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## Protocol for a process evaluation of a stepped wedge randomised controlled trial to reduce unnecessary hospitalisations of older people from residential aged care: the EDDIE+ study

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3 4 5	1	Protocol for a process evaluation of a stepped wedge randomised controlled trial to reduce					
6 7	2	unnecessary hospitalisations of older people from residential aged care: the EDDIE+ study					
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31 Abstract

## 32 Introduction

The Early Detection of Deterioration in Elderly residents (EDDIE+) program is a theory-informed, multi-component intervention aimed at upskilling and empowering nursing and personal care staff to identify and manage early signs of deterioration in residents of aged care facilities. The intervention aims to reduce unnecessary hospital admissions from residential aged care homes. Alongside a stepped wedge randomised controlled trial, an embedded process evaluation will be conducted to assess the fidelity, acceptability, mechanisms of action and contextual barriers and enablers of the EDDIE+ intervention.

## 40 Methods and Analysis

Twelve residential aged care homes in Queensland, Australia are participating in the study. A comprehensive mixed methods process evaluation, informed by the integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework, will assess intervention fidelity, contextual barriers and enablers, mechanisms of action, and the acceptability of the program from various stakeholder perspectives. Quantitative data will be collected prospectively from project documentation, including baseline context mapping of participating sites, activity tracking and regular check-in communication sheets. Qualitative data will be collected post-intervention via semi-structured interviews with a range of stakeholder groups. The i-PARIHS constructs of innovation, recipients, context, and facilitation will be applied to frame the analysis of quantitative and qualitative data.

## 51 Ethics and dissemination

Ethical approval for this study has been granted by the Bolton Clarke Human Research Ethics Committee (approval number: 170031) with administrative ethical approval granted by the Queensland University of Technology University Human Research Ethics Committee [2000000618]. Full ethical approval includes a waiver of consent for access to residents' demographic, clinical and health services de-identified data. A separate health services data linkage based on RAC home addresses will be sought through a Public Health Act (PHA) 

1 2		
- 3 4	58	application. Study findings will be disseminated through multiple channels, including journal
5	59	publications, conference presentations and interactive webinars with a stakeholder network.
7 8	60	Trial registration:
9 10	61	The trial is prospectively registered with the Australia New Zealand Clinical Trial Registry
11 12	62	(ACTRN12620000507987, registered 23/04/2020).
13 14 15	63	Strengths and limitations of this study
16 17	64	Theory-informed process evaluation, framed by the integrated-Promoting Action on
18 19	65	Research Implementation in Health Services framework and an intervention logic model.
20 21	66	Process data from a range of sources to assess implementation processes and outcomes.
22	67	Outcomes could help inform planning for future development and implementation of
23 24	68	hospital avoidance strategies in residential aged care facilities.
25 26	69	• High staff turnover and workload within the residential aged care sector may impact staff
27 28	70	availability to participate in surveys and interviews.
29 30	71	<ul> <li>Data relating to residents' experiences will be collected from family members and</li> </ul>
31 32	72	nominated advocated, rather than directly from residents.
33 34	73	
35 36 37	74	Introduction
38 39	75	When older adults living in Residential Aged Care (RAC) are admitted to hospital, they face
40 41	76	increased risk of hospital associated complications and invasive interventions (1). Hospital
42 43	77	presentations and admissions amongst this population group are relatively high and there is
44 45	78	evidence to suggest some hospital encounters are avoidable (2). A report published by the
46	79	Australian Medical Association estimated 27,000 potentially preventable admissions from RAC
47 48	80	homes in Australia in 2021, equating to 160,000 bed days with a cost of \$312 million Australian
49 50	81	dollars (3). RAC residents, family members and staff express a preference for care to be
51 52	82	provided in their home where possible (4). Previous research indicates that this is possible and
53 54 55	83	will reduce hospital presentations and admissions from RAC, from implementing models of care
56 57 58 59		3

that provide access to resources and improve the clinical skills and confidence of nursing staff (5). 

The 'Early Detection of Deterioration In Elderly residents' or 'EDDIE' program was developed in Queensland, Australia as a hospital avoidance intervention targeted at nursing and other care staff working in RAC. The aim was to empower and enable staff to identify and appropriately respond to early clinical signs of a deteriorating resident (5, 6). An initial pilot of EDDIE demonstrated that the intervention was feasible and acceptable to RAC staff, reduced hospital transfer rates and resulted in a 41 per cent reduction in total hospital bed days (7). EDDIE+ builds upon the learning from the EDDIE pilot (5, 6, 8) and aims to develop and test a scalable hospital avoidance intervention in RAC. The evaluation study involves a type 1 stepped-wedge randomized controlled effectiveness-implementation trial (9) with embedded economic and process evaluation. Details of the trial, which involves 12 participating RAC homes in metropolitan and regional Queensland, have been described in a previously published protocol paper (10). This paper presents the protocol for the process evaluation component of the study. 4.04

The EDDIE+ Intervention

EDDIE+ focuses on upskilling nursing and personal care staff working within RAC, by giving them the knowledge, skills and support needed to manage sub-acute episodes such as urinary tract infections, chest pain, falls and dyspnoea within the home setting. It comprises four components: advanced clinical skills education and training (provided initially by a project-funded nurse educator), decision support tools, provision of diagnostic equipment (for example, bladder scanners and vital signs monitors) and implementation facilitation and support (via a locally appointed clinical facilitator supported by a project implementation facilitator) (6). The development of EDDIE+ was underpinned by a widely used implementation framework, the integrated Promoting Action of Research Implementation in Health Services (i-PARIHS) framework (11). i-PARIHS proposes that the successful implementation of evidence-informed innovations results from the active facilitation of an innovation with the intended 

1 2		
2 3 4	112	recipients of implementation within their local, organisational and system context. As such,
5	113	attention to facilitation, engagement with RAC stakeholders, involvement of staff and
6 7 8	114	responsiveness to context are key features of EDDIE+.
9 10	115	By embedding implementation facilitation within the bundle of components that comprise
11 12	116	EDDIE+, implementation is integral to the intervention. Consistent with facilitation as an
13	117	primary implementation strategy, clinical facilitators can tailor the implementation of EDDIE+
14 15	118	according to their own home's needs. This will be achieved through the identification of core
16 17 18	119	and adaptable features of each EDDIE+ component [Table 1].
19 20	120	Figure 1 presents a logic model summarising how EDDIE+ is expected to work and produce
21 22	121	intended changes to processes and outcomes of care.
22 23 24	122	[Figure 1 about here]
25 26	123	
27 28	125	
29 30	124	Methods and analysis
30 31 32	125	Process evaluation
33 34	126	Process evaluations are increasingly recognised as an important part of developing and testing
35 36	127	complex interventions such as EDDIE+, which comprises multiple components and is being
37 38	128	implemented across multiple settings (12, 13). While the trial component of the study focuses
39	129	on intervention effectiveness, the process evaluation aims to understand how and why the
40 41	130	intervention works in real-world contexts. This involves examining whether the intervention has
42 43	131	been implemented as planned and resulted in expected outcomes. Understanding whether and
44 45	132	how an intervention is affecting change can provide insights into the processes of
46 47	133	implementation and the extent to which these account for positive or negative study outcomes.
48 49	134	This is particularly helpful if the actual study outcomes differ from expected outcomes, enabling
50 51	135	the study team to understand whether there has been implementation failure, such as poor
52	136	delivery of the intervention, or intervention failure, such as poor or inappropriate design (14).
53 54	137	This might inform planning of future interventions and implementation strategies.
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Advanced clinical skills education and training Training on clinical management of specific conditions identified as likely to result in	Mode of delivery
hospitalisation (e.g., UTIs, chest pain, falls, delirium, dehydration, dyspnoea, palliative care, constipation)	Number and type of ponditions covered Mode of delivery Staff involved in to the second
Core set of educational materials	န်းနို့်နို့ Additional site-specific materials
Decision support tools Core decision support tool for management of clinical deterioration across specific conditions	Number and type of conditions covered Format of tool Observation chart (egg., track & trigger too Communication tool e.g., ISBAR - (Introduction, Site atton, Background Assessment, Recent meendation)
Diagnostic equipment (bladder scanner, ECG machine, vital signs monitor, oximeter)Each home assessed for equipment needs Provision and training in use of equipment as per home requirements	Type of equipment to individual home needs
Implementation facilitation Appointment of clinical facilitator	Role-sharing by
and support Train-the-trainer model for clinical facilitator	Opt-in by other Registered Nurses
Communication channel established for discussing concerns about resident deterioration	Tailored to individuate home needs

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1 2		
3 4	139	To evaluate how and how well EDDIE+ was implemented, the process evaluation of EDDIE+ will
5 6	140	follow published guidance on conducting and reporting studies with a process evaluation
7 8	141	component (12). Consistent with the application of i-PARIHS to inform the development of
9	142	EDDIE+, the process evaluation will be framed by i-PARIHS and the intervention logic model
10 11	143	that was developed at the study design stage (Figure 1). Implementation outcomes of interest
12 13	144	in the process evaluation include fidelity and acceptability of EDDIE+ to multiple stakeholders,
14 15	145	the mechanisms through which EDDIE+ achieves an effect (or not), and contextual barriers and
16 17	146	enablers of implementation.
18 19 20	147	Aims
21 22	148	The aim of the process evaluation is to track the implementation of EDDIE+ in the 12
23 24	149	participating RAC homes to:
25		
26 27	150	1. Assess EDDIE+ intervention fidelity
28 29	151	2. Assess the acceptability of EDDIE+ from the perspective of staff, residents' family
30 31	152	members, EDDIE+ facilitators and wider stakeholders
32 33	153	3. Identify the mechanisms of impact
34 35	154	<ol><li>Identify contextual barriers and enablers of implementation.</li></ol>
36	155	Study Design and Data Collection
37 38		
39 40	156	An embedded and formative mixed methods process evaluation will be undertaken. This will be
41 42	157	guided by a series of templates based on i-PARIHS to assess fidelity and acceptability of EDDIE+,
43 44	158	mechanisms of impact, and contextual barriers and enablers within and across the 12 regional
45	159	and metropolitan homes. Data from all four intervention phases of the stepped wedge trial will
46 47	160	be collected and analysed. These are the preparation, baseline exposure, intervention
48 49	161	introduction and intervention exposure phases.
50 51	162	We first summarise how the theoretical propositions of the i-PARIHS framework inform the
52 53	163	questions of interest within the process evaluation, before describing the methods of data
54	164	collection and analysis (Tables 2 and 3).
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7 8 9			Data Sourc	e				for	' on 16 F	Data Analysis	Approach
10 11	i-PARIHS	Process Evaluation	EDDIE+	Comm and	Context	Interviews	Self-	Family related	ebrua E	Quantitative	Qualitative
12 13	Constructs	Component	Check in	Activity	mapping		Efficacy	advoca	ry 202 rasmu		
14 15			Form	Tracking			Surveys	questic			
16 17 18	Innovation and	Fidelity	~			~		Family relation advocate question data	vnloade	~	✓
19 20	Recipients	Acceptability	~	~	6	~		a mining,	.om		<b>v</b>
21 22 22	Facilitation	Mechanisms of	✓		0	<b>`</b>	<ul> <li>✓</li> </ul>		http://bmjopen.bmj.com/	<ul> <li>✓</li> </ul>	✓
23 24 25		Impact			L L	10,		Al training,	bmjop		
26 27	Context	Barriers and	✓	✓	✓	~~			en.bm		$\checkmark$
28 29		Enablers					0	and similar	j.com/		
30 31	167 <b>Table 2.</b>	Overview of process ev	valuation da	ta collection a	and analysis			techr			
32 33 34	168							technologies.	on April 30,		
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	Data Source	Description	Purpose $\frac{1}{3}$ $\frac{1}{3}$	Aim*
	Communication and Activity	Conversational data, hours of training,	Provide picture of homes actors the picture of homes actors and the picture of homes actors actors actors and the picture of homes actors	1, 3, 4
	Tracking	details of home, education, and	intervention period and record and r	
		training, field notes	critical time junctures	
	Baseline context mapping	Description of home characteristics	Provide baseline overview og hog he,	4
		before EDDIE+ intervention	including likely barriers and analytics of	
		K	implementation	
	Check In Forms	Hours of training, EDDIE+ activities,	Describe EDDIE+ activities und Baken	1, 2, 3, 4
		general updates	and program progress over	
			period no state	
	Semi-structured interviews	Interviews with staff, residents and	Understand stakeholder vie៉្លី <u>ទី</u> ខ្លួំង	2,4
		family members, EDDIE+ facilitators	experiences of EDDIE+ 클. ㅎ	
		and external stakeholders		
	Self-efficacy surveys	Pre and post surveys	Determine if EDDIE+ has im	3
			efficacy and upskilled staff	
	Family member or nominated	Traffic light system with three	Determine family members <b>and</b>	2
	advocate questionnaire	questions related to the EDDIE+	advocates views on the programs and	
		program	impact 🛐 👼	
172 173	Table 3: Description of process	evaluation data sources	om/ on Aj ilar techr	
174	*Aims - 1: Assess the EDDIE+ interven	tion fidelity; 2: Assess the acceptability and views o	f the EDDIE+ program from the perक्रूective of staff,	resident families,
175	EDDIE+ facilitators and external stakel	nolders; 3: Identify mechanisms of impact; 4: Identi	fy contextual barriers and enablers in involvementati	on success
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#### i-PARIHS theoretical framing

