

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

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## ABSTRACT

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

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

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

**Trial registration number** ACTRN12620001173987.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Randomised controlled trial design provides a rigorous test of the effectiveness of nurse-led volunteer support and technology-driven pain assessment versus usual care for hospitalised older adults.
- ⇒ Use of an electronic comprehensive assessment instrument will allow measurement of a Frailty Index at admission and discharge.
- ⇒ Interventions will be randomised at the level of the ward (ie, cluster randomisation) rather than the individual due to practical constraints of the hospital environment.

## INTRODUCTION

Hospitalisation is associated with a high risk of iatrogenic harm.<sup>1</sup> There is an urgent need to develop interventions that prevent functional decline among older people requiring acute care (AC).<sup>2</sup> Older patients, particularly those who are frail, are at increased risk of adverse health-related outcomes including increased length of stay, increased risk of clinical incidents and postoperative complications, decreased functionality post discharge, readmission to hospital and death, all of which result in increased healthcare costs.<sup>3-6</sup> Evidence suggests that outcomes for frail patients can be improved, with the Asia-Pacific Clinical Practice Guidelines for the Management of Frailty recommending effective interventions including validated frailty assessment, multicomponent interventions and frailty clinical pathways.<sup>7</sup>

Pain and frailty are common in older adults; however, pain is often managed inadequately

and can accelerate functional decline,<sup>8</sup> leading to behavioural and psychosocial disturbances, such as agitation, aggression, depression, anxiety, delirium, impaired quality of life and poor clinical outcomes.<sup>9–11</sup> Therefore, effective pain assessment is critical for older adults as part of the multicomponent interventions for managing frailty.<sup>12</sup> Assessing pain usually begins with a person's verbal or non-verbal self-report using pain assessment tools but this can be challenging in older patients, consequently, technology-driven pain assessments have been developed to improve pain assessment in these patients.<sup>13–15</sup> One such application is PainChek Universal ([www.painchek.com](http://www.painchek.com)), which has sound psychometric validity and reliability and enables better assessment of pain at the point of care for patients whose ability to communicate fluctuates. PainChek Universal contains two scales: a Numeric Rating Scale for those who can self-report pain and the PainChek scale for those who cannot self-report pain. PainChek uses automated facial recognition and analysis to identify pain-related facial micro-expressions, together with a series of user completed checklists of pain behaviours to produce a pain score.<sup>13–15</sup> PainChek has been implemented and evaluated in aged care settings; however, no previous studies have evaluated its effectiveness in an AC setting.<sup>13–16</sup>

Multicomponent interventions involving volunteers for hospitalised older adults improve clinical outcomes, with a reduction in fall rates, incidences of delirium, pain and reduced length of stay.<sup>17</sup> Volunteer programmes such as the Hospital Elder Life Program (HELP), which includes multicomponent physical, nutritional and cognitive strategies, have been implemented successfully around the world and have been shown to improve quality and effectiveness of care of hospitalised older adults; to maintain cognitive and physical functioning of high-risk older adults throughout hospitalisation; maximise independence at discharge; assist with the transition from hospital to home; and prevent unplanned hospital readmissions.<sup>18–19</sup> The HELP goals were initially targeted for the prevention of delirium; however, this programme has been modified for use with frail older adults and has been found to be effective in supporting frail older people undergoing surgery.<sup>20</sup> Other volunteer programmes to support patient care have been implemented and have shown a positive impact on health outcomes for older patients in hospital related to nutrition, falls and delirium.<sup>21</sup> Nurse-led models of volunteer support that capitalise on the expertise and clinical skills of nurses are emerging,<sup>22</sup> but evaluation is limited and no rigorous clinical or cost-effectiveness analyses have been conducted. There is a knowledge gap in relation to the potential of technology-driven pain assessment, nurse-led volunteer support or a combination of the two interventions to reduce negative clinical outcomes for frail older patients in hospital.

