Trials

STUDY PROTOCOL

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Nurse-led framework to improve the safety and quality of residential aged care (HIRAID® Aged Care): protocol for a stepped-wedge cluster randomised controlled trial

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Abstract

Background The health issues experienced by older people can often be severe and complex, and an increasing number are using residential aged care services to meet their care needs. High-quality nursing care is fundamental to the health and safety of aged care residents and is contingent on nurses' accurate assessment, informed decision-making, and delivery of timely interventions. However, the role of the aged care nurse is often challenging, impeded by factors such as understaffing, high workloads, and a lack of access to clinical infrastructure and resources. When these challenges mount, residents are put at greater risk of adverse outcomes, such as avoidable clinical deterioration and hospital transfers. This study describes the adaptation and implementation of the emergency nursing framework, HIRAID® (History including Infection risk, Red Flags, Assessment, Interventions, Diagnostics, reassessment, communication and plan)—a tool to assist nurses' assessment, decision-making and care in residential aged care.

Methods The HIRAID® framework will be adapted for residential aged care using a real-time Delphi and panel of aged care and nursing experts. The co-designed HIRAID® Aged Care framework will be trialled in 23 residential aged care homes in Sydney, Australia, in a modified stepped-wedge cluster randomised controlled trial design. All homes will be randomised into one of four clusters. Outcomes of interest include the rate of clinical deterioration events resulting from nurses' actions, the rate of hospital transfers determined to be inappropriate, performance against the national mandatory aged care quality indicators, resident satisfaction with care, nurse and medical staff satisfaction with communication, and the quality of nursing documentation. These outcomes will be evaluated using a combination of qualitative and quantitative analysis of routinely collected resident data, expert assessments of facility documentation events against validated criteria, and pre- and post-intervention surveys of residents, family carers, nurses, and medical staff.

Discussion This protocol describes a pragmatic trial that aims to translate an evidence-based framework from the emergency care context into residential aged care. The adapted HIRAID® Aged Care framework will be

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the first of its kind to standardise and guide holistic nursing assessment, decision-making, and documentation in residential aged care in Australia.

Ethics and dissemination This research has been approved by the Western Sydney Local Health District Human Research Ethics Committee: 2023/ETH00523. A waiver of consent has been approved to access resident health data and nursing documentation at each participating site.

Trial registration Australian and New Zealand Clinical Trial Registry, ACTRN12623000481673. Registered 12 May 2023.

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Keywords Nursing, Homes for the aged, Residential facilities, Hospitalization, Nursing care, Clinical deterioration, Quality of health care, Health services research, Health services for the aged

Background

An increasing number of older people are using aged care services in Australia and around the world. These services may be provided in the home, community, and residential aged care settings. In Australia, of the 1.3 million people who use aged care services, approximately 180,000 are residents of residential aged care homes (RACH, henceforth referred to as 'homes') [1]. Currently, there are over 750 residential aged care organisations that oversee 2700 homes across the country [2]. Most people entering residential aged care have complex clinical and healthcare needs, often presenting with a mix of acute and chronic health issues, including dementia, heart disease, neurological disorders, arthritis, pain, and depression [3].

Care in these homes is provided by a mixed multidisciplinary workforce that typically includes registered nurses (RN), enrolled nurses (EN; the equivalent of licensed practical nurses), nurse practitioners (NP), personal care workers, allied health professionals, general practitioners, and geriatricians. The RN's role is particularly critical. They are the key providers of clinical care for residents on a day-to-day basis and are ultimately responsible for the ongoing assessment and management of residents' acute and chronic health needs. However, the proportion of RNs in residential aged care has been declining over the past two decades, from comprising 21% of the direct care workforce in 2003 to 15.7% in 2020 [4]. Moreover, the quality-of-care provided by RNs is often challenged by factors such as the lack of access to the same type of resources available in acute care settings, low nurse-to-resident ratios and high staff turnover [5]. When combined with the high-risk clinical profiles of aged care residents, these factors increase the likelihood of negative health outcomes, such as avoidable deterioration, emergency department attendance, and hospital admissions [6–9].

The pressure on RNs to ensure the provision of timely and high-quality clinical care is continuing to mount. In March 2021, following the severe impact of the COVID-19 pandemic on Australian aged care homes, the Australian Royal Commission into Aged Care Quality and Safety proposed significant reforms to improve the quality and safety of residential aged care [7]. These included minimum staffing requirements that would require facilities to have at least one RN on-duty 24 h/day and a minimum of 44 min of RN face-to-face care time per resident per day. As expectations increase, new tools and resources are needed to support the fidelity and consistency of RNs' assessments, decision-making, and actions, and which allow for early detection and response to changes in a resident's condition.

Rationale

Currently, there are no industry-standardised nursing assessment frameworks to structure the holistic assessment of residents by RNs when their condition declines or deteriorates. We aim to address this by adapting the eight-element HIRAID® framework (History including Infection risk, Red Flags, Assessment, Intervention, Diagnostics, reassessment, communication and plan) for the residential aged care context. HIRAID® was first developed for emergency departments (ED) and provides a holistic and structured approach to RN assessment that improves the quality and consistency of RNs' judgement, care, and documentation (Fig. 1). When applied in the ED, HIRAID® has been demonstrated as a cost-effective [10] method for reducing the rate of patient deterioration [11], improving the accuracy of nursing documentation [12], and increasing nurse self-efficacy and clinical performance [13].