#### Innovation

According to the theoretical proposition of i-PARIHS, implementation effectiveness is enhanced if there is support for the innovation to be implemented. The innovation in this case is EDDIE+, an intervention to improve the identification and management of clinical deterioration in residents within the home setting and in turn, reduce unnecessary hospital transfers. Support is more likely if key stakeholders including RAC staff, managers, residents, family members and external care providers, agree with the idea of keeping residents at home where possible and perceive implementation to be workable in practice. In relation to EDDIE+, this includes support for the education and training offered and the introduction and use of new diagnostic equipment. Therefore, it will be important to collect stakeholder views on the acceptability, relevance, and importance of EDDIE+ within the context of the RAC home setting.

#### Recipients

i-PARIHS proposes that recipients of an innovation (for example, staff, residents, and family members) need both 'want to' and 'can do' factors to achieve successful implementation (15). RAC staff in particular have to be motivated to address the issue of clinical deterioration in residents and have the capacity and capability to implement EDDIE+. These areas will be explored as part of the data collection.

#### Context

Contextual factors at multiple levels are identified as important barriers or enablers of implementation in i-PARIHS and will be examined as part of the process evaluation. The inner context spans the local and organisational settings. At a local level, inner context refers to the immediate place of implementation - the RAC home - and encompasses factors such as the workplace culture, management and leadership support, workload, receptiveness, and attitudes to change. The local context is embedded within the organisational context - the aged care provider organisation - where factors relating to culture, leadership, support and resources are also important. Outer context relates to the wider aged care system, including policy drivers, regulatory standards and frameworks, other initiatives that influence the care of 

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deteriorating residents, and more general health, social and economic issues that affect aged care. Initial mapping of contextual factors will be undertaken pre-implementation and tracked throughout the intervention phase of the study.

Facilitation

Facilitation in the i-PARIHS framework is positioned as the active ingredient of implementation, comprising facilitator roles and the use of enabling facilitation strategies. It is the facilitator's role to assess innovation, recipient and contextual factors that present barriers to or enablers of implementation and plan appropriate facilitation strategies to address these. The main facilitator role in EDDIE+ is the clinical facilitator appointed from within the RAC home to support implementation, with funding provided for backfill support. The clinical facilitator receives additional support from the EDDIE+ project team including the nurse educator and the project implementation facilitator. This is based on a model of internal-external facilitation (16). The nurse educator is responsible for developing and delivering the training on clinical deterioration and the diagnostic equipment to RAC staff, whilst the implementation facilitator will undertake the baseline context assessment and support the clinical facilitators to develop facilitation skills. As part of the process evaluation, it will be important to collect data about the different facilitator roles, the strategies used to facilitate implementation and how well these worked. 

Process evaluation elements 

Fidelity 

Fidelity will be evaluated in relation to the delivery of EDDIE+ as intended, namely: attendance at mandatory EDDIE+ training by nurses and personal care workers, number of EDDIE+ sessions delivered/attended, use of the new equipment, and recruitment and retention of clinical facilitators. These data will be extracted from EDDIE+ check in forms completed by the nominated clinical facilitator at each site and the communication and tracking data collected from the project team, including education attendance records [see Supplementary file]. Additional data sources will be used to determine any critical time junctures such as COVID-19 

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231 lockdowns, infection outbreaks and other events that may have impacted the implementation
 232 of EDDIE+.

233 Acceptability

Data will be collected on the acceptability of EDDIE+ from the perspective of four stakeholder groups: RAC staff including Registered Nurses, Enrolled Nurses and Personal Care Workers, family members or nominated advocates of residents, clinical facilitators, and local and external stakeholders [see Tables 2 & 3]. Semi-structured interviews will be conducted with these different groups to ascertain their views about EDDIE+. Family members and nominated advocates will be asked about their awareness and experiences of EDDIE+ and how it impacted the resident's care. RAC staff and other stakeholders will be interviewed about EDDIE+ and how it was implemented to determine what they found most and least helpful about EDDIE+ and whether they thought the intervention was transferable to other RAC homes [see Supplementary file]. Additionally, a three-question traffic light survey will be distributed to family members and nominated advocates to determine if their experience with EDDIE+ was positive, negative, or neutral, if EDDIE+ impacted the care of their loved one in a good way, and their views on whether EDDIE+ should be introduced into other RAC homes [see Supplementary file]. 

## <sup>36</sup> 248 Mechanisms of impact <sup>37</sup>

As illustrated in the logic model in Figure 1, the EDDIE+ intervention is expected to produce improvements in resident, staff, and system level outcomes through mechanisms including enhanced staff knowledge and skills, increased staff confidence and sense of empowerment, and greater confidence of family members and external care providers in the ability of RAC home staff to provide appropriate clinical care for residents. These mechanisms will be explored through several data sources. RAC staff will be requested to complete a self-efficacy survey pre and post EDDIE+ implementation using a validated self-efficacy questionnaire (17) to evaluate reported changes in staff confidence and capability. Questionnaire data will be supplemented with data from semi-structured interviews conducted with RAC staff, clinical facilitators, managers, and external care providers, such as general practitioners, to assess 

2		
3 4	259	mechanisms relating to confidence, staff empowerment and skills and knowledge
5 6	260	development.
7 8	261	Understanding barriers and enablers
9 10	262	Consistent with the i-PARIHS framework, barriers and enablers to implementation will be
11 12	263	explored in relation to the EDDIE+ intervention (acceptability and feasibility), recipient
13 14	264	characteristics (RAC staff 'want to' and 'can do' factors) and the inner and outer context.
15 16	265	During semi-structured interviews, RAC staff and wider stakeholders will be asked to provide
17 18	266	specific examples of barriers and enablers of EDDIE+, what worked well (or less well) in their
19 20	267	own RAC home and what would need to be considered for future implementation in other
21	268	facilities. Supplementary information related to barriers and enablers will be extracted from the
22 23	269	baseline context mapping, communication and activity tracking spreadsheets and check in
24 25	270	forms completed by clinical facilitators and the nurse educator and project implementation
26 27	271	facilitator.
28 29	272	Setting and participant recruitment for process evaluation
30		
31 32	273	Twelve Bolton Clarke Residential Aged Care Facilities in Queensland, Australia were recruited to
33 34	274	participate in the EDDIE+ study. The stepped wedge design involved 4 phases (preparation,
35 36	275	baseline/usual care exposure, intervention introduction and intervention exposure) that took
37 38	276	place from March 2021 to May 2022. The process evaluation will be conducted from May to
39	277	September 2022 with data from all participating homes. This will include recruitment of RAC
40 41	278	staff, clinical facilitators, family members of residents (where applicable), and local and external
42 43	279	stakeholders including GPs, home managers and allied health managers [see Table 2].
44 45	280	Quantitative Data
46 47	281	Quantitative data will be extracted from baseline context mapping, communication, activity
48 49	282	tracking and check in sheets, and resident family awareness questionnaires [see Table 2]. These
50 51	283	data will include the hours of EDDIE+ training, days of intervention exposure, home structure
52 53	284	(bed number, staff, occupancy), local services, and communication mechanisms. The evaluation
54	285	of these data will inform intervention fidelity.
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Pre and post intervention staff-efficacy surveys will be collected using a validated questionnaire (17). The questionnaire comprises three sections. Section one provides information about the staff member's demographics, their role at the facility, years worked at the facility, years worked in aged care and their qualifications. Section two is a 5-point Likert scale with 10 statements related to job self-efficacy. The statements include job related confidence and ability, having the required skills to perform the job well and how they compare themselves to others in the field. Section three is a 5-point Likert scale with 7 statements related to team selfefficacy. Section three has questions related to team members' skills, abilities and effectiveness in relation to completing their own tasks and functioning as a team.

### 295 Qualitative Data

Qualitative data will be primarily collected from a series of semi-structured interviews with staff, family members and advocates of residents, EDDIE+ clinical facilitators, the nurse educator, project implementation facilitator and external stakeholders. Interviewees will be recruited by email and direct correspondence. Participation will be voluntary and informed consent will be obtained prior to the conduct of the interview. Additional qualitative data will be extracted from communication tracking field notes, baseline context assessments and check in forms where relevant. These data will address multiple aims of the process evaluation such as the acceptability of EDDIE+, contextual barriers and enablers, and the mechanisms of action (Table 2).

