project results. If you do not want the patient's data to be included, you must tell the researchers when you withdraw from the research project.

What will happen to information about the patient?
By providing written consent you consent to the relevant research staff collecting and using personal information about the patient for the research project. Any information obtained in connection with this research project that can identify you and the patient will remain confidential. Prior to analysis all data will be de-identified (i.e., names will be removed) and each participant will be allocated a unique code. Hard copy (paper) forms will be stored in locked filing cabinets accessible only by Edith Cowan University research team members. Data and participant information will be stored securely on University servers only accessible by Edith Cowan University research team members on password protected computers. The interRAI™ data will be stored on a secure server at the University of Queensland accessible only by the research team via password. Patient information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All data will be destroyed after seven years in line with University guidelines.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the patient cannot be identified, except with your permission. Given that all data will be de-identified prior to analysis identification to one single participant will be impossible.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the patient's information collected and stored by the research team. You also have the right to request that any information with which you disagree

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
be corrected. Please contact the study team member named at the end of this
document if you would like to access your information.

If you would like to receive copies of publications resulting from this research, please
tick the box below and provide your email or postal address (see next page):

☐ Yes, I would like to receive publications resulting from this research, via:

Email: ____________________________________________

OR Post: ____________________________________________

Who is organizing and funding the research?
This research project is being conducted by the School of Nursing and Midwifery at
Edith Cowan University in collaboration with Hollywood Private Hospital. The project
has been funded by the Ramsay Hospital Research Foundation.

Further information and who to contact
If you have any questions about the research, you can contact the following people:

Dr Rosemary Saunders
Phone: (08) 6304 3513
Email: Rosemary.Saunders@ecu.edu.au

Associate Professor Christopher Etherton-Beer
Lead Researcher
Phone: (08) 9224 2750
Email: Christopher.Etherton-Beer@uwa.edu.au

Ethics Approval
This research project has been approved by the Ramsay Health Care WA/SA Human
Research Ethics Committee (ref 2057) and the Edith Cowan University Human
Research Ethics Committee (ref 2021-02210-SAUNDERS).

If you have any concerns or complaints about the research project and wish to talk to
an independent person, you may contact:

Executive Officer
WA/SA Human Research Ethics Committee
Ramsay Health Care
Phone: (08) 9400 9400 (ext. 6404)
Or: (08) 9400 9897
Email: RamsayHREC.WA-SA@ramsayhealth.com.au

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Research Ethics Officer
Edith Cowan University
270 Joondalup Drive
Joondalup WA 6027
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Participant Consent Form (Intervention – Family Proxy)

**Title:** Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: a cluster randomised control trial.

**Lead Researchers:** Dr Rosemary Saunders, School of Nursing and Midwifery, Edith Cowan University and Associate Professor Christopher Etherton-Beer, Medical School, University of Western Australia

**Study Site:** Hollywood Private Hospital, Gate 2/101 Monash Ave, Nedlands WA 6009

**Declaration by Person Responsible**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to both myself (the 'Family-Participant' & 'Person Responsible') and the patient (the 'Patient-Participant') taking part in this research project as described and understand that I am free to withdraw myself or them at any time during the project without affecting their future care.

I understand that I will be given a signed copy of this document to keep.

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**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible for the participant has understood that explanation.

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† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Medical Research involving Research Decision-Maker

Research Study Title

Optimising outcomes for frail hospitalised older adults – nurse led volunteer support and pain assessment interventions: A cluster randomised control trial

Short Title

Nurse Led Volunteer Support and PainChek®: Frailty Trial (VP-Frailty)

Protocol Number

ACTRN12620001173987p

Lead Researcher (must be a medical practitioner)

Dr Christopher Etherton-Beer

Study Site

Hollywood Private Hospital

Declaration by Research Decision Maker

- I am the Research Decision Maker who may consent or refuse consent for ________ [Participant's Name] (the Participant) to participate in Medical Research.
- I am over 18 years of age.
- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I have received and considered the determinations of an independent medical practitioner, Dr ____________________________ [Name of Independent Medical Practitioner] regarding the best interests and risk to the Participant with regards to their participation in this Medical Research.
- I believe that the participation of the participant in this study is in their best interests or not adverse to their interests. Specifically as I understand it, the research that the Participant will participate in:
  o will only involve observing the candidate or carrying out another non-invasive examination, treatment or procedure; or
  o will not involve any known substantial risks to the candidate; or
  o will not involve any known substantial risks to the candidate greater than the risks associated with the existing treatment available to the Participant; or
  o will not involve substantial risks to the candidate greater than if the candidate did not participate in the research.
- I have made a decision to allow the participant to participate in this research project as described and understand that I am free to revoke this decision at any time during the research project without affecting the Participants future health care.
- If the Participant attains the ability to consent in the timeframe for this research (as approved by the RHC WA|SA HREC), then my ability to make a decision regarding the Participants participation in this research study will cease and their participation will also cease and not be recommenced unless the Participant provides their own.
- I am not aware of any advance health directive relating to the Participant that would prevent their participation in this Medical Research.

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I understand that I will be given a signed copy of this document to keep on behalf of the Participant.

Name of Participant (please print)______________________________

Name of Research Decision Maker (please ________________________

Relationship of Research Decision Maker to Participant ________________

Signature of Research Decision __________________ Date ____________

* Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness* to informed consent is required

Name of Witness* to Research Decision Maker’s Signature
(please print) _____________________________________________________

Signature __________________ Date __________________

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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