In this study, we will adapt and then implement HIRAID® for residential aged care. Cognisant of the significant contextual, demographic, and service delivery differences between residential aged care and ED settings, the study will employ a two-stage design. In stage 1, the existing HIRAID® framework will be adapted and recontextualised for residential aged care using a

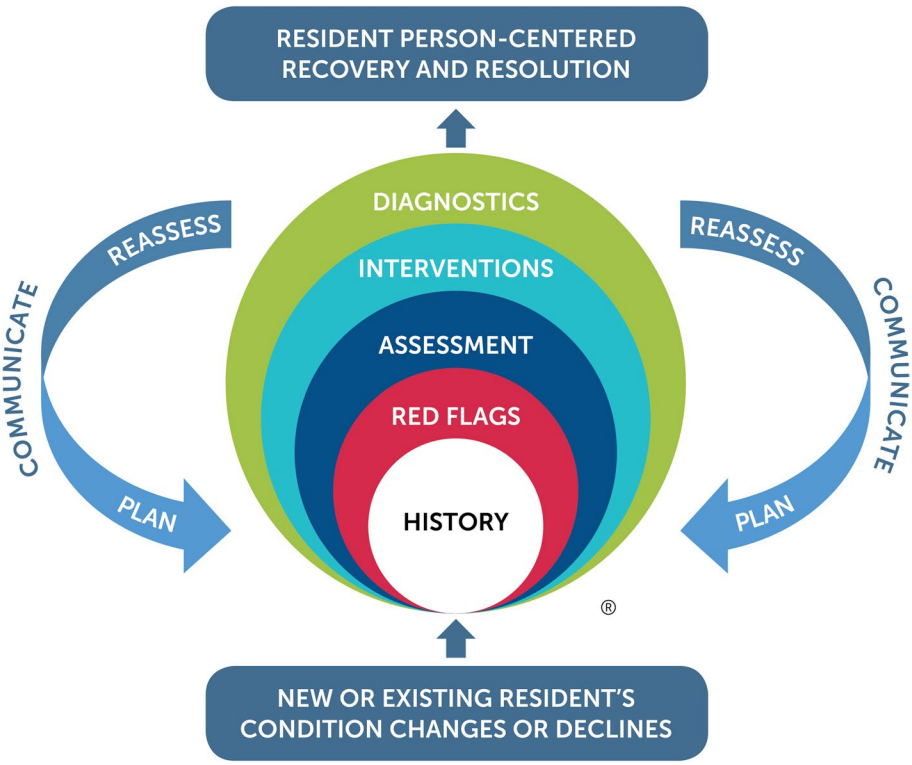

Fig. 1 A preliminary model of the HIRAID® Aged Care framework to be put forward for adaptation via the Delphi technique

real-time Delphi. In stage 2, the finalised HIRAID® Aged Care framework will be rolled out as part of a modified stepped-wedge cluster randomised controlled trial (SW-cRCT) in 23 homes in Sydney, Australia. The intervention aims to improve clinical outcomes for residents by reducing avoidable clinical deterioration and hospital transfer, improve resident satisfaction with care, improve nurse and medical staff satisfaction with communication, and improve the quality and quantity of nursing documentation.

Methods

Stage 1: Adaptation and co-design of HIRAID® Aged Care

Study design

The adaptation of the HIRAID® framework for residential aged care will be achieved using a real-time Delphi. This Delphi technique will allow experts to view panel responses and feedback in real-time and change their own responses within a set timeframe [14, 15].

Participants

The panel will purposively recruit experts from two populations:

- Academic experts in the fields of aged care, nursing pedagogy, education, and training, including researchers involved in the development and implementation of the original HIRAID® framework in the ED context
- Clinical and management experts in aged care, including registered nurses, nurse educators, and facility managers, from six residential aged care organisations

Given the focused aim of the Delphi and the homogeneity of the expert population, this study will recruit 12 participants to the panel.

Data collection

Prior to commencing the Delphi, a semi-structured facilitated discussion with HIRAID® and aged care experts will be conducted to identify key questions and items for the survey. The session will occur in tandem with an onsite demonstration of HIRAID® at an ED framework where the framework is active to enable aged care experts to understand how HIRAID® operates in established practice. The discussion session will include members of the expert panel for the Delphi study as well as non-panel members and stakeholders. No members of the panel will be individually identified during the session.

The Delphi will combine the functionality of real-time consensus with iterative survey rounds and will be hosted

on *Calibrum* (Calibrum International, USA, calibrum.com). The first round of survey items will be developed using feedback generated from the facilitated discussion. The survey will contain a combination of open-ended questions and Likert scale items. The level of consensus for each item will be calculated by the proportion of experts who gave a rating of the same valency, that is, if more than 80% of experts responded 'somewhat agree', 'agree', or 'strongly agree' on a 7-point Likert scale, an agreement consensus is reached for that item. The same 80% threshold applies for disagree responses to reject an item.

The survey will comprise nine sections, including a short demographic questionnaire and then one for each of the eight elements of the original HIRAID® framework (Fig. 1). During each survey round, panel members will be able to review anonymised responses in real-time. This information will include the distribution of panel members' votes, comments, and responses to open-ended questions. Each round of the survey will be distributed to panel members via email and open for 2 weeks. Experts will be able to begin the survey and revise their responses at any time during this period.

Data analysis and outcomes

Summative responses from round 1 will be provided to panel members and used to inform the items in the subsequent round. Data will be exported from *Calibrum* into IBM SPSS Statistics V28 (IBM Corp., Armonk, NY, USA) for descriptive analysis [16]. Qualitative data will be exported to NVivo 14 (Lumivero, Denver, CO, USA) for content analysis, where responses will be coded by two members of the research team [17]. Qualitative outcomes will inform the questions in the subsequent survey round, including how items that do not reach consensus are modified and whether new items are added. Only items that reach 80% consensus with a positive valency will be included in the HIRAID® Aged Care framework. Items that do not reach consensus after two rounds will be rejected. The Delphi will terminate once no items remain for review. The final HIRAID® Aged Care framework and implementation package will be co-designed by the research team and aged care partners based on the outcomes of the Delphi.