305 Staff, Local and External Stakeholder interviews

At intervention completion the RAC staff, including those in managerial positions, and external stakeholders such as GPs and allied health providers, will be invited to participate in semistructured interviews. Interviews will be up to 30 minutes in length and completed via telephone or Microsoft Teams. Topics to be covered during the interview include feasibility of implementation, adaptation and tailoring of EDDIE+, what worked and did not work, and factors to consider for sustainability and future scale up of EDDIE+ in other RAC homes[see Supplementary file]. Additionally, an open-ended interview will be conducted with the nurse

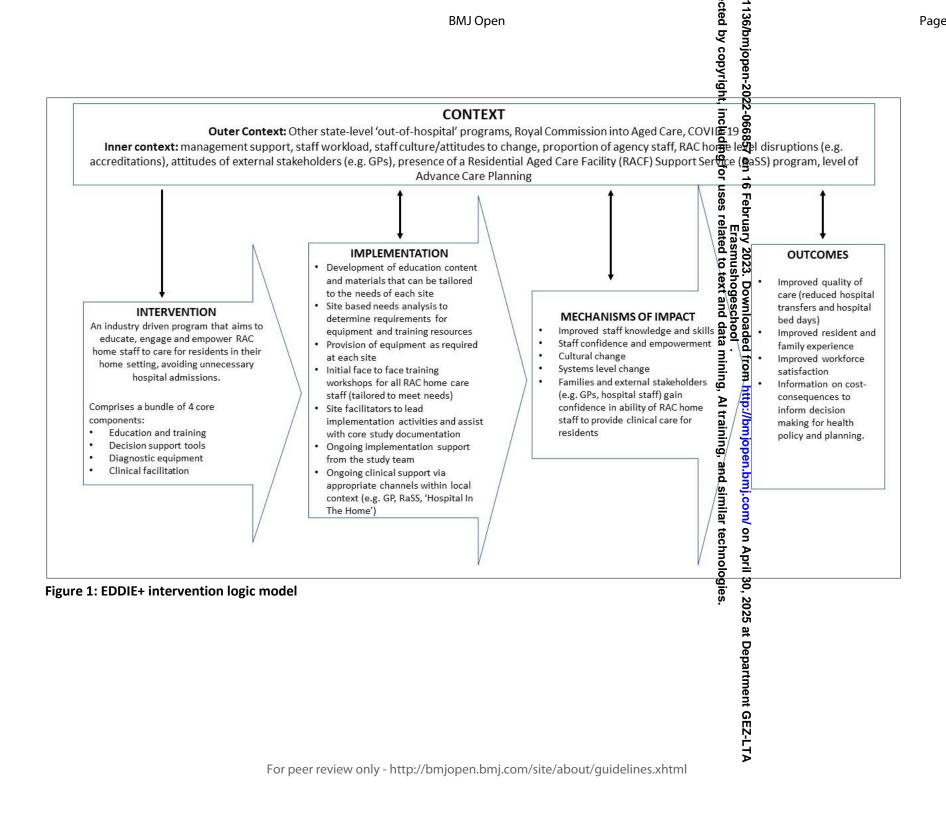
1 2							
3 4	313	educator and project implementation facilitator after the completion of the trial to ascertain					
5 6	314	their reflections and experience of the EDDIE+ intervention and implementation process.					
7 8 9	315	Family and nominated advocate interviews					
10 11	316	At intervention completion, family members and nominated advocates of residents, including					
12	317	those who have and those who have not experienced clinical deterioration, will be invited to					
13 14	318	participate in a short interview either via telephone or using Microsoft Teams. Interviews with					
15 16	319	family members and advocates are anticipated to take around 15 minutes dependent upon					
17 18	320	interviewee responses and knowledge of the program. Questions will explore their awareness					
19 20	321	and experience of EDDIE+ [see Supplementary file].					
21 22	322	All interviewees who have signed the consent form and completed an interview will be					
23 24	323	allocated a unique identifier to maintain confidentiality. No identifiable information will be					
25 26	324	reported in the findings from these interviews. Interviews will take place up to four months					
27 28	325	post-trial with a maximum of 30 interviews per stakeholder group across the 12 sites.					
29 30 31	326	Data Analysis					
32 33 34	327	Quantitative Data					
35 36	328	Descriptive statistics related to the process evaluation (counts, mean, standard deviations) will					
37 38	329	be analysed in Microsoft Excel to determine the communication level and engagement from					
39 40	330	each site based on the quantity of emails, meetings, and phone calls. Self-efficacy data from					
41 42	331	nursing and personal care workers will be subject to descriptive and inferential analysis using					
43 44	332	SPSS to assess whether EDDIE+ improved staff's perceived self-efficacy.					
45 46 47	333	Qualitative Data					
48 49	334	Semi-structured Interviews will be digitally recorded with consent from the interviewee and					
50 51	335	transcribed using Microsoft software. Once transcribed and checked for accuracy, interview					
52 53	336	transcripts will be mapped against the i-PARIHS constructs of innovation, recipients, context,					
54 55	337	and facilitation using NVivo qualitative data software. Additionally, qualitative data will be					
56	338	extracted from the baseline context mapping as well as communication, activity tracking and					
57 58		15					
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml					

1 2		
3 4	339	check in forms where appropriate and mapped to the i-PARIHS framework. Data that do not
5 6	340	align with the i-PARIHS framework will be analysed using a descriptive qualitative approach
7	341	(18). Transcripts will be read by two members of the project team with qualitative research
8 9	342	experience and content analysis will be used to code data, group codes into categories and
10 11	343	identify major themes (19). The analysis will be complete once agreement between researchers
12 13 14	344	is attained and no new themes emerge.
15 16	345	Integrating results of data analysis
17 18	346	Process evaluation data analysis will be undertaken independently of the analysis of the
19	347	effectiveness data from the trial. Once the trial results are available, combined analysis will be
20 21	348	undertaken to determine the extent to which the process evaluation helps explain the main
22 23	349	trial findings.
24 25 26	350	Patient and public involvement
27 28	351	No resident or public involvement in the design of the process evaluation. Family members and
29 30	352	nominated advocates of residents will be invited to participate in interviews and surveys as part
31 32	353	of the process evaluation.
33 34 35	354	Ethics and dissemination
36	355	Ethical approval for this study has been granted by the Bolton Clarke Human Research Ethics
37 38	356	Committee (approval number: 170031) with administrative ethical approval granted by the
39 40	357	Queensland University of Technology University Human Research Ethics Committee
41 42	358	[2000000618]. Full ethical approval includes a waiver of consent for access to residents'
43 44	359	demographic, clinical and health services de-identified data. A separate health services data
45 46	360	linkage based on RAC home addresses will be sought through a Public Health Act (PHA)
47	361	application. Group or individual interviews will require written consent prior to
48 49	362	commencement. Protocol amendments will be submitted as variations to the approving ethics
50 51	363	committees at time of identification. Additionally, the project manager will notify committees
52 53	364	in the circumstance of protocol deviations and adverse events in accordance with local
54 55	365	procedures.
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59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2							
3 4 5 6 7 8 9 10 11 12 13 14 15 16	366	Study findings will be disseminated through traditional academic channels, such as journal					
	367	publications and conference presentations, alongside more interactive strategies, including					
	368	engagement with a stakeholder network established to embed knowledge translation within					
	369	the research.					
	370	Discussion					
	371	Early detection and management of deterioration in residents of aged care homes could result					
	372	in a decrease of avoidable and unnecessary hospital transfers. The original EDDIE program was					
17 18	373	considered feasible, well received, and reduced total hospital bed days by 41% (6, 7). However,					
19 20	374	these promising results were inferred using a relatively small sample size and a pre-post design					
21	375	that did not control for external trends. Following the success of EDDIE in a single site, a					
22 23	376	modified version of the pilot (EDDIE+) was developed. A stepped wedge randomised controlled					
24 25	377	trial involving 12 RAC homes will evaluate the effectiveness and cost-consequences of EDDIE+					
26 27	378	with the aim of confirming preliminary findings and strengthening the evidence base for wider					
28 29	379	implementation. The embedded process evaluation will explore whether the scaled-up					
30	380	intervention was delivered and implemented as originally proposed, if EDDIE+ was acceptable					
31 32	381	from the perspective of various stakeholders, the mechanisms of impact through which EDDIE+					
33 34	382	improved outcomes (or not), and contextual barriers and enablers that may have influenced					
35 36	383	implementation. A mixed method, theory-informed approach will provide an in-depth					
37 38	384	evaluation of the EDDIE+ program and valuable insights into determinants of implementation					
39 40	385	success across multiple sites. This could help to identify key factors to consider in the future					
41 42	386	development and implementation of hospital avoidance programs such as EDDIE+.					
43 44 45	387						
46 47	388	Supplementary information					
48 49	389	Supplementary file – example data collection tools					
50 51	390	Contributors					
52 53 54 55	391	HC, NG, XL, GH, TD, EC, CM, FO conceived of the EDDIE+ study. GH, EB and MA have led the					
	392	development of the process evaluation. EB and GH drafted the manuscript with input from all					
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3 4	393	contributing authors. All authors critically revised the manuscript and approved the final				
5 6	394	version to be published.				
7 8	395	Competing interests				
9 10	396	None declared.				
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17 18	400	body did not have a role in the study design and subsequent protocol paper, nor are the				
19 20	401	funders involved with ongoing data collection, management, analysis, and interpretation.				
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25 26	404	thank the following partnering institutions: Flinders University, Central Queensland University,				
27 28	405	Bolton Clarke, University of the Sunshine Coast, Metro North Hospital and Health Service and				
20 29 30	406	University of Newcastle.				
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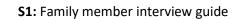
EDDIE+ Supplementary file – examples of data collection tools

- S1: Family member interview guide
- S2: Stakeholder interview guide
- **S3:** Staff self-efficacy survey (RN, EN, PCW)
- S4: Family member or nominated advocate questionnaire

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## Family member interview example topic guide

The following guide is intended to be used to conduct post implementation reviews of EDDIE+.

### **Objective:**

Identify family or nominated advocate awareness and experience of the EDDIE+ program.

#### **Participants:**

Interviews will be held with family members or nominated advocate of residents.

Notes – might not be one episode of care – could be multiple within the intervention period.

#### Introduction

EDDIE+ is a research project that has been introduced at RAC home name. The purpose of this research project is to implement and evaluate a RAC home-driven hospital avoidance program that aims to upskill, empower and provide support for nursing and care staff to detect deterioration in elderly residents early, so that they can provide care in place (at RAC home name), avoid residents being transferred unnecessarily to hospital, and reduce hospital length of stay if patients are admitted.

#### Questions

- How did you find your experience with this program?
- What has changed in your life because of using this program?
- What would you tell a friend/family member about the program? •

## EDDIE<sup>+</sup> Researching Early Detection of Deterioration in Elderly residents

## RAC stakeholder interview example topic guide

The following guide is intended to be used to conduct post implementation reviews of EDDIE+.

#### **Objective:**

Identify factors that supported and barriers that impeded the implementation and success of the project, including factors that may be important for scale-up or adoption in other RAC homes.

#### **Participants:**

Interviews will be held with the following key groups as applicable:

- Nurses and carers
- Other RAC home stakeholders

The number and mix of groups will be dependent on the RAC home.

Key topic	Prompt questions
How was the intervention tailored and implemented?	<ol> <li>Can you describe how the intervention was implemented?</li> <li>Was the intervention implemented according to the implementation plan?</li> <li>Who were the key stakeholders to get on board with the intervention?</li> <li>To what extent were the needs and preferences of clients considered when deciding to implement the intervention?</li> </ol>
What about the intervention worked?	<ol> <li>What did you like about the program?</li> <li>What has been most helpful to you?</li> <li>What were implementation facilitators?</li> </ol>
What about the intervention didn't	1. What didn't you like about the program?
worked?	2. What has been least helpful to you?
What factors will be important for scale-up	1. How do you think this would work in other RAC homes?
and/or sustainability?	2. What is important for this to work in other RAC homes?
Is EDDIE+ generalisable to other RAC home settings?	1. What would need to be considered?

## S3: Staff self-efficacy survey (RN, EN, PCW)







## Researching Early Detection of Deterioration In **Elderly residents**

## Nurse and carer questionnaire

This survey will ask some general questions about you, as well as some questions about your role atBolton Clarke. There are no right or wrong answers to these questions. All answers will remain confidential. Only the EDDIE+ team at the Queensland University of Technology (QUT) will see your answers.

It will take about 10 minutes to complete.

Please do NOT complete this survey if you are under 18 years of age.

We would like to ask you similar questions at the end of the EDDIE+ trial. To help us match your responses please make yourself a code. The code is unique to you and we cannot identify you in any way from this code.