The primary objective of the study is to evaluate the effectiveness of using nurse-led volunteer support interventions and a technology-driven pain assessment (PainChek Universal) tool compared with standard care,

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

## METHODS AND ANALYSIS

### Study design and setting

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

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

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

The primary outcome will be the change in frailty from admission to discharge as measured by the Frailty Index generated by the InterRAI Tool,<sup>23</sup> and change in frailty from admission to 30 days post discharge as measured by the modified Reported Edmonton Frail Scale (mod-REFS),<sup>24</sup> both tools have been validated for use in Australian hospitals. Secondary outcome measures include length of stay, adverse events (falls, death, delirium), activities of daily living, continence, discharge destination, quality of life, depression, cognitive function, functional independence, pain scores, pain management intervention (type and frequency including analgesic use) and unplanned 30-day readmissions.

This study will be conducted at the largest acute private hospital in Perth, Western Australia. The hospital has

over 800 licensed beds and provides a range of services including cardiology, gastroenterology, general medicine, general surgery, neurosurgery, oncology, orthopaedics, palliative care, psychiatry, rehabilitation and urology. The study will be conducted across 4 medical wards totalling 100 beds.

### Recruitment

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

Inclusion criteria:

- ▶ Patients aged 65 years and over.
- ▶ Anticipated length of stay 48 hours or longer.

Exclusion criteria:

- ▶ Non-medical patients admitted to the medical ward.
- ▶ Severe intellectual disability.
- ▶ Patients who requires isolation due to infection control precautions.

Eligible participants will be provided with verbal and written information about the study by the project nurse and will be required to provide written consent (see online supplemental material). Where a patient is unable to provide informed written consent due to cognitive impairment or inability to communicate verbally, written proxy consent will be sought from their guardian or next-of-kin following guidelines from the Western Australian Department of Health to adhere to the requirements of the Guardianship and Administration Act 1990 (WA).<sup>25</sup> Recruitment for the intervention will continue for 12 months (March 2021 to February 2022).

The interventions will be provided for the duration of the patient's hospital admission. The intervention will be discontinued if the patient is transferred off the intervention ward, becomes infectious or requests withdrawal from the study.

### Sample size calculation

The lack of literature on interventions for frailty in hospitalised older adults precludes the calculation of a required

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

### Intervention

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

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

**Table 1** Volunteer support activities in the study

Volunteer support activities	
Orientation support	Orientate patient to ward and room; place signs in room as prompts; orientate patient to date and time; situational awareness—location
Sensory support	Check glasses are clean; check glasses are on patient; check hearing aids are in position and turned on; place equipment within reach of patient; adjust TV/radio; set up music therapy
Mobility support	Check patient is wearing footwear for walking; encourage patient to walk; prompt and encourage exercises
Nutritional support	Assist patient to order meals (likes/dislikes); encourage patient to sit out in chair for meal; declutter table and arrange tray and utensils; set up for meal—open packets/take lids off; cut up food if required; encourage patient to eat and drink
Cognitive support	Read newspaper or letters/email; discuss current event; discuss areas of interest (family, photos); play games; read a book or set up talking book; reminisce (talking about past); engage in creative activities (eg, colouring)
Other support	Brush hair; provide a foot or hand massage; refresh flowers (prompt for conversation); tidy room (safe environment); assist with using phone

this information will be recorded on a pain assessment chart, which will be kept in the patients' room.

### Stakeholder evaluation

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

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

### Economic evaluation

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

### Data collection

All participants will be recruited within 24 hours of hospital admission where possible. The research nurse will complete an admission assessment with all participants, using the InterRAI AC<sup>26</sup> assessment tool and the mod-REFS Tool.<sup>24</sup> The assessments will take up to 25 min to administer and data will be entered into the online databases via a laptop. The InterRAI AC assessment will also be completed on discharge. All participants will be followed up by telephone at 30 days post discharge, and information on hospital readmissions will be collected, and the frailty (mod-REFS)<sup>24</sup> and Quality of Life (12-item

AQoL-4D)<sup>27</sup> tools will be administered. For patients for whom proxy consent was obtained, the hospital readmission questionnaire and mod-REFS will be completed by the proxy on behalf of the patient. Figure 1 presents a summary of the data collection and the details of the measurements for assessing the primary and secondary outcomes are summarised in table 2.