Stage 2: Implementation and evaluation of HIRAID® Aged Care

Study design

In stage 2, the HIRAID® Aged Care framework will be implemented using a modified SW-cRCT design, where each cluster undergoes 6 months of baseline observations, followed by a 6-month intervention transition period and then 12 months of post-intervention data collection [18]. A SW-cRCT design was selected as it is advantageous for implementing and evaluating health service interventions where participants belong to predetermined groups (i.e. homes) and cannot be randomly assigned. Furthermore, the design has the ethical benefit of allowing all participants to receive the intervention, ensuring that potentially beneficial treatments are not withheld from control participants. The design also provides important logistical advantages, including optimising implementation and data collection resources, and accommodating for temporal issues, such as delays in implementation [19]. HIRAID® Aged Care implementation will be evaluated using a type 1 effective-implementation hybrid design to simultaneously assess the effectiveness of the implementation strategies in supporting HIRAID® Aged Care uptake, sustainability and impact [20].

The sequence of treatments will be identical for all clusters and will comprise three consecutive phases (Fig. 2): a baseline phase where usual care is provided (B-BD), an intervention transition phase when the intervention is provided (I-T), and a post-intervention data collection phase (I-D). The commencement of the sequence at each cluster will be staggered at 3-month intervals. Each cluster will be randomly allocated to a sequence by the study statistician. Each sequence is expected to be completed within 24 months and the whole trial within 33 months.

The intervention

HIRAID® Aged Care is an eight-element framework (History including Infection risk, Red Flags, Assessment, Interventions, Diagnostics, reassessment, communication, plan) that will provide RNs with an evidence-based, systematised approach to completing and documenting point-of-care assessments and decisions in residential aged care. The delivery of the intervention will be multipronged and supported by strategies informed by behaviour change and implementation science, including the assessment of enablers and barriers to HIRAID® Aged Care implementation, a co-designed and scaffolded education program, and integration of HIRAID® Aged Care into homes' documentation systems. The evaluation of the intervention will test six primary hypotheses listed in Table 1.

Study setting

The study will be conducted in 23 homes located across Sydney, Australia. To be eligible, all homes must be located within the greater Sydney area, have permanently employed RNs, and must belong to one of six organisations: Southern Cross Care, Hardi Aged Care, United Protestant Association of NSW Ltd., Opal Health Care, Minchinbury Manor, and Gallipoli Home.

Participating homes were selected by executives from each organisation based on their suitability and readiness to adopt the intervention. Selected homes vary in size and total bed numbers (ranging from 25 to 149, Table 2) and include a mix of not-for-profit, for-profit, faith-based, and non-faith-based organisations.

Participants and eligibility criteria

Nursing staff All RNs, ENs, and NPs employed by partnering aged care organisations will be enrolled to complete the HIRAID® Aged Care training to implement the framework in routine practice. Furthermore, nursing staff will also be invited to participate in the evaluation of the intervention (i.e. surveys, interviews to assess the

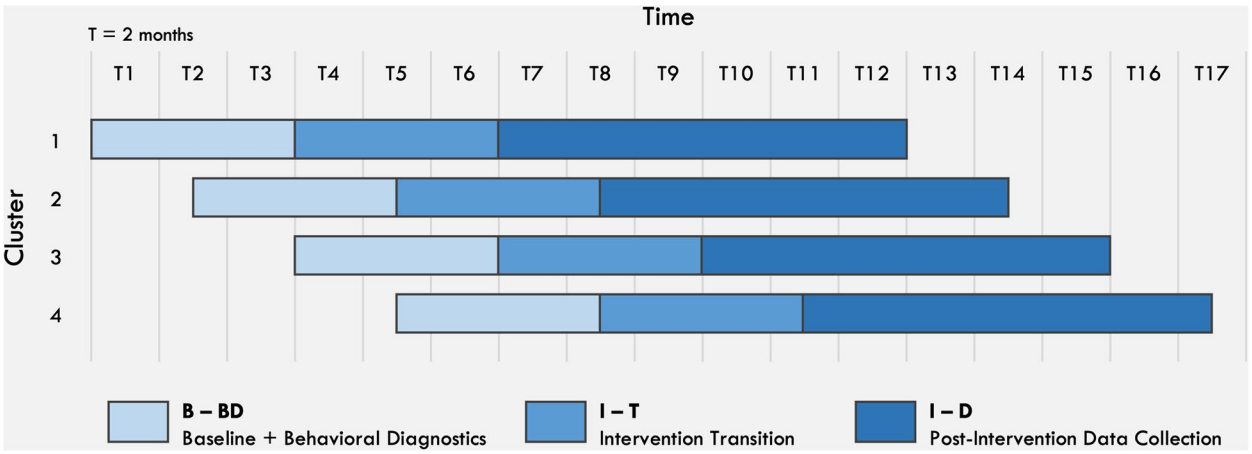

Fig. 2 The modified stepped-wedge cluster randomised controlled trial design for the implementation of HIRAID® Aged Care across four clusters. Each sequence comprises a 6-month baseline control condition, a 6-month intervention transition period, and a 12-month intervention exposure condition

Table 1 List of the six primary hypotheses to be tested through the implementation and evaluation of HIRAID® Aged Care

Hypothesis	Implementation of HIRAID® Aged Care will result in a…
H1	… *10% reduction in the rate of nurse-associated clinical deterioration events*
H2	… *10% reduction in the rate of Inappropriate hospital transfers*
H3	… *10% improvement in performance against national mandatory quality indicators*
H4	… *5% increase in resident and family-of-resident satisfaction with care*
H5	… *5% increase in staff reported self-efficacy and satisfaction with communication*
H6	… *10% increase in the quantity and quality of nursing documentation*

Table 2 Profiles of the six participating aged care organisations, including the number of participating homes, number of homes with > 100 beds, total beds across homes, and approximate number of RNs employed across all homes

Institution	Number of participating homes	Number of homes with > 100 beds	Total number of beds	Total number of RNs
Organisation 1	2	0	124	30
Organisation 2	11	3	705	120
Organisation 3	6	4	601	83
Organisation 4	2	2	276	47
Organisation 5	1	1	102	22
Organisation 6	1	1	146	27
Total	23	11	1,954	329

effectiveness of HIRAID® Aged Care against the outcomes of interest and the success of the implementation process). To be eligible, nursing staff must be employed by a participating aged care organisation during the study period and have received the HIRAID® Aged Care training. Sampling will be stratified based on the bed numbers of each home.