Write the first 3 letters of your mother's surname? (e.g. Davis will be DAV) Write the numbers of your birth month (e.g. February is 02)

	ABOUT YOU
First, p	lease tell us a bit about yourself:
1.	Ageyears
2.	What best describes your gender?
	Female
	Male
	Other (please specify)
	Prefer not to say
3.	What best describes your work role at Bolton Clark?
	Registered nurse
	Enrolled nurse
	Personal care worker
	Other (please specify)
4.	How long have you cared for residents at Bolton Clarke? years
	· · · · · · · · · · · · · · · · · · ·
5.	How long have you care for residents in a Residential Aged Care home?years
6.	What qualifications have you completed? (tick all that apply)
	□ None
	Registered nurse
	Enrolled Nurse
	Certificate III in Aged Care/Community Care, Disability or Individual Support
	CHCCS305C – Assist clients with medication
	First Aid/CPR certificate
	Other certificate, not sure of name
	Other (please specify)

## Job related self-efficacy

Please circle how much you agree or disagree with the following statements.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. I have confidence in my ability to do my job.	1	2	3	4	5
2. There are some tasks required by my job that I cannot do well.	1	2	3	4	5
3. When my performance is poor, it is due to my lack of ability.	1	2	3	4	5
4. I doubt my ability to do my job.	1	2	3	4	5
5. I have all the skills needed to perform my job very well.	1	2	3	4	5
6. Most people in my line of work can do this job better than I can.	1	2	3	4	5
7. I am an expert at my job.	1	2	3	4	5
8. My future in this job is limited because of my lack of skills.	1	2	3	4	5
9. I am very proud of my job skills and abilities.	1	2	3	4	5
10. I feel threatened when others watch me work.	1	2	3	4	5

## Group related self-efficacy

Please circle how much you agree or disagree with the following statements.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. The group I work with has above average ability.	1	2	3	4	5
2. This group is poor compared to other groups doing similar work.	1	2	3	4	5
3. This group is not able to perform as well as it should.	1	2	3	4	5
4. The members of this group have excellent job skills.	1	2	3	4	5
5. Some members of this group should be excluded due to lack of ability.	1	2	3	4	5
6. This group is not very effective.	1	2	3	4	5
7. Some members in this group cannot do their tasks well.	1	2	3	4	5

Thank you for completing this survey. Please return to the nurse educator or place it in the box provided.

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### S4: Family member or nominated advocate questionnaire







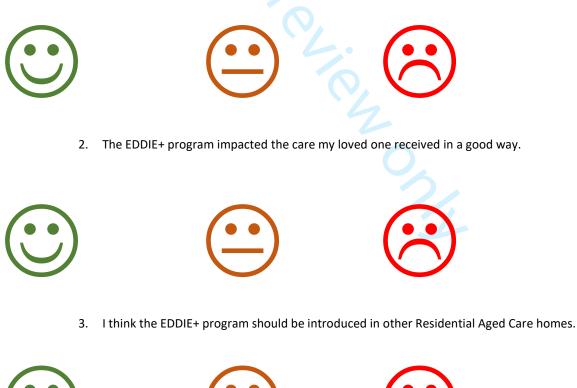
**Researching Early Detection of Deterioration In Elderly residents** 

## Family member or nominated advocate questionnaire

This survey asks your opinions about the EDDIE+ program at Bolton Clarke and how you feel it has affected thecare your family member has received. There are no right or wrong answers to these questions.

Please circle the face that most reflects how you feels about the following statements.

1. How did you find your experience with the EDDIE+ program?





Thank you for completing this survey.



## Protocol for a process evaluation of a stepped wedge randomised controlled trial to reduce unnecessary hospitalisations of older people from residential aged care: the EDDIE+ study

Journal:	BMJ Open
Manuscript ID	bmjopen-2022-066857.R1
Article Type:	Protocol
Date Submitted by the Author:	22-Dec-2022
Complete List of Authors:	Bracci, Ella; Flinders University Caring Futures Institute, College of Nursing and Health Sciences Allen, Michelle; Queensland University of Technology Faculty of Health, AusHSI Carter, Hannah; Queensland University of Technology, AusHSI Cyarto, Liz; Queensland University of Technology Dwyer, Trudy; Central Queensland University, Higher education Graves, Nicholas; National University of Singapore, Duke-NUS Postgraduate Medical School Lee, Xing; Queensland University of Technology, School of Mathematical Sciences Meyer, Claudia; Bolton Clarke Research Institute Oprescu, Florin; University of the Sunshine Coast Harvey, Gillian; Flinders University, Caring Futures Institute
<b>Primary Subject Heading</b> :	Geriatric medicine
Secondary Subject Heading:	Evidence based practice, Health services research, Nursing
Keywords:	Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, EDUCATION & TRAINING (see Medical Education & Training), QUALITATIVE RESEARCH



2 3						
4	1	Protocol for a process evaluation of a stepped wedge randomised controlled trial to reduce				
5 6 7	2	unnecessary hospitalisations of older people from residential aged care: the EDDIE+ study				
8 9	3	Authors				
10 11	4	Ella Bracci <sup>1</sup> , Michelle Allen <sup>2</sup> , Hannah Carter <sup>2</sup> , Liz Cyarto <sup>3</sup> , Trudy Dwyer <sup>4</sup> , Nick Graves <sup>2,5</sup> , Xing				
12 13	5	Lee <sup>3</sup> , Claudia Meyer <sup>6</sup> , Florin Oprescu <sup>7</sup> , Gill Harvey <sup>1,2</sup>				
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35	Abstract
36	Introduction
37	The Early Detection of Deterioration in Elderly residents (EDDIE+) program is a theory-informed,
38	multi-component intervention aimed at upskilling and empowering nursing and personal care
39	staff to identify and manage early signs of deterioration in residents of aged care facilities. The
40	intervention aims to reduce unnecessary hospital admissions from residential aged care homes.
41	Alongside a stepped wedge randomised controlled trial, an embedded process evaluation will
42	be conducted to assess the fidelity, acceptability, mechanisms of action and contextual barriers
43	and enablers of the EDDIE+ intervention.
44	Methods and Analysis
45	Twelve residential aged care homes in Queensland, Australia are participating in the study. A
46	comprehensive mixed methods process evaluation, informed by the integrated Promoting
47	Action on Research Implementation in Health Services (i-PARIHS) framework, will assess
48	intervention fidelity, contextual barriers and enablers, mechanisms of action, and the
49	acceptability of the program from various stakeholder perspectives. Quantitative data will be
50	collected prospectively from project documentation, including baseline context mapping of
51	participating sites, activity tracking and regular check-in communication sheets. Qualitative
52	data will be collected post-intervention via semi-structured interviews with a range of
53	stakeholder groups. The i-PARIHS constructs of innovation, recipients, context, and facilitation
54	will be applied to frame the analysis of quantitative and qualitative data.
55	Ethics and dissemination
56	Ethical approval for this study has been granted by the Bolton Clarke Human Research Ethics
57	Committee (approval number: 170031) with administrative ethical approval granted by the
58	Queensland University of Technology University Human Research Ethics Committee
59	[2000000618]. Full ethical approval includes a waiver of consent for access to residents'
60	demographic, clinical and health services de-identified data. A separate health services data
61	linkage based on RAC home addresses will be sought through a Public Health Act (PHA)

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62	application. Study findings will be disseminated through multiple channels, including journal
63	publications, conference presentations and interactive webinars with a stakeholder network.
64	Trial registration:
65	The trial is prospectively registered with the Australia New Zealand Clinical Trial Registry
66	(ACTRN12620000507987, registered 23/04/2020).
67	Strengths and limitations of this study
68	Theory-informed process evaluation, framed by the integrated-Promoting Action on
69	Research Implementation in Health Services framework and an intervention logic model.
70	Process data from a range of sources to assess implementation processes and outcomes.
71	Outcomes could help inform planning for future development and implementation of
72	hospital avoidance strategies in residential aged care facilities.
73	High staff turnover and workload within the residential aged care sector may impact staff
74	availability to participate in surveys and interviews.
75	<ul> <li>Data relating to residents' experiences will be collected from family members and</li> </ul>
76	nominated advocates, rather than directly from residents.

#### Introduction

When older adults living in Residential Aged Care (RAC) are admitted to hospital, they face increased risk of hospital associated complications and invasive interventions (1). Hospital presentations and admissions amongst this population group are relatively high and there is evidence to suggest some hospital encounters are avoidable (2). A report published by the Australian Medical Association estimated 27,000 potentially preventable admissions from RAC homes in Australia in 2021, equating to 160,000 bed days with a cost of \$312 million Australian dollars (3). RAC residents, family members and staff express a preference for care to be provided in their home where possible (4). Previous research indicates that this is possible and will reduce hospital presentations and admissions from RAC, from implementing models of care that provide access to resources and improve the clinical skills and confidence of nursing staff (5). 

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The 'Early Detection of Deterioration In Elderly residents' or 'EDDIE' program was developed in Queensland, Australia as a hospital avoidance intervention targeted at nursing and other care staff working in RAC. The aim was to empower and enable staff to identify and appropriately respond to early clinical signs of a deteriorating resident (5, 6). An initial pilot of EDDIE demonstrated that the intervention was feasible and acceptable to RAC staff, reduced hospital transfer rates and resulted in a 41 per cent reduction in total hospital bed days (7). EDDIE+ builds upon the learning from the EDDIE pilot (5, 6, 8) and aims to develop and test a scalable hospital avoidance intervention in RAC. The evaluation study involves a type 1 stepped-wedge randomized controlled effectiveness-implementation trial (9) with embedded economic and mixed methods process evaluation. Details of the trial, which involves 12 participating RAC homes in metropolitan and regional Queensland, have been described in a previously published trial protocol paper (10). This paper presents the protocol for the process evaluation component of the study. Process evaluations are increasingly recognised as an important part of developing and testing complex interventions such as EDDIE+, which comprises multiple components and is implemented across multiple sites (12, 13). Process evaluations often include assessing an intervention's fidelity, namely, if the intervention was implemented as intended, the acceptability of an intervention from various stakeholder perspectives, the mechanism of impact, or what initiates a change, and an assessment of barriers and enablers to implementation.