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

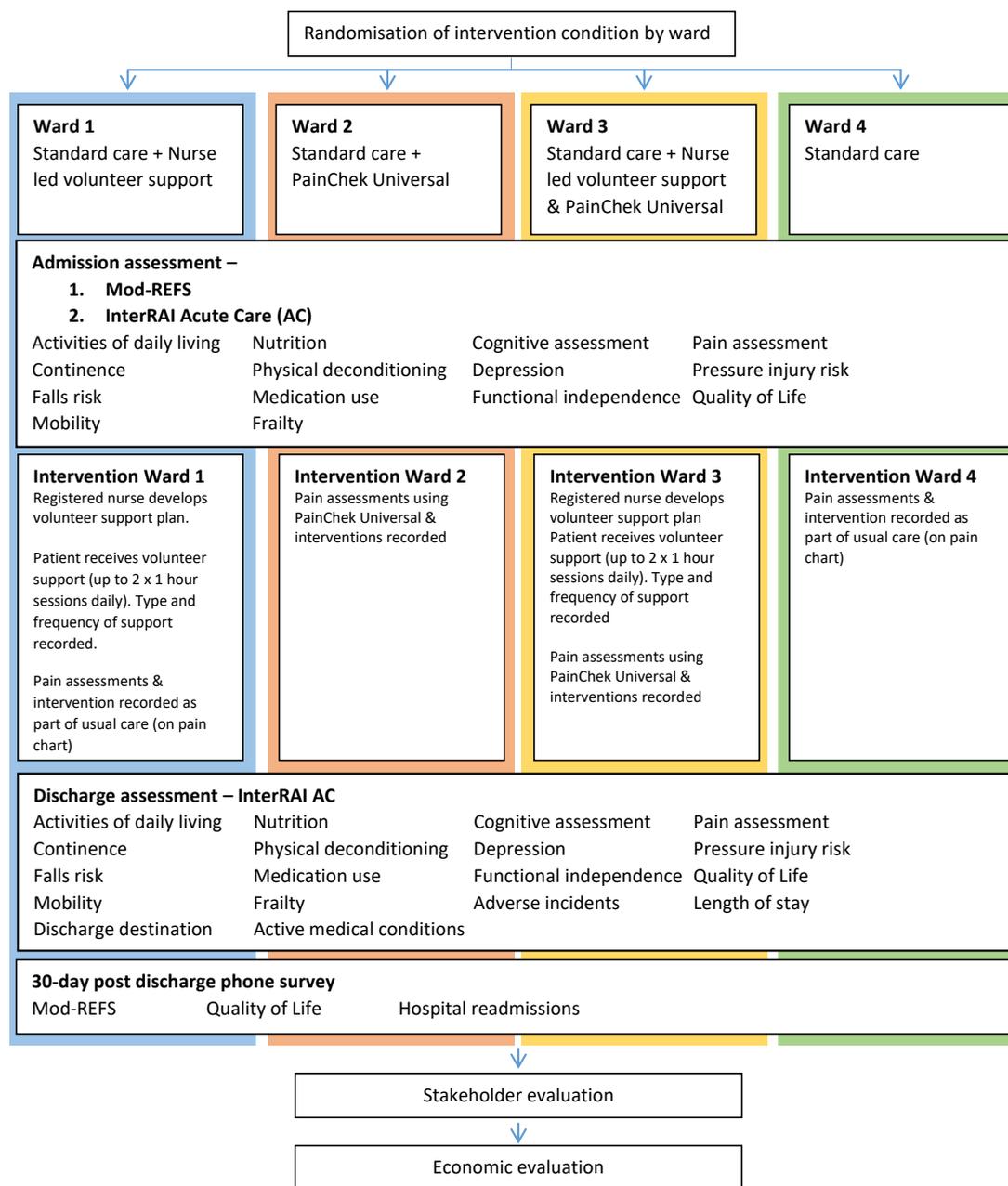
Human Research Ethics Committee (HREC) approval did not require a data monitoring committee. Data monitoring will be undertaken by the research committee and reported to the HREC and funding bodies. Any adverse events will be reported as per the HREC guidelines.