Medical staff Medical and allied healthcare staff employed or contracted by partnering organisations will be eligible to participate in the evaluation of the intervention with no exclusions. Participation will include the completion of surveys and interviews to understand how the intervention has changed their working relationship and communication with aged care nursing staff.

Residents All persons who reside or come to reside in participating homes during the study period will be included for the evaluation of the intervention. A waiver of consent has been approved for the collection of de-identified resident data, which will include medical records, care plans, charts, progress notes, and all associated documentation pertaining to clinical deterioration, incidents, and hospital transfers. Residents will also be able to participate in surveys and interviews to see if the intervention has changed their satisfaction with care.

Family of residents Family members and/or guardians of residents will be invited to participate in the evaluation of the intervention via surveys and interviews, as described above. To be eligible, they must be over 18 years of age and visit the resident at least once during the study period.

Research implementation officers All research implementation officers employed by the study will be included to evaluate implementation fidelity, as they will be responsible for the implementation of HIRAID® Aged Care.

Randomisation

A restricted randomisation process will be employed to allocate participating homes into four clusters. The allocation will balance for home size and ensure an even distribution of bed numbers across clusters. A geographical restriction will also be applied to minimise large distances between homes within the same cluster for practicality. Each cluster will then be randomly allocated to one of four starting dates. Randomisation will be completed by the study statistician using computer-generated numbers. No participating homes will be able to influence their allocation before the randomisation occurs, meaning that the allocation sequence will be concealed until participating homes are assigned. To minimise the risk of bias, there will be no changes to clusters after allocation.

Blinding

Given the nature of the intervention, it is impractical to blind investigators and staff delivering the intervention to the cluster allocation after it has been randomly assigned. However, the researchers recording and evaluating outcomes for nurse-associated clinical deterioration events, inappropriate hospital transfers, and nursing documentation will be blinded to the cluster and intervention sequencing. Specific participants population who are not directly involved in the delivering or receiving the intervention (i.e. residents, family of residents) will also be blinded to their cluster allocation.

Study plan

Tailoring the implementation strategies Site-specific implementation strategies will be guided by the integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework and behaviour change wheel (BCW) [21, 22]. Behavioural diagnostics will be undertaken during baseline data collection to identify enablers and barriers to implementation. This will be measured using the *Practice Environment Scale of the Nursing Work Index (PES-NWI)* [23], which will assess nurses' perception of the practice environment and identify organisational and external factors that influence nurses' ability to practice skilfully and deliver high-quality care. Nursing staff will also complete a short survey that will be co-designed using the i-PARIHS Framework [21, 24] to identify local enablers and barriers to implementing HIRAID® Aged Care.

The outcomes from both instruments will be reviewed to identify the primary facilitators and barriers to the implementation of HIRAID® Aged Care and will inform the development, adaptation, and preparation of site-specific implementation strategies. The BCW will be used to map facilitators and barriers to specific intervention functions and techniques for sustained behaviour change. The final implementation strategy will be refined using mechanisms from the behaviour change techniques taxonomy and the APEASE criteria [22]. This approach has previously been used to inform the implementation strategies for HIRAID® in the ED [25].

Education and training of nursing staff All nursing staff will receive pedagogically informed education regarding the theory and practice of HIRAID® Aged Care. The

education approach will be co-designed with experts from the six participating organisations and will be grounded in principles of constructive alignment [26–28], backwards design [29], and scaffolded learning [30]. HIRAID® Aged Care training will first be delivered to all NPs and senior RNs employed at each site, and then in a separate session, to the remainder of the RN and EN workforce. In addition to HIRAID® Aged Care training, NPs and senior RNs will also complete HIRAID® Aged Care instructor training. This component will prepare staff to independently deliver HIRAID® Aged Care training to ensure sustainability. Completion of HIRAID® Aged Care training will be mandatory for all incoming nursing staff and having an instructor base will enable integration into orientation and onboarding programs.

Integration of framework into documentation systems HIRAID® Aged Care documentation templates will be integrated into local electronic and paper documentation systems. A standard documentation template will be created for HIRAID® Aged Care that contains fields and prompts for each of its elements. Integration of documentation templates will be adapted based on local factors, such as use of electronic or paper-based documentation, and in the case of electronic documentation, the product(s) used (e.g. AutumnCare [31], ManAd [32]), automation capabilities, and capacity to communicate with existing assessment tools. The documentation templates will be tailored to maximise the efficiency of documentation of assessments whilst reducing duplication, administrative burdens, and redundancies for nurses.

Supporting materials Several strategies tailored to local facilitators and barriers will be deployed to support implementation. These include co-designed educational materials that provide easy access to learning and support. Environmental cues such as posters and reference cards will act as immediate reminders of the structure of HIRAID® Aged Care. Uptake of HIRAID® Aged Care will also be positively reinforced by implementation officers and nurse champions seconded from the existing nursing workforce. Research implementation officers will perform fortnightly audits of nursing documentation to ascertain uptake, maintain a record of implementation strategies executed within their allocated sites, and regularly correspond with the research team to provide updates, identify teaching opportunities, and address implementation issues.

The general phases of the study are summarised in Fig. 3.

Outcomes

Nurse-associated clinical deterioration The outcome will measure the mean difference in the rate of nurse-associated resident clinical deterioration events between baseline and post-intervention. Clinical deterioration is broadly described as the worsening of an individual's clinical state, putting them at increased risk of greater morbidity and mortality, with nurse-associated clinical deterioration pertaining to deterioration events that are directly influenced by a nurse's involvement, such as their capacity to recognise, react, or respond to events [33–35]. In this study, a clinical deterioration event will be defined by the activation of local clinical deterioration pathways, which will be identified through the review of residents' medical records and progress notes. All participating homes maintain policies and systems for identifying and responding to clinical deterioration. These pathways typically require the initiation of ongoing vital sign monitoring, escalation for medical officer review, progress note documentation and, if required, hospital transfer.