#### 39 108 The EDDIE+ Intervention

EDDIE+ focuses on upskilling nursing and personal care staff working within RAC, by giving them
the knowledge, skills and support needed to manage sub-acute episodes such as urinary tract
infections, chest pain, falls and dyspnoea within the home setting. It comprises four
components: advanced clinical skills education and training (provided initially by a projectfunded nurse educator), decision support tools, provision of diagnostic equipment (for
example, bladder scanners and vital signs monitors) and implementation facilitation and
support (via a locally appointed clinical facilitator supported by a project implementation
facilitator) (6). The development of EDDIE+ was underpinned by a widely used implementation
framework, the integrated Promoting Action of Research Implementation in Health Services (i-

PARIHS) framework (11). i-PARIHS proposes that the successful implementation of evidence-informed innovations results from the active facilitation of an innovation with the intended recipients of implementation within their local, organisational and system context. As such, attention to facilitation, engagement with RAC stakeholders, involvement of staff and responsiveness to context are key features of EDDIE+. By embedding implementation facilitation within the bundle of components that comprise EDDIE+, implementation is integral to the intervention. Consistent with facilitation as a primary implementation strategy, clinical facilitators can tailor the implementation of EDDIE+ according to their own home's needs. This will be achieved through the identification of core and adaptable features of each EDDIE+ component [Table 1]. Figure 1 presents a logic model summarising how EDDIE+ is expected to work and produce intended changes to processes and outcomes of care. [Figure 1 about here] è le v Methods and analysis Process evaluation While the trial component of the study focuses on intervention effectiveness, the process evaluation aims to understand how and why the intervention works in real-world contexts. This involves examining whether the intervention has been implemented as planned and resulted in expected outcomes. Understanding whether and how an intervention is affecting change can provide insights into the processes of implementation and the extent to which these account for positive or negative study outcomes. This is particularly helpful if the actual study outcomes differ from expected outcomes, enabling the study team to understand whether there has been implementation failure, such as poor delivery of the intervention, or intervention failure, such as poor or inappropriate design (14). This might inform planning of future interventions and implementation strategies. For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml 

EDDIE+ Component	Fixed element (core)	Flexible genyent (adaptable)
Advanced clinical skills education and training	Initial training mandatory for Registered Nurses, Enrolled Nurses, and Personal Care Workers	Mode of delivers Timing and organs Timing and organs
	Training on clinical management of specific conditions identified as likely to result in hospitalisation (e.g., UTIs, chest pain, falls, delirium, dehydration, dyspnoea, palliative care, constipation)	Number and type of foonditions covered Mode of delivery Staff involved in Staff invo
	Core set of educational materials	နိုင်ငံနိုင်ငံ Additional site-sခြင်ငံနိုင်ငံကျော်ကျော်
Decision support tools	Core decision support tool for management of clinical deterioration across specific conditions	Number and type of conditions covered Format of tool Observation charge (egg., track & trigger Communication tool e.g., ISBAR - (Introduction, Site at on, Background Assessment, Recommendation)
Diagnostic equipment (bladder scanner, ECG machine, vital signs monitor, oximeter)	Each home assessed for equipment needs Provision and training in use of equipment as per home requirements	Type of equipment tailored to individua home needs
Implementation facilitation	Appointment of clinical facilitator	Role-sharing by
and support	Train-the-trainer model for clinical facilitator	Opt-in by other ਸ਼ਿੰਦ gisttered Nurses
	Communication channel established for discussing concerns about resident deterioration and/or need for hospital transfer	Tailored to indivie ua home needs
Table 1: Core and adaptable com	ponents of EDDIE+ intervention	Department GEZ-LTA

1 2							
- 3 4	145	To evaluate how and how well EDDIE+ was implemented, the process evaluation of EDDIE+ will					
5	146	follow published guidance on conducting and reporting studies with a process evaluation					
6 7	147	component (12). Consistent with the application of i-PARIHS to inform the development of					
8 9	148	EDDIE+, the process evaluation will be framed by i-PARIHS and the intervention logic model					
10 11	149	that was developed at the study design stage (Figure 1). Implementation outcomes of interest					
12 13	150	in the process evaluation include fidelity and acceptability of EDDIE+ to multiple stakeholders,					
14 15	151	the mechanisms through which EDDIE+ achieves an effect (or not), and contextual barriers and					
16 17	152	enablers of implementation.					
18 19 20	153	Aims					
21 22	154	The aim of the process evaluation is to track the implementation of EDDIE+ in the 12					
23 24	155	participating RAC homes to:					
25							
26 27	156	1. Assess EDDIE+ intervention fidelity					
28 29	157	2. Assess the acceptability of EDDIE+ from the perspective of staff, residents' family					
30 31	158	members, EDDIE+ facilitators and wider stakeholders					
32 33	159	<ol> <li>Identify the mechanisms of impact</li> <li>Identify contextual barriers and enablers of implementation</li> </ol>					
34 35	160	<ol><li>Identify contextual barriers and enablers of implementation.</li></ol>					
36 37	161	Study Design and Data Collection					
38 39	162	An embedded and formative mixed methods process evaluation will be undertaken. This will be					
40 41	163	guided by a series of templates based on i-PARIHS to assess fidelity and acceptability of EDDIE+,					
42	164	mechanisms of impact, and contextual barriers and enablers within and across the 12 regional					
43 44	165	and metropolitan homes. Data from all four intervention phases of the stepped wedge trial will					
45 46	166	be collected and analysed. These are the preparation, baseline exposure, intervention					
47 48	167	introduction and intervention exposure phases.					
49 50	168	We first summarise how the theoretical propositions of the i-PARIHS framework inform the					
51 52	169	questions of interest within the process evaluation, before describing the methods of data					
53 54	105	collection and analysis (Tables 2 and 3).					
55 56	1,0						
57 58		0					
59		<b>8</b> For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml					
60		for peer review only intep://binjopen.binj.com/atc/about/guidelines.kntmi					

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6 7 8 9	Data Source								Data Analysis	Approach	
) 10 11	i-PARIHS	Process Evaluation	EDDIE+	Comm and	Context	Interviews	Self-	Family	e brua	Quantitative	Qualitative
12	Constructs	Component	Check in	Activity	mapping		Efficacy	advoca	ary 20		
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>25</li> <li>26</li> <li>27</li> <li>28</li> <li>29</li> </ol>			Form	Tracking			Surveys	Family advoca questio			
	Innovation and	Fidelity	<b>~</b>			~			nloade school	✓	✓
	Recipients	Acceptability	~	~	r r	~		✓	om M		✓
	Facilitation	Mechanisms of Impact	<b>√</b>		101		~		http://bmjope	V	<ul> <li>✓</li> </ul>
	Context	Barriers and Enablers	~	✓	√	1	0		http://bmjopen.bmj.com/		×
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		1136/bmjopen-202 cted by copyright,	
Data Source	Description	Purpose	Aim*
Communication and Activity	Conversational data, hours of training,	Provide picture of homes actors the	1, 3, 4
Tracking	details of home, education, and	intervention period and record and r	
	training, field notes	critical time junctures	
Baseline context mapping	Description of home characteristics	Provide baseline overview og hog he,	4
	before EDDIE+ intervention	including likely barriers and anapplers of implementation	
Check In Forms	Hours of training, EDDIE+ activities,	Describe EDDIE+ activities un describe EDDIE+ activities un describe EDDIE+ activities un describe et al activities activitities activities activities act	1, 2, 3, 4
	general updates	and program progress over	
Semi-structured interviews	Interviews with staff, residents and	Understand stakeholder vie	2, 4
	family members, EDDIE+ facilitators	experiences of EDDIE+	
	and external stakeholders	experiences of EDDIE+ m. from	
Self-efficacy surveys	Pre and post surveys	Determine if EDDIE+ has imaoved	3
		efficacy and upskilled staff	
Family member or nominated	Traffic light system with three	Determine family members	2
advocate questionnaire	questions related to the EDDIE+	advocates views on the programs and	
	program	impact 🛐 👼	
*Aims - 1: Assess the EDDIE+ interven	evaluation data sources tion fidelity; 2: Assess the acceptability and views o	f the EDDIE+ program from the permettive of staff	recident famil
		gi ö	
	holders; 3: Identify mechanisms of impact; 4: Identi		ion success
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## 182 <u>i-PARIHS theoretical framing</u>

183 Innovation

According to the theoretical proposition of i-PARIHS, implementation effectiveness is enhanced 184 185 if there is support for the innovation to be implemented. The innovation in this case is EDDIE+, 186 an intervention to improve the identification and management of clinical deterioration in residents within the home setting and in turn, reduce unnecessary hospital transfers. Support is 187 more likely if key stakeholders including RAC staff, managers, residents, family members and 188 189 external care providers, agree with the idea of keeping residents at home where possible and 190 perceive implementation to be workable in practice. In relation to EDDIE+, this includes support for the education and training offered and the introduction and use of new diagnostic 191 192 equipment. Therefore, it will be important to collect stakeholder views on the acceptability, 193 relevance, and importance of EDDIE+ within the context of the RAC home setting.

7 194 Recipients

i-PARIHS proposes that recipients of an innovation (for example, staff, residents, and family
 members) need both 'want to' and 'can do' factors to achieve successful implementation (15).
 RAC staff in particular have to be motivated to address the issue of clinical deterioration in
 residents and have the capacity and capability to implement EDDIE+. These areas will be
 explored as part of the data collection.

200 Context

Contextual factors at multiple levels are identified as important barriers or enablers of 201 202 implementation in i-PARIHS and will be examined as part of the process evaluation. The inner 203 context spans the local and organisational settings. At a local level, inner context refers to the 204 immediate place of implementation - the RAC home - and encompasses factors such as the workplace culture, management and leadership support, workload, receptiveness, and 205 206 attitudes to change. The local context is embedded within the organisational context - the aged 207 care provider organisation - where factors relating to culture, leadership, support and resources are also important. Outer context relates to the wider aged care system, including policy 208 55 56 209 drivers, regulatory standards and frameworks, other initiatives that influence the care of 57

deteriorating residents, and more general health, social and economic issues that affect aged
 care. Initial mapping of contextual factors will be undertaken pre-implementation and tracked
 throughout the intervention phase of the study.

213 Facilitation

Facilitation in the i-PARIHS framework is positioned as the active ingredient of implementation, comprising facilitator roles and the use of enabling facilitation strategies. It is the facilitator's role to assess innovation, recipient and contextual factors that present barriers to or enablers of implementation and plan appropriate facilitation strategies to address these. The main facilitator role in EDDIE+ is the clinical facilitator appointed from within the RAC home to support implementation, with funding provided for backfill support. The clinical facilitator receives additional support from the EDDIE+ project team including the nurse educator and the project implementation facilitator. This is based on a model of internal-external facilitation (16). The nurse educator is responsible for developing and delivering the training on clinical deterioration and the diagnostic equipment to RAC staff, whilst the implementation facilitator will undertake the baseline context assessment and support the clinical facilitators to develop facilitation skills. As part of the process evaluation, it will be important to collect data about the different facilitator roles, the strategies used to facilitate implementation and how well these worked. 

- 38 228 Process evaluation elements
- 41 229 Fidelity

Fidelity will be evaluated in relation to the delivery of EDDIE+ as intended, namely: attendance at mandatory EDDIE+ training by nurses and personal care workers (expressed as a percentage of total staff employed who attended training), number of EDDIE+ sessions delivered/attended, use of the new equipment, and recruitment and retention of clinical facilitators. These data will be extracted from EDDIE+ check in forms completed by the nominated clinical facilitator at each site and the communication and tracking data collected from the project team, including education attendance records [see Supplementary file]. Additional data sources will be used to 

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2 3	237	determine any critical time junctures such as COVID-19 lockdowns, infection outbreaks and				
4 5 7 8 9 10 11	238	other events that may have impacted the implementation of EDDIE+.				
	250	other events that may have impacted the implementation of EDDIE+.				
	239	Acceptability				
	240	Data will be collected on the acceptability of EDDIE+ from the perspective of four stakeholder				
12	241	groups: RAC staff including Registered Nurses, Enrolled Nurses and Personal Care Workers,				
13 14	242	family members or nominated advocates of residents, clinical facilitators, and local and external				
15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39	243	stakeholders [see Tables 2 & 3]. Semi-structured interviews will be conducted with these				
	244	different groups to ascertain their views about EDDIE+. Family members and nominated				
	245	advocates will be asked about their awareness and experiences of EDDIE+ and how it impacted				
	246	the resident's care. RAC staff and other stakeholders will be interviewed about EDDIE+ and how				
	247	it was implemented to determine what they found most and least helpful about EDDIE+ and				
	248	whether they thought the intervention was transferable to other RAC homes [see				
	249	Supplementary files S1 and S2 for interview guides]. Additionally, a three-question traffic light				
	250	survey will be distributed to family members and nominated advocates to determine if their				
	251	experience with EDDIE+ was positive, negative, or neutral, if EDDIE+ impacted the care of their				
	252	loved one in a good way, and their views on whether EDDIE+ should be introduced into other				
	253	RAC homes [see Supplementary file S3].				
	254	Mechanisms of impact				
	234					
	255	As illustrated in the logic model in Figure 1, the EDDIE+ intervention is expected to produce				
40 41	256	improvements in resident, staff, and system level outcomes through mechanisms including				
42 43	257	enhanced staff knowledge and skills, increased staff confidence and sense of empowerment,				
44 45	258	and greater confidence of family members and external care providers in the ability of RAC				
46	259	home staff to provide appropriate clinical care for residents. These mechanisms will be				
47 48	260	explored through several data sources. RAC staff will be requested to complete a self-efficacy				
49 50	261	survey pre and post EDDIE+ implementation using a validated self-efficacy questionnaire (17) to				
51 52	262	evaluate reported changes in staff confidence and capability [Supplementary file S4].				
53 54	263	Questionnaire data will be supplemented with data from semi-structured interviews conducted				
55 56	264	with RAC staff, clinical facilitators, managers, and external care providers, such as general				
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58 59		13				

265 practitioners, to assess mechanisms relating to confidence, staff empowerment and skills and
 266 knowledge development [Supplementary files S1 and S2].

