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:

   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

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:

   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

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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:

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).

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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<th>Name of Participant (please print)</th>
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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 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:

- 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

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:

- 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 discontinue and withdraw from the project at any time, without providing an

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
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
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
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
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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<thead>
<tr>
<th>Name of Participant (please print)</th>
<th>Signature</th>
<th>Date</th>
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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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<tr>
<th>Name of Researcher† (please print)</th>
<th>Signature</th>
<th>Date</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 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.

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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
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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  
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   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:

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

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).

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.

<table>
<thead>
<tr>
<th>Name of Participant (please print)</th>
<th></th>
</tr>
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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.

<table>
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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.
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.

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:** 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.

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   Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
Who is organizing and funding the research?
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Further information and who to contact
If you have any questions about the research, you can contact the following people:

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Email: Rosemary.Saunders@ecu.edu.au

Associate Professor Christopher Etherton-Beer
Lead Researcher
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Deb Scaini
Project Nurse
Phone: (08) 9346 6023
Email: scainid@ramsayhealth.com.au

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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.

<table>
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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 – 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

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

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Further information and who to contact
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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).

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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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<tr>
<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:
  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(ISA 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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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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* 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:

1) 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 device’s 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://painchk.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)
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
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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<td>Signature of Family-Participant and Person Responsible __________________________ 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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† 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 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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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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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

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:

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.

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:

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.

Nurse Led Volunteer Support and PainChek: Frailty Trial (VP Frailty)
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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<tr>
<th>Name of Patient-Participant (please print)</th>
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<tr>
<th>Name of Family-Participant and Person Responsible for Patient-Participant (please print)</th>
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<tr>
<th>Relationship of Person Responsible to Patient-Participant</th>
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<tr>
<th>Signature of Family-Participant and Person Responsible</th>
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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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‡ 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.

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

<p>| Name of Witness* to |</p>
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<th>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.

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