For all identified clinical deterioration events, the associated medical records, clinical data, forms, and documents

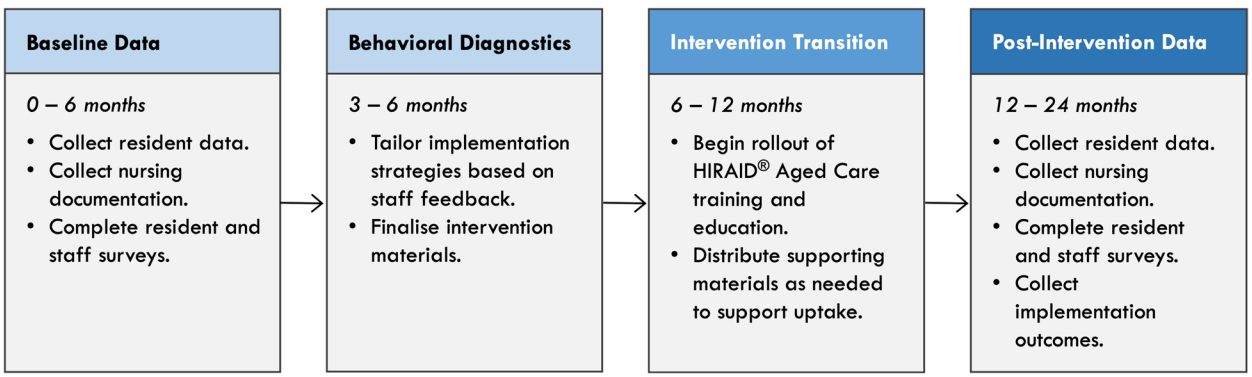

Fig. 3 Overall process for the implementation and outcome measurement of the HIRAID® Aged Care intervention

will be reviewed by a panel of experienced aged care clinicians to identify the prime causal factors. The *Human Factors Classification Framework* [36] for patient safety will be used to assess the degree of nurse involvement as a causal factor for the event. The framework distinguishes several factors that may have directly led to or increased the likelihood of a clinical deterioration event, including those relating to staff action. All reviewers will complete an initial review of 10 duplicate records to ensure consistent scoring. Inter-rater reliability will be examined for all items using Cohen's kappa. Major discrepancies in scores between reviewers will be re-evaluated and resolved by an additional independent reviewer. All reviewers will be blinded to whether the record was created during baseline or post-intervention and to the identity of the nurses. This framework has been previously described to evaluate the effect of HIRAID® on nurse-associated clinical deterioration in the ED [11].

Inappropriate hospital transfer This outcome will measure the mean difference in the rate of inappropriate transfer to the hospital or ED between baseline and post-intervention. The rate and outcomes of ED transfer will be extracted from data that is routinely collected and reported as part of residential aged care services. To identify the proportion of inappropriate transfers, a panel of experienced aged care clinicians will review data from the ED medical charts, transfer and discharge forms of discharged residents. The inappropriateness of the transfer will be assessed against an adapted version of Codde et al.'s (2010) criteria that is co-designed with aged care partners to take into consideration local policies and procedures [37, 38].

Aged care quality indicators This outcome will measure the mean difference in the performance on quality indicators reported between baseline and post-intervention [39]. The National Aged Care Mandatory Quality Indicators Program (QI Program) defines 11 quality indicators relevant to resident care and wellbeing, which aged care organisations are required to report for each home quarterly. Performance on each indicator is measured as the percentage of residents that meet a specified criteria for that indicator (Table 3).

Resident and family carer satisfaction Resident and family carer satisfaction with care and perception of the person-centredness of care will be compared at baseline and post-intervention. Satisfaction with care will be determined by mean scores on *Schmidt's Perceptions of Nursing Care Survey (SPNCS)*, which comprises 15 items on a 5-point Likert scale [40]. Perception of person centredness of care will be determined by mean scores on the *Person-Centred Practice Inventory-Care (PCPI-C)* [41].

Staff satisfaction with communication Satisfaction with communication amongst nursing and medical staff will be compared at baseline and post-intervention. Satisfaction will be measured using a previously validated instrument that asks staff to rate 8 items on a 11-point Likert scale, 5 yes/no questions, and one free-response question [42]. The instrument assesses overall satisfaction with nurse communication and the quality of information received during handover.

Table 3 The 11 quality indicators reported to the National Aged Care Mandatory Quality Indicators Program for homes every 3 months

Indicator	Criteria
Pressure injuries	• Percentage of care recipients with one or more pressure injuries, reported against six pressure injury stages
Physical restraint	• Percentage of care recipients who were physically restrained
Unplanned weight loss	• Percentage of care recipients who experienced significant unplanned weight loss (5% or more) • Percentage of care recipients who experienced consecutive unplanned weight loss
Falls and major injury	• Percentage of care recipients who experienced one or more falls • Percentage of care recipients who experienced one or more falls resulting in major injury
Medication management	• Percentage of care recipients who were prescribed nine or more medications • Percentage of care recipients who received antipsychotic medications
Activities of daily living	• Percentage of care recipients who experienced a decline in activities of daily living
Incontinence care	• Percentage of care recipients who experienced incontinence associated dermatitis
Hospitalisation	• Percentage of care recipients who had one or more emergency department presentations
Workforce	• Percentage of staff turnover
Consumer experience	• Percentage of care recipients who report 'good' or 'excellent' experience of the service
Quality of life	• Percentage of care recipients who report 'good' or 'excellent' quality of life

Nursing staff capability Nursing staff capability will be compared at baseline and post-intervention across three self-reported domains: self-efficacy, anxiety, and perception of person-centredness of care provided. Nurse self-efficacy will be measured using the *Self-Efficacy in Clinical Performance Scale*, where nurses rate their level of confidence for 14 items on an 11-point Likert scale [13]. Anxiety will be measured using the *State-Trait Anxiety Inventory*, where nurses rate the relatability of 20 statements on a 4-point Likert scale [43]. Finally, nurses' perception of the person-centredness of care will be measured using the *Person-Centred Practice Inventory-Staff (PCPI-S)*, which consists of 59 items for which nurses indicate their agreement on a 5-point Likert scale [44, 45].