#### 267 Understanding barriers and enablers

Consistent with the i-PARIHS framework, barriers and enablers to implementation will be explored in relation to the EDDIE+ intervention (acceptability and feasibility), recipient characteristics (RAC staff 'want to' and 'can do' factors) and the inner and outer context. During semi-structured interviews, RAC staff and wider stakeholders will be asked to provide specific examples of barriers and enablers of EDDIE+, what worked well (or less well) in their own RAC home and what would need to be considered for future implementation in other facilities. Supplementary information related to barriers and enablers will be extracted from the baseline context mapping, communication and activity tracking spreadsheets and check in forms completed by clinical facilitators and the nurse educator and project implementation facilitator. 

#### <sup>28</sup> 29 278 <u>S</u>

#### 8 Setting and participant recruitment for process evaluation

Twelve Bolton Clarke Residential Aged Care Facilities in Queensland, Australia have been recruited to participate in the EDDIE+ study. The stepped wedge design involved 4 phases (preparation, baseline/usual care exposure, intervention introduction and intervention exposure) that took place from March 2021 to May 2022. The process evaluation will be conducted from May to September 2022 with data from all participating homes. This will include recruitment of RAC staff, clinical facilitators, family members of residents (where applicable), and local and external stakeholders including GPs, home managers and allied health managers [see Table 2].

#### 47 287 <u>Quantitative Data</u>

Quantitative data will be extracted from baseline context mapping, communication, activity tracking and check in sheets, and resident family awareness questionnaires [see Table 2]. These data will include the hours of EDDIE+ training, days of intervention exposure, home structure (bed number, staff, occupancy), local services, and communication mechanisms. The evaluation of these data will inform intervention fidelity. 

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293 Pre and post intervention staff-efficacy surveys will be collected using a validated questionnaire 294 (17). The questionnaire comprises three sections. Section one provides information about the 295 staff member's demographics, their role at the facility, years worked at the facility, years 296 worked in aged care and their qualifications. Section two is a 5-point Likert scale with 10 297 statements related to job self-efficacy. The statements include job related confidence and ability, having the required skills to perform the job well and how they compare themselves to 298 299 others in the field. Section three is a 5-point Likert scale with 7 statements related to team selfefficacy. Section three has questions related to team members' skills, abilities, and 300 effectiveness in relation to completing their own tasks and functioning as a team. 301

#### 302 <u>Qualitative Data</u>

Qualitative data will be primarily collected from a series of semi-structured interviews with 303 304 staff, family members and advocates of residents, EDDIE+ clinical facilitators, the nurse 305 educator, project implementation facilitator and external stakeholders. Interviewees will be recruited by email and direct correspondence. Staff at participating RAC sites will be invited to 306 participate in an interview by the project implementation facilitator during one of the end of 307 308 intervention site visits. Relevant family members and stakeholders from the participating RAC 309 homes will be identified by the EDDIE+ facilitator and BC investigators and details forwarded to the QUT project team. The QUT project team will then make contact through email 310 311 correspondence. Once written consent is obtained, interviewee details will be passed on 312 through email to investigators leading the process evaluation (EB and GH) who will coordinate a mutual time for the interview. 313

Participation will be voluntary and informed consent will be obtained prior to the conduct of
the interview. Additional qualitative data will be extracted from communication tracking field
notes, baseline context assessments and check in forms where relevant. These data will address
multiple aims of the process evaluation such as the acceptability of EDDIE+, contextual barriers
and enablers, and the mechanisms of action (Table 2).

319 Staff, Local and External Stakeholder interviews

At intervention completion the RAC staff, including those in managerial positions, and external stakeholders such as GPs and allied health providers, will be invited to participate in semi-structured interviews. Interviews will be up to 30 minutes in length and completed via telephone or Microsoft Teams. Topics to be covered during the interview include feasibility of implementation, adaptation and tailoring of EDDIE+, what worked and did not work, and factors to consider for sustainability and future scale up of EDDIE+ in other RAC homes [see Supplementary file]. Additionally, an open-ended interview will be conducted with the nurse educator and project implementation facilitator after the completion of the trial to ascertain their reflections and experience of the EDDIE+ intervention and implementation process. Family and nominated advocate interviews At intervention completion, family members and nominated advocates of residents, including those who have and those who have not experienced clinical deterioration, will be invited to participate in a short interview either via telephone or using Microsoft Teams. Interviews with family members and advocates are anticipated to take around 15 minutes dependent upon interviewee responses and knowledge of the program. Questions will explore their awareness and experience of EDDIE+. All interviewees who have signed the consent form and completed an interview will be allocated a unique identifier to maintain confidentiality. No identifiable information will be reported in the findings from these interviews. Interviews will take place up to four months post-trial with a maximum of 30 interviews per stakeholder group across the 12 sites. Data Analysis Quantitative Data Descriptive statistics related to the process evaluation (counts, mean, standard deviations) will be analysed in Microsoft Excel to determine the communication level and engagement from each site based on the quantity of emails, meetings, and phone calls. Job-related and team-related self-efficacy data from nursing and personal care workers will be subject to descriptive 

and inferential analysis using SPSS to assess whether EDDIE+ improved staff's perceived self-

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efficacy post-intervention. The baseline self-efficacy survey will be completed immediately prior
to the participant's (RN, EN, PCW) first EDDIE+ training session while post intervention selfefficacy surveys will be provided to staff between the final two weeks of the intervention
exposure and up to two weeks post trial.

351 Internal consistency of job-related and team-related self-efficacy will be assessed separately using Cronbach's Alpha. Differences between mean baseline and post intervention scores on 352 the self-efficacy measures will be assessed using t-tests, to determine if there is a statistically 353 significant (p < .05) change in job-related self-efficacy and team-related self-efficacy. Linear 354 regression will be used to determine the contribution of staff-related factors including role, 355 356 experience, age, gender, and location, to changes in job-related and team-related self-efficacy scores. Missing outcome data from staff lost to follow-up will be treated as missing completely 357 358 at random (MCAR) and handled using complete case analysis.

#### 359 Qualitative Data

360 Semi-structured Interviews will be digitally recorded with consent from the interviewee and transcribed using Microsoft software. Once transcribed and checked for accuracy, interview 361 transcripts will be mapped against the i-PARIHS constructs of innovation, recipients, context, 362 and facilitation using NVivo qualitative data software. Additionally, qualitative data will be 363 364 extracted from the baseline context mapping as well as communication, activity tracking and 365 check in forms where appropriate and mapped to the i-PARIHS framework. Data that do not align with the i-PARIHS framework will be analysed using a descriptive qualitative approach 366 367 (18). Transcripts will be read by two members of the project team with qualitative research experience and content analysis will be used to code data, group codes into categories and 368 369 identify major themes (19). The analysis will be complete once agreement between researchers 370 is attained and no new themes emerge.

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<sup>1</sup> 371 Integrating results of data analysis

372 Process evaluation data analysis will be undertaken independently of the analysis of the
 373 effectiveness data from the trial. Once the trial results are available, combined analysis will be

3 4	374	undertaken to determine the extent to which the process evaluation helps explain the main
5 6	375	trial findings.
7 8 9 10 11 12 13 14 15 16	376	Patient and public involvement
	377	There is no planned resident or public involvement in the design of the process evaluation due
	378	to the Covid-19 pandemic and restricted access to residential aged care settings. Whilst
	379	recognising this as a potential limitation to the study, family members and nominated
	380	advocates of residents will be invited to participate in interviews and surveys as part of the
17 18 19	381	process evaluation.
20 21	382	Ethics and dissemination
22 23	383	Ethical approval for this study has been granted by the Bolton Clarke Human Research Ethics
24	384	Committee (approval number: 170031) with administrative ethical approval granted by the
25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42	385	Queensland University of Technology University Human Research Ethics Committee
	386	[2000000618]. Full ethical approval includes a waiver of consent for access to residents'
	387	demographic, clinical and health services de-identified data. A separate health services data
	388	linkage based on RAC home addresses will be sought through a Public Health Act (PHA)
	389	application. Group or individual interviews will require written consent prior to
	390	commencement. Protocol amendments will be submitted as variations to the approving ethics
	391	committees at time of identification. Additionally, the project manager will notify committees
	392	in the circumstance of protocol deviations and adverse events in accordance with local
	393	procedures.
43	394	Study findings will be disseminated through traditional academic channels, such as journal
44 45	395	publications and conference presentations, alongside more interactive strategies, including
46 47	396	engagement with a stakeholder network established to embed knowledge translation within
48 49 50	397	the research.
51 52	398	Discussion
53 54	399	Early detection and management of deterioration in residents of aged care homes could result
55 56 57	400	in a decrease of avoidable and unnecessary hospital transfers. The original EDDIE program was
58 59		18
60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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considered feasible, well received, and reduced total hospital bed days by 41% (6, 7). However, these promising results were inferred using a relatively small sample size and a pre-post design that did not control for external trends. Following the success of EDDIE in a single site, a modified version of the pilot (EDDIE+) was developed. A stepped wedge randomised controlled trial involving 12 RAC homes will evaluate the effectiveness and cost-consequences of EDDIE+ with the aim of confirming preliminary findings and strengthening the evidence base for wider implementation. The embedded process evaluation will explore whether the scaled-up intervention was delivered and implemented as originally proposed, if EDDIE+ was acceptable from the perspective of various stakeholders, the mechanisms of impact through which EDDIE+ improved outcomes (or not), and contextual barriers and enablers that may have influenced implementation. A mixed method, theory-informed approach will provide an in-depth evaluation of the EDDIE+ program and valuable insights into determinants of implementation success across multiple sites. This could help to identify key factors to consider in the future development and implementation of hospital avoidance programs such as EDDIE+. 

#### 415 Limitations

416 Direct resident involvement in the evaluation of EDDIE+ would strengthen the process
 417 evaluation, however, this is not achievable during a pandemic that has led to strict visitor
 418 lockdowns in RAC. As an alternative strategy, data to reflect residents' experiences will be
 419 collected from family members and nominated advocates.