### Data reporting and analysis

All analyses will be conducted on an intention-to-treat basis. Descriptive statistics will be calculated using mean with SD, median and IQR and frequency for baseline characteristics. The primary outcomes, change in frailty during hospital admission and change in frailty between admission and 30 days post discharge, will be analysed using generalised linear mixed models, comparing the intervention wards with the control wards, adjusting the standard errors for clustering. Models will be adjusted for age, gender, Charlson Comorbidity Score and for clustering by ward.<sup>28</sup> All quantitative analysis will be conducted in STATA.<sup>29</sup> Qualitative data generated from the interviews and focus groups will be managed for analyses using NVivo software, adopting the six phases of thematic analysis by Braun and Clarke.<sup>30</sup> Analyses will be conducted independently by two researchers to look for emerging themes, and then discussed and organised using the NVivo software. A cost-benefit analysis from an Australian health perspective will be undertaken.

### Data management

Data will be managed according to the Australian National Statement on Ethical Conduct in Human Research. Consent forms and hard copy data forms will be stored in locked filing cabinets accessible only by Edith Cowan University (ECU) research team members. Deidentified data and participant information will be stored securely on University servers only accessible by ECU research team members on password-protected computers. PainChek Universal data will be stored in a repository within the PainChek secure cloud database.<sup>31</sup> Data will only be accessible by the research team members via a password-protected web administration portal. InterRAI data will be stored on a secure server at the University of Queensland accessible only by the research team via password. All data will be kept for a minimum of 7 years in line



**Figure 1** Data collection flowchart. mod-REFS, modified Reported Edmonton Frail Scale.

with ECU guidelines. Ultimately, data will be destroyed by deletion of electronic files, and disposal of hard copy documents via secure confidential bins.

### Patient and public involvement

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

### ETHICS AND DISSEMINATION

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

The final dataset will be available from the first author on reasonable request. Results of this study will be disseminated across the international healthcare organisation, presented at conferences and published in relevant

**Table 2** Measurements used to assess primary and secondary outcomes

Outcome measure	Measurement	Details of the measurement	Completed by
<b>Primary outcomes</b>			
Change in frailty from admission to discharge	Frailty Index generated by the InterRAI AC <sup>23</sup>	A Frailty Index is derived from the outcome of the assessments in the interRAI assessment system for AC <sup>23</sup>	Nurse researcher
Change in frailty from admission to 30 days post discharge	Modified Reported Edmonton Frail Scale (mod-REFS) <sup>24</sup>	The mod-REFS is a 13-item self-report questionnaire scored from 0 to 18, where a score of 8 and above is classified as frail. Severity classification: not frail (0–5), apparently vulnerable (6–7), mild frailty (8–9), moderate frailty (10–11) and severe frailty (12–18) <sup>24</sup>	Patient or proxy
<b>Secondary outcomes</b>			
Length of stay, activities of daily living, continence, discharge destination, quality of life, depression, cognitive function, functional independence	Scores collected by the InterRAI AC will be used to measure the outcomes <sup>32</sup>	The interRAI AC is a nursing assessment instrument consisting of 56 items that determine functional and psychosocial needs and includes diagnostic and risk screeners <sup>32</sup>	Nurse researcher
Adverse events (falls, death, delirium)	Frequency and type of incident	Obtained from clinical administrative database	Nursing staff
Pain scores, pain management intervention	Frequency of pain, pain levels, type of pain management intervention, types of analgesic use	Obtained from PainChek Universal database using both the Numerical Rating Score 0–10 or PainChek scores: no pain (0–6), mild (7–11), moderate (12–15) and severe ( $\geq 16$ ) <sup>13–15</sup>	Nursing staff
AC, acute care.			

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

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

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

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

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