Quality and quantity of nursing documentation The quality (accuracy) and quantity (completeness) of nursing documentation will be assessed by two experienced nurse clinicians through the review of resident electronic and paper medical records using the modified D-Catch tool [12, 46]. Average ranks and distribution of ranks in documentation quantity and quality will be compared at baseline and post-intervention. Inter-rater reliability will be examined for all items using Cohen's kappa, and major discrepancies in scores between reviewers will be re-evaluated and resolved by an additional independent reviewer.

Implementation fidelity Differences in the delivery of the intervention between sites may impact the outcomes of the intervention at those sites [47]. Implementation will be assessed throughout the intervention transition and post-intervention periods by research implementation officers, who will score implementation strategies against two criteria: whether the intervention was implemented (from 0 = not implemented, to 2 = fully implemented) and how much the intervention deviated from the plan (from 1 = just as planned to 4 = many changes). Implementation fidelity scores will be considered when evaluating the effect of the HIRAID® Aged Care intervention across different sites.

Finally, nurses' overall perceptions and experiences of HIRAID® Aged Care and its implementation will be collected through a formal feedback survey and online interviews. The survey will comprise a selection of Likert scale and free responses questions where nurses rate the utility and useability of HIRAID® Aged Care from an end-user perspective. Nurses who complete the survey will also be invited to participate in a semi-structured interview with a member of the research team. Outcomes from the survey and interviews will inform improvements to both the HIRAID® Aged Care framework and future implementation strategies.

All outcome measures are summarised in Table 4.

Sample size

Sample sizes were calculated for each of the six hypotheses (Table 5) and assumed an intracluster correlation coefficient of 3%, 5% significance (two-tailed) and 80% power. Baseline and attrition values are estimates based on existing literature scans and values derived from participating aged care organisations as well as similar projects previously completed by the research team.

Data collection

Resident health records and nursing documentation Resident medical records, charts, progress notes, and associated documentation will be extracted from each home's electronic databases monthly. Quality indicator data are routinely collected by aged care organisations to meet mandatory reporting requirements and will also be obtained quarterly from databases. If a site uses mixed documentation methods, both electronic and paper documents will be obtained and paper documents will be scanned and stored electronically.

Resident and family-of-resident surveys Residents will be approached and invited to complete the surveys onsite. Residents who have cognitive or communication issues will be invited following consultation with their guardians and/or treating clinician and may have a family member complete the survey on their behalf. Family-of-residents will be invited to complete the surveys during their visitations and will be given the option to complete the survey on paper, online, or over-the-phone. Participants opting to complete the survey online will receive a link to the REDCap™ survey via their provided email address. Gift vouchers (AU$10) will be offered to both residents and family-of-residents to incentivise participation. Baseline surveys will be administered three months prior to commencement of the intervention-transition period, and post-intervention surveys will be administered three months after the intervention-transition period is completed.

Medical and nursing staff surveys All nursing and medical staff surveys will be hosted on REDCap™ and will be distributed electronically to staff emails via the office of the aged care organisation. Baseline surveys for both medical and nursing staff will be distributed 3 months prior to commencement of the intervention. Post-intervention surveys will be distributed three months after the intervention-transition period has concluded. Gift

Table 4 Summary of HIRAID® Aged Care outcome measures and associated measurement instruments, data collection methods, and measurement timepoints (by 3-month intervals)

Outcome	Outcome description	Outcome measure	Data collection	Baseline		Intervention		Post-Intervention			
				1	2	3	4	5	6	7	8
Resident health outcomes											
Outcome 1	Nurse-associated clinical deterioration	Proportion of clinical deterioration events associated with nursing assessment and care	Resident health records	✓	✓	-	-	✓	✓	✓	✓
Outcome 2	Inappropriate hospital transfer	Proportion of hospital transfers that are inappropriate and/or unnecessary	Resident health records, hospital transfer forms	✓	✓	-	-	✓	✓	✓	✓
Outcome 3	Mandatory quality indicators	Proportion of residents who report an adverse outcome on a mandatory quality indicator	Administrative database	✓	✓	-	-	✓	✓	✓	✓
Resident satisfaction outcomes											
Outcome 4	Resident and family satisfaction with care received	Average score reported on the Schmidt's Perceptions of Nursing Care Survey (SPNCS)	Resident and family survey	✓	-	-	-	-	✓	-	-
Outcome 5	Resident and family perception of person-centredness of care received	Average score reported on the Person-centred Practice Inventory-Care (PCPI-C)	Resident and family survey	✓	-	-	-	-	✓	-	-
Staff satisfaction outcomes											
Outcome 6	Nurse satisfaction with communication	Average score on the satisfaction with communication survey	Nursing staff survey	✓	-	-	-	-	✓	-	-
Outcome 7	Medical staff satisfaction with communication	Average score on the satisfaction with communication survey	Medical staff survey	✓	-	-	-	-	✓	-	-
Nurse capability outcomes											
Outcome 8	Self-efficacy	Average score on the Self-Efficacy in Clinical Performance Scale	Nursing staff survey	✓	-	-	-	-	✓	-	-
Outcome 9	Anxiety	Average score on the State-Trait Anxiety Inventory	Nursing staff survey	✓	-	-	-	-	✓	-	-
Outcome 10	Perception of person-centredness of care	Average score on the Person-Centred Practice Inventory-Staff (PCPI-S)	Nursing staff survey	✓	-	-	-	-	✓	-	-
Outcome 11	Quality and quantity of nursing documentation	Average score of D-Catch score for the quality and quantity of nursing documentation	Progress notes	✓	✓	-	-	✓	✓	✓	✓
Implementation outcomes											
Outcome 12	Implementation fidelity	Outcomes reported in the implementation fidelity surveys and nurse interviews	Audits, nursing staff interviews	-	-	✓	✓	✓	✓	✓	✓