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Another potential limitation is that EDDIE+ is being implemented and evaluated with a single aged care provider in Queensland which could compromise transferability to other aged care settings and providers. However, the RAC facilities involved in EDDIE+ represent a range of metropolitan and rural settings and different socioeconomic populations across Queensland. Furthermore, the original EDDIE intervention was undertaken with a different aged care provider allowing for some comparison. Applying the i-PARIHS framework to collect and analyse data at an individual facility level will enable us to identify the detailed relationships between contextual factors, implementation processes and outcomes, which could inform future scaleup of EDDIE+. Future studies and process evaluations could further explore the generalisability 

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3 4	429	and applicability to other aged care facilities and directly involve residents in the feedback and		
5 6	430	evaluation of such programs.		
7 8	431	Supplementary information		
8 9 10	432	Supplementary file – example data collection tools		
11 12	433	Contributors		
13 14	434	HC, NG, XL, GH, TD, LC, CM, FO conceived of the EDDIE+ study. GH, EB and MA have led the		
15	435	development of the process evaluation. EB and GH drafted the manuscript with input from all		
16 17	436	contributing authors. All authors critically revised the manuscript and approved the final		
18 19 20	437	version.		
20 21 22	438	Competing interests		
23 24	439	None declared.		
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42 43 44	449	University of Newcastle.		
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EDDIE+ Supplementary file - examples of data collection tools

- **S1:** Family member interview guide
- S2: Stakeholder interview guide
- <text> S3: Family member or nominated advocate questionnaire
- S4: Staff self-efficacy survey (RN, EN, PCW)

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#### **S1:** Family member interview guide







# Family member interview example topic guide

The following guide is intended to be used to conduct post implementation reviews of EDDIE+.

#### **Objective:**

Identify family or nominated advocate awareness and experience of the EDDIE+ program.

#### Participants:

Interviews will be held with family members or nominated advocate of residents.

Notes – might not be one episode of care – could be multiple within the intervention period.

#### Introduction

EDDIE+ is a research project that has been introduced at *RAC home name*. The purpose of this research project is to implement and evaluate a RAC home-driven hospital avoidance program that aims to upskill, empower and provide support for nursing and care staff to detect deterioration in elderly residents early, so that they can provide care in place (at *RAC home name*), avoid residents being transferred unnecessarily to hospital, and reduce hospital length of stay if patients are admitted.

#### Questions

- How did you find your experience with this program?
- What has changed in your life because of using this program?
- What would you tell a friend/family member about the program?

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# EDDIE<sup>+</sup> Researching Early Detection of Deterioration in Elderly residents

# RAC stakeholder interview example topic guide

The following guide is intended to be used to conduct post implementation reviews of EDDIE+.

## **Objective:**

Identify factors that supported and barriers that impeded the implementation and success of the project, including factors that may be important for scale-up or adoption in other RAC homes.

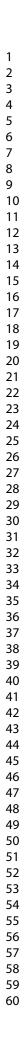
## Participants:

Interviews will be held with the following key groups as applicable:

- Nurses and carers
- Other RAC home stakeholders

The number and mix of groups will be dependent on the RAC home.

Key topic	Prompt questions
How was the intervention tailored and implemented?	<ol> <li>Can you describe how the intervention was implemented?</li> <li>Was the intervention implemented according to the implementation plan?</li> <li>Who were the key stakeholders to get on board with the intervention?</li> <li>To what extent were the needs and preferences of clients considered when deciding to implement the intervention?</li> </ol>
What about the intervention worked?	<ol> <li>What did you like about the program?</li> <li>What has been most helpful to you?</li> <li>What were implementation facilitators?</li> </ol>
What about the intervention didn't	1. What didn't you like about the program?
worked?	2. What has been least helpful to you?
What factors will be important for scale-up	1. How do you think this would work in other RAC homes?
and/or sustainability?	2. What is important for this to work in other RAC homes?
Is EDDIE+ generalisable to other RAC home settings?	1. What would need to be considered?



**S3:** Family member or nominated advocate guestionnaire







Researching Early Detection of Deterioration In Elderly residents

# Family member or nominated advocate questionnaire

This survey asks your opinions about the EDDIE+ program at Bolton Clarke and how you feel it has affected thecare your family member has received. There are no right or wrong answers to these questions.

Please circle the face that most reflects how you feels about the following statements.

1. How did you find your experience with the EDDIE+ program?







2. The EDDIE+ program impacted the care my loved one received in a good way.









# S4: Staff self-efficacy survey (RN, EN, PCW)







# Researching Early Detection of Deterioration In Elderly residents

# Nurse and carer questionnaire

This survey will ask some general questions about you, as well as some questions about your role atBolton Clarke. There are no right or wrong answers to these questions. All answers will remain confidential. Only the EDDIE+ team at the Queensland University of Technology (QUT) will see your answers.

It will take about 10 minutes to complete.

Please do NOT complete this survey if you are under 18 years of age.

We would like to ask you similar questions at the end of the EDDIE+ trial. To help us match your responses please make yourself a code. The code is unique to you and we cannot identify you in any way from this code.

Write the first 3 letters of your mother's surname?(e.g. Davis will be DAV)Write the numbers of your birth month(e.g. February is 02)

	ABOUT YOU
First, p	lease tell us a bit about yourself:
-	Ageyears
2	What best describes your gender?
Ζ.	what best describes your gender:
	Female
	Male
	Other (please specify)
	Prefer not to say
з	What best describes your work role at Bolton Clark?
5.	
	Registered nurse
	Enrolled nurse
	Personal care worker
	Other (please specify)
4.	How long have you cared for residents at Bolton Clarke? years
5.	How long have you cared for residents in a Residential Aged Care home?years
6.	What qualifications have you completed? (tick all that apply)
	□ None
	Registered nurse
	Enrolled Nurse
	Certificate III in Aged Care/Community Care, Disability or Individual Support
	CHCCS305C – Assist clients with medication
	First Aid/CPR certificate
	<ul> <li>Other certificate, not sure of name</li> <li>Other (please specify)</li> </ul>

# Job related self-efficacy

Please circle how much you agree or disagree with the following statements.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. I have confidence in my ability to do my job.	1	2	3	4	5
2. There are some tasks required by my job that I cannot do well.	1	2	3	4	5
3. When my performance is poor, it is due to my lack of ability.	1	2	3	4	5
4. I doubt my ability to do my job.	1	2	3	4	5
5. I have all the skills needed to perform my job very well.	1	2	3	4	5
6. Most people in my line of work can do this job better than I can.	1	2	3	4	5
7. I am an expert at my job.	1	2	3	4	5
8. My future in this job is limited because of my lack of skills.	1	2	3	4	5
9. I am very proud of my job skills and abilities.	1	2	3	4	5
10. I feel threatened when others watch me work.	1	2	3	4	5

# Group related self-efficacy

Please circle how much you agree or disagree with the following statements.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. The group I work with has above average ability.	1	2	3	4	5
2. This group is poor compared to other groups doing similar work.	1	2	3	4	5
3. This group is not able to perform as well as it should.	1	2	3	4	5
4. The members of this group have excellent job skills.	1	2	3	4	5
5. Some members of this group should be excluded due to lack of ability.	1	2	3	4	5
6. This group is not very effective.	1	2	3	4	5
7. Some members in this group cannot do their tasks well.	1	2	3	4	5

Thank you for completing this survey. Please return to the nurse educator or place it in the box provided.

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#### Protocol for a process evaluation of a stepped wedge randomised controlled trial to reduce unnecessary hospitalisations of older people from residential aged care: the EDDIE+ study

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Manuscript ID	bmjopen-2022-066857.R2
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Date Submitted by the Author:	30-Jan-2023
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<b>Primary Subject Heading</b> :	Geriatric medicine
Secondary Subject Heading:	Evidence based practice, Health services research, Nursing
Keywords:	Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, EDUCATION & TRAINING (see Medical Education & Training), QUALITATIVE RESEARCH



2 3									
4	1	Protocol for a process evaluation of a stepped wedge randomised controlled trial to reduce							
5 6 7	2	unnecessary hospitalisations of older people from residential aged care: the EDDIE+ study							
8 9	3	Authors							
10 11	4	Ella Bracci <sup>1</sup> , Michelle Allen <sup>2</sup> , Hannah Carter <sup>2</sup> , Liz Cyarto <sup>3</sup> , Trudy Dwyer <sup>4</sup> , Nick Graves <sup>2,5</sup> , Xing							
12 13	5	Lee <sup>3</sup> , Claudia Meyer <sup>6</sup> , Florin Oprescu <sup>7</sup> , Gill Harvey <sup>1,2</sup>							
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31 32	17	<sup>6</sup> Bolton Clarke Research Institute, Forest Hill, Victoria, Australia							
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46 47 48 49	25 26	Co-Director, Aged Care Partnering Program, Aged Care Centre for Growth and Translational Research							
50	27	College of Nursing and Health Sciences							
51 52	28	Flinders University							
53 54	29	Email: gillian.harvey@flinders.edu.au							
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35	Abstract						
36	Introduction						
37	The Early Detection of Deterioration in Elderly residents (EDDIE+) program is a theory-informed,						
38	multi-component intervention aimed at upskilling and empowering nursing and personal care						
39	staff to identify and manage early signs of deterioration in residents of aged care facilities. The						
40	intervention aims to reduce unnecessary hospital admissions from residential aged care homes.						
41	Alongside a stepped wedge randomised controlled trial, an embedded process evaluation will						
42	be conducted to assess the fidelity, acceptability, mechanisms of action and contextual barriers						
43	and enablers of the EDDIE+ intervention.						
44	Methods and Analysis						
45	Twelve residential aged care homes in Queensland, Australia are participating in the study. A						
46	comprehensive mixed methods process evaluation, informed by the integrated Promoting						
47	Action on Research Implementation in Health Services (i-PARIHS) framework, will assess						
48	intervention fidelity, contextual barriers and enablers, mechanisms of action, and the						
49							
50	collected prospectively from project documentation, including baseline context mapping of						
51	participating sites, activity tracking and regular check-in communication sheets. Qualitative						
52	data will be collected post-intervention via semi-structured interviews with a range of						
53	stakeholder groups. The i-PARIHS constructs of innovation, recipients, context, and facilitation						
54	will be applied to frame the analysis of quantitative and qualitative data.						
55	Ethics and dissemination						
56	Ethical approval for this study has been granted by the Bolton Clarke Human Research Ethics						
57	Committee (approval number: 170031) with administrative ethical approval granted by the						
58	Queensland University of Technology University Human Research Ethics Committee						
59	[2000000618]. Full ethical approval includes a waiver of consent for access to residents'						
60	demographic, clinical and health services de-identified data. A separate health services data						
61	linkage based on RAC home addresses will be sought through a Public Health Act (PHA)						

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62	application. Study findings will be disseminated through multiple channels, including journal
63	publications, conference presentations and interactive webinars with a stakeholder network.
64	Trial registration:
65	The trial is prospectively registered with the Australia New Zealand Clinical Trial Registry
66	(ACTRN12620000507987, registered 23/04/2020).
67	Strengths and limitations of this study
68	Theory-informed process evaluation, framed by the integrated-Promoting Action on
69	Research Implementation in Health Services framework and an intervention logic model.
70	Process data from a range of sources to assess implementation processes and outcomes.
71	Outcomes could help inform planning for future development and implementation of
72	hospital avoidance strategies in residential aged care facilities.
73	High staff turnover and workload within the residential aged care sector may impact staff
74	availability to participate in surveys and interviews.
75	<ul> <li>Data relating to residents' experiences will be collected from family members and</li> </ul>
76	nominated advocates, rather than directly from residents.