Table 5 Sample size calculations for six hypotheses showing the target total and per arm sample sizes

Hypothesis	Power analysis		Sample size (*n*)	
	Baseline	Estimated attrition (%)	Total	Per arm
H1: 10% reduction in the rate of nurse-associated clinical deterioration events	35%	10	1840	920
H2: 10% reduction in the rate of Inappropriate hospital transfers	35%	10	1840	920
H3: 10% improvement in performance against national mandatory quality indicators	30%	10	1968	984
H4: 5% increase in resident and family-of-resident satisfaction with care	4.4 (SD: 1.0)	5	684	342
H5: 5% increase in staff reported self-efficacy and satisfaction with communication	7.5 (SD: 1.43)	5	220	110
H6: 10% increase in the quantity and quality of nursing documentation	35%	-	820	410

vouchers (AU$10–$20) will be offered to nursing and medical staff to incentivise survey participation.

Nursing interviews All nursing staff completing the post-intervention survey will be invited to participate in an interview, which will supplement data collected from the post-intervention feedback surveys. Interviews will follow a semi-structured interview guide and may be completed in-person, over the phone, or via teleconferencing software. The interview will be audio recorded and then transcribed verbatim for data analysis. Interviews participants will be offered an AU$20 gift voucher.

Implementation audits Implementation fidelity data will be collected by research implementation officers through regular audits during the intervention transition and post-intervention periods. Data will be entered for each site into standardised implementation logs and a fidelity scoring framework hosted on REDCap™.

Statistical methods

Quantitative data Data will be analysed using SPSS V28[16] and by intention-to-treat. The demographic and clinical characteristics of residents will be summarised descriptively using mean and standard deviation for numeric data and frequency and percentage for categorical data. Bivariate analyses between all study and the outcome variables will be applied using Student *T*-test or ANOVA for continuous variables and chi-squared test or Fisher exact test for categorical variables. Logistic regression analyses will be employed for investigating the effect of the intervention on the outcome measures with adjustment for potential confounding variables identified in the bivariate analyses, such as seasonal variations, cluster start date, and the introduction of independent practice initiatives running in parallel.

Qualitative data Qualitative data will be analysed thematically using an inductive approach by two independent researchers. This approach was selected as the qualitative aspect of the study is exploratory and will serve to provide more information about different staff, resident, and family experiences of care and how they change throughout the intervention. Responses will be coded line by line, and content analysis will be used to develop the thematic organisation of responses [48]. The software program NVivo 14 [17] will be used to facilitate coding of all qualitative data.

Process evaluation For behavioural diagnostic data, quantitative items will be determined to be facilitators if they are a positive valence and reach greater or equal to 70% agreement [49, 50]. The same threshold applies to barriers and negative valence items. A sentiment analysis will be performed on qualitative data to identify additional facilitators or barriers based on positively or negatively worded statements [51, 52]. Sub-analyses will be conducted to identify specific barriers or facilitators by location to tailor implementation. Post-intervention measures of implementation fidelity and intervention feedback will be collated and analysed for each site. Categorical fidelity measures will be incorporated and adjusted for within the logistic regression analyses.

Economic evaluation An economic evaluation will be conducted to measure potential reductions in treatment costs associated with fewer adverse resident events and hospitalisations associated with the intervention. Discrete event simulation extrapolation modelling will be performed to estimate local and other system-wide implications of the implementation of HIRAID® Aged Care (versus non-adoption) over 5 and 10 years using trial data and published literature to inform assumptions [53–55].

Data management

Data storage and access Data will be managed in accordance with the University of Sydney's Research Data Management Policy and Procedures. Paper records will be scanned and stored electronically on the University of Sydney Research Data Store (RDS) and destroyed securely, as recommended by the policy. Where relevant, the contents of paper records (e.g. surveys) will be digitally transcribed into a standardised form on REDCap™. Paper records that cannot be digitised immediately following collection will be stored at a secure location. All data will be kept for a minimum of 15 years [56].

Data de-identification and linkage To maintain privacy and confidentiality, all resident data will be de-identified by the project statistician prior to linkage and analysis. A unique record identifier (ID) will be assigned to each record when a dataset is received. The full dataset will be split into two sets after the assignment of record IDs: [1] one with research and clinical information and [2] one with personal identifiable information. Data analysis will be conducted using dataset 1. In situations when data from different sources need to be linked, dataset 2 will be used. All data containing identifying details will be stored separately and encrypted with a linkage or study ID key. These data will only be accessible to the statistician, the chief investigator, and designated members of the research team. Identifiable information collected during interviews will be removed at transcription or replaced with broader, non-specific terms (e.g. names of specific facilities replaced with jurisdictional descriptors).

Ethics and dissemination

Data monitoring Given the low-risk nature of the intervention and the absence of significant blinding, a data monitoring committee will not be necessary for this trial. Data will be monitored on an ongoing basis by the project statistician to ensure consistency. Data entered by research officers into REDCap™ will undergo automated plausibility checks (i.e. acceptable value range, detection of invalid characters) and regular audits.

Harms All adverse events will be recorded and maintained by the chief investigator and will be reported in accordance with the NHMRC Guidance Safety Monitoring and Reporting guidelines and the University of Sydney's Safety Reporting Guidelines 2021. All serious adverse events will be reported to the University of Sydney Clinical Trial Support Office and to the relevant governance office of the affected aged care facility.

Dissemination Irrespective of outcome, the results of this research will be disseminated in a variety of forums, including open access peer reviewed scientific journals, conference proceedings, and other local, national, and international presentations. Authorship for publications will be decided prior to each publication and will comply with the International Committee of Medical Journal Editors (ICMJE) guidelines for peer-reviewed publications [57]. Anticipating intervention efficacy, results will be promulgated to relevant national agencies and aged care stakeholders to inform nursing practice, health policy, and nurse education.

Discussion

HIRAID® Aged Care aims to improve nursing care by providing a standardised and evidence-informed framework to guide nurses' assessment, decision-making, and action. In stage 1, HIRAID® Aged Care will be adapted from the HIRAID® emergency nursing assessment framework[58, 59] using a real-time Delphi [14, 15]. In stage 2, the adapted HIRAID® Aged Care framework will be implemented in 23 homes in a SW-cRCT and evaluated for its impact on nurse-associated clinical deterioration, inappropriate hospital transfer, resident satisfaction with care, staff satisfaction with communication, and the quality of nursing documentation.

A major advantage of this study is that the methodological design, theoretical foundations, and implementation strategies will be underpinned by empirical evidence previously established during development, implementation, and refinement of HIRAID® in the ED [11, 25, 42, 58, 59]. Whilst contextually different, emergency and aged care share the similarity of being complex, dynamic, and resource-challenged environments [5]. The experience and evidence generated from implementing HIRAID® in emergency care provides a useful foundation for the development of enabling mechanisms and strategies for behaviour change to maximise the success of implementing and sustaining HIRAID® Aged Care.

Furthermore, a diverse sample of aged care organisations will be engaged in this study to maximise the generalisability of findings and provide important insights regarding the essential requirements for site-specific adaptations and considerations. Evaluation of both implementation and economic effects will be critical to supporting scalability of the intervention into broader aged care settings as well as providing a foundational methodological model for adapting a nurse framework from one healthcare context to another.

Trial status

The protocol is Version 1.0 dated 6 February 2024. Recruitment is scheduled to begin on 1 April 2024 and will be completed approximately on 31 December 2026.

Methodological considerations and risks

The study will require substantial commitment across its aged care partners, not only in the co-design of HIRAID® Aged Care but also in its implementation, maintenance, and evaluation. This intervention comes during a time of significant reform in the Australian aged care sector, following the introduction of new legislations, standards, and mandates, adding significant administrative pressure to facilities and staff [7]. Whilst the HIRAID® Aged Care intervention ultimately aims to reduce assessment burdens for RNs and improve overall efficiency, it is acknowledged that the successful introduction of a new intervention will need to be cognisant of inherent challenges in this setting.

Furthermore, the aged care setting itself is unique and presents many intrinsic challenges to implementation. Chief amongst these is the ongoing risk of infectious disease and COVID-19, which continue to impact the health of residents and the aged care workforce [60, 61]. A COVID-19 risk management and safety plan has been established to ensure minimal disruption to research activities in the event of increased risk of infectious disease outbreaks. Furthermore, whilst the advantages of the SW-cRCT have been previously highlighted, there are also notable risks attached to this design. These include the time cost to rollout the intervention to all sites and the potential impact of uncontrollable secular trends, events, or service changes impacting outcome measured independent of the intervention (e.g. COVID-19 outbreaks, discontinuation of mobile diagnostic services leading to increased hospital transmissions) [19, 62].

Blinding is also limited due to the nature of the intervention. Whilst recipients of the intervention will be blinded to their allocated cluster order, they will not be blinded to the transition from control to intervention conditions. Consequently, self-report measures taken during these periods are at specific risk of participant bias, particularly those taken from RNs. For non-self-reporting outcomes, these biases will be reduced due to the objective nature of the measurements, as well as the repetition and/or longitudinal nature of the measures across multiple timepoints during both baseline and post-intervention periods. In general, most outcome measures will be collected for 12 months post-intervention to reduce potential participant biases and allows for sensitivity to long-term outcomes and possible relapse effects.

Conclusion

Effective and timely nursing care is critical for ensuring the safety and wellbeing of residents living in residential aged care homes. With incoming changes to standards and legislative mandates in Australia, aged care nurses are under increasing pressure to continue to deliver high-quality clinical care and make accurate and evidence-informed judgments and decisions. HIRAID® Aged Care will provide nurses with a much-needed tool to guide, inform and standardise the holistic assessment process.

Abbreviations

BCW	Behaviour change wheel
ED	Emergency department
RACH	Residential aged care homes
RN	Registered nurse
EN	Enrolled nurse
GP	General practitioner
HIRAID®	History including Infection risk, Red flags, Assessment, Interventions, Diagnostics, communication, reassessment and plan
ICC	Intraclass correlation coefficient
NP	Nurse practitioner
NSW	New South Wales
SW-cRCT	Stepped-wedge cluster randomised controlled trial
WSLHD	Western Sydney Local Health District
HREC	Human Research Ethics Committee

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Authors' contributions

RZS and KC conceived and conceptualised the intervention and the design of the study. MF led and provided expertise in the development of the phase 1 Delphi study design. JC provided expertise in nursing pedagogy and the development of education and training materials for the intervention. BMC, DP, LFL, YHJ, RIL, DW, KW, and MD provided expertise in aged care, geriatrics, person-centred care, and clinical trial designs. MKL provided statistical expertise and sample size calculations. GS, LT, AS, MB, JD, CR, and JG are representatives of the aged care partners and consumers participating in the trial and provided practical input to the intervention design and delivery. CV prepared and drafted the initial manuscript. All listed authors provided substantial feedback and contributed to the revisions of the manuscript.

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Data availability

Not applicable.

Declarations

Ethics approval and consent

This research has been approved by the Western Sydney Local Health District (WSLHD) Human Research Ethics Committee (HREC): 2023/ETH00523. This trial is sponsored by the University of Sydney. Any modifications to the protocol will be submitted to the ethics committee and trial sponsor for review and

approval. A waiver of consent has been approved to secure access to resident health data and nursing documentation as obtaining consent from all residents for their health information to be included in the study is impracticable, and an incomplete data set will substantially impair the research by introducing bias and reducing the validity and generalisability of the research. Furthermore, the proposed research involves no more than low risk to participants, with sufficient protection of their privacy, and a plan to protect the confidentiality of data. The waiver approves access to retrospective data collection from the health record of residents. Standard informed consent will be obtained for all other means of data collection.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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