#### Introduction

When older adults living in Residential Aged Care (RAC) are admitted to hospital, they face increased risk of hospital associated complications and invasive interventions (1). Hospital presentations and admissions amongst this population group are relatively high and there is evidence to suggest some hospital encounters are avoidable (2). A report published by the Australian Medical Association estimated 27,000 potentially preventable admissions from RAC homes in Australia in 2021, equating to 160,000 bed days with a cost of \$312 million Australian dollars (3). RAC residents, family members and staff express a preference for care to be provided in their home where possible (4). Previous research indicates that this is possible and will reduce hospital presentations and admissions from RAC, from implementing models of care that provide access to resources and improve the clinical skills and confidence of nursing staff (5). 

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The 'Early Detection of Deterioration In Elderly residents' or 'EDDIE' program was developed in Queensland, Australia as a hospital avoidance intervention targeted at nursing and other care staff working in RAC. The aim was to empower and enable staff to identify and appropriately respond to early clinical signs of a deteriorating resident (5, 6). An initial pilot of EDDIE demonstrated that the intervention was feasible and acceptable to RAC staff, reduced hospital transfer rates and resulted in a 41 per cent reduction in total hospital bed days (7). EDDIE+ builds upon the learning from the EDDIE pilot (5, 6, 8) and aims to develop and test a scalable hospital avoidance intervention in RAC. The evaluation study involves a type 1 stepped-wedge randomized controlled effectiveness-implementation trial (9) with embedded economic and mixed methods process evaluation. Details of the trial, which involves 12 participating RAC homes in metropolitan and regional Queensland, have been described in a previously published trial protocol paper (10). This paper presents the protocol for the process evaluation component of the study. Process evaluations are increasingly recognised as an important part of developing and testing complex interventions such as EDDIE+, which comprises multiple components and is implemented across multiple sites (11,12). Process evaluations often include assessing an intervention's fidelity, namely, if the intervention was implemented as intended, the acceptability of an intervention from various stakeholder perspectives, the mechanism of impact, or what initiates a change, and an assessment of barriers and enablers to implementation. 

#### 39 108 The EDDIE+ Intervention

EDDIE+ focuses on upskilling nursing and personal care staff working within RAC, by giving them the knowledge, skills and support needed to manage sub-acute episodes such as urinary tract infections, chest pain, falls and dyspnoea within the home setting. It comprises four components: advanced clinical skills education and training (provided initially by a project-funded nurse educator), decision support tools, provision of diagnostic equipment (for example, bladder scanners and vital signs monitors) and implementation facilitation and support (via a locally appointed clinical facilitator supported by a project implementation facilitator) (6). The development of EDDIE+ was underpinned by a widely used implementation framework, the integrated Promoting Action of Research Implementation in Health Services (i-

PARIHS) framework (13). i-PARIHS proposes that the successful implementation of evidence-informed innovations results from the active facilitation of an innovation with the intended recipients of implementation within their local, organisational and system context. As such, attention to facilitation, engagement with RAC stakeholders, involvement of staff and responsiveness to context are key features of EDDIE+. By embedding implementation facilitation within the bundle of components that comprise EDDIE+, implementation is integral to the intervention. Consistent with facilitation as a primary implementation strategy, clinical facilitators can tailor the implementation of EDDIE+ according to their own home's needs. This will be achieved through the identification of core and adaptable features of each EDDIE+ component [Table 1]. Figure 1 presents a logic model summarising how EDDIE+ is expected to work and produce intended changes to processes and outcomes of care. [Figure 1 about here] è le v Methods and analysis Process evaluation While the trial component of the study focuses on intervention effectiveness, the process evaluation aims to understand how and why the intervention works in real-world contexts. This involves examining whether the intervention has been implemented as planned and resulted in expected outcomes. Understanding whether and how an intervention is affecting change can provide insights into the processes of implementation and the extent to which these account for positive or negative study outcomes. This is particularly helpful if the actual study outcomes differ from expected outcomes, enabling the study team to understand whether there has been implementation failure, such as poor delivery of the intervention, or intervention failure, such as poor or inappropriate design (14). This might inform planning of future interventions and implementation strategies. 

EDDIE+ Component	Fixed element (core)	Flexible gement (adaptable		
Advanced clinical skills education and training	Initial training mandatory for Registered Nurses, Enrolled Nurses, and Personal Care Workers	Mode of delivers		
	Training on clinical management of specific conditions identified as likely to result in hospitalisation (e.g., UTIs, chest pain, falls, delirium, dehydration, dyspnoea, palliative care, constipation)	Number and type of foonditions covered Mode of delivery Staff involved in Staff invo		
	Core set of educational materials	နိုင်ငံနိုင်ငံ Additional site-sခြင်ငံနိုင်ငံကျော်ကျော်		
Decision support tools	Core decision support tool for management of clinical deterioration across specific conditions	Number and type of conditions covered Format of tool Observation charge (egg., track & trigger Communication tool e.g., ISBAR - (Introduction, Site at on, Background Assessment, Recommendation)		
Diagnostic equipment (bladder scanner, ECG machine, vital signs monitor, oximeter)	Each home assessed for equipment needs Provision and training in use of equipment as per home requirements	Type of equipment tailored to individua home needs		
Implementation facilitation	Appointment of clinical facilitator	Role-sharing by		
and support	Train-the-trainer model for clinical facilitator	Opt-in by other ਸ਼ਿੰਦ gisttered Nurses		
	Communication channel established for discussing concerns about resident deterioration and/or need for hospital transfer	Tailored to indivie ua home needs		
Table 1: Core and adaptable com	ponents of EDDIE+ intervention	Department GEZ-LTA		

1 2									
- 3 4	145	To evaluate how and how well EDDIE+ was implemented, the process evaluation of EDDIE+ will							
5	146	follow published guidance on conducting and reporting studies with a process evaluation							
6 7	147	component (12). Consistent with the application of i-PARIHS to inform the development of							
8 9	148	EDDIE+, the process evaluation will be framed by i-PARIHS and the intervention logic model							
10 11	149	that was developed at the study design stage (Figure 1). Implementation outcomes of interest							
12 13	150	in the process evaluation include fidelity and acceptability of EDDIE+ to multiple stakeholders,							
14 15	151	the mechanisms through which EDDIE+ achieves an effect (or not), and contextual barriers and							
16 17	152	enablers of implementation.							
18 19 20	153	Aims							
21 22	154	The aim of the process evaluation is to track the implementation of EDDIE+ in the 12							
23 24	155	participating RAC homes to:							
25									
26 27	156	1. Assess EDDIE+ intervention fidelity							
28 29	157	2. Assess the acceptability of EDDIE+ from the perspective of staff, residents' family							
30 31	158	members, EDDIE+ facilitators and wider stakeholders							
32 33	159	<ol> <li>Identify the mechanisms of impact</li> <li>Identify contextual barriers and anablers of implementation</li> </ol>							
34 35	160	<ol><li>Identify contextual barriers and enablers of implementation.</li></ol>							
36 37	161	Study Design and Data Collection							
38 39	162	An embedded and formative mixed methods process evaluation will be undertaken. This will be							
40 41	163	guided by a series of templates based on i-PARIHS to assess fidelity and acceptability of EDDIE+,							
42	164	mechanisms of impact, and contextual barriers and enablers within and across the 12 regional							
43 44	165	and metropolitan homes. Data from all four intervention phases of the stepped wedge trial will							
45 46	166	be collected and analysed. These are the preparation, baseline exposure, intervention							
47 48	167	introduction and intervention exposure phases.							
49 50	168								
51 52	169	We first summarise how the theoretical propositions of the i-PARIHS framework inform the questions of interest within the process evaluation, before describing the methods of data							
53 54	105	collection and analysis (Tables 2 and 3).							
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59		<b>8</b> For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml							
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1 2 3 4 5	171								1136/bmjopen-2022-066857 o oted by convrict+ including			
6 7 8 9	172	Data Source								Data Analysis	Approach	
10	i-PARIHS	Process Evaluation	EDDIE+	Comm and	Context	Interviews	Self-	Family	e brua	Quantitative	Qualitative	
<ol> <li>11</li> <li>12</li> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>25</li> <li>26</li> <li>27</li> <li>28</li> <li>29</li> </ol>	Constructs	Component	Check in	Activity	mapping		Efficacy	advoca	ary 20			
			Form	Tracking			Surveys	Family advoca questio				
	Innovation and	Fidelity	<b>~</b>			~			nloade school	✓	✓	
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	Facilitation	Mechanisms of Impact	<b>√</b>		101		~		http://bmjope	V	<ul> <li>✓</li> </ul>	
	Context	Barriers and Enablers	~	✓	√	1	05		http://bmjopen.bmj.com/		×	
30 31											11	
32 33 34	173       Table 2. Overview of process evaluation data collection and analysis         174       April 30, yes         174       Yes											
35 36	175								2025 at I			
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40 41 42 43 44 45 46 47	177		For peer rev	view only - http:/	<b>9</b> //bmjopen.bmj	j.com/site/abou	t/guidelines.x	html	2025 at Department GEZ-LTA s			

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		1136/bmjopen-202 cted by copyright,				
Data Source	Description	Purpose	Aim*			
Communication and Activity	Conversational data, hours of training,	Provide picture of homes actors the	1, 3, 4			
Tracking	details of home, education, and	intervention period and record and r				
	training, field notes	critical time junctures				
Baseline context mapping	Description of home characteristics	Provide baseline overview og hog he,	4			
	before EDDIE+ intervention	including likely barriers and anapplers of implementation				
Check In Forms	Hours of training, EDDIE+ activities,	Describe EDDIE+ activities un describe EDDIE+ activities un describe EDDIE+ activities un describe et al activities activitities activities activities act	1, 2, 3, 4			
	general updates	and program progress over				
Semi-structured interviews	Interviews with staff, residents and	Understand stakeholder vie	2, 4			
	family members, EDDIE+ facilitators	experiences of EDDIE+				
	and external stakeholders	experiences of EDDIE+ m. from				
Self-efficacy surveys	Pre and post surveys	Determine if EDDIE+ has imaoved	3			
		efficacy and upskilled staff				
Family member or nominated	Traffic light system with three	Determine family members	2			
advocate questionnaire	questions related to the EDDIE+	advocates views on the programs and				
	program	impact 🛐 👼				
*Aims - 1: Assess the EDDIE+ interven	evaluation data sources tion fidelity; 2: Assess the acceptability and views o	f the EDDIE+ program from the permettive of staff	recident famil			
		gi ö				
	holders; 3: Identify mechanisms of impact; 4: Identi		ion success			
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#### 182 <u>i-PARIHS theoretical framing</u>

183 Innovation

According to the theoretical proposition of i-PARIHS, implementation effectiveness is enhanced 184 185 if there is support for the innovation to be implemented. The innovation in this case is EDDIE+, 186 an intervention to improve the identification and management of clinical deterioration in residents within the home setting and in turn, reduce unnecessary hospital transfers. Support is 187 more likely if key stakeholders including RAC staff, managers, residents, family members and 188 189 external care providers, agree with the idea of keeping residents at home where possible and 190 perceive implementation to be workable in practice. In relation to EDDIE+, this includes support for the education and training offered and the introduction and use of new diagnostic 191 192 equipment. Therefore, it will be important to collect stakeholder views on the acceptability, 193 relevance, and importance of EDDIE+ within the context of the RAC home setting.

7 194 Recipients

i-PARIHS proposes that recipients of an innovation (for example, staff, residents, and family
 members) need both 'want to' and 'can do' factors to achieve successful implementation (15).
 RAC staff in particular have to be motivated to address the issue of clinical deterioration in
 residents and have the capacity and capability to implement EDDIE+. These areas will be
 explored as part of the data collection.

200 Context

Contextual factors at multiple levels are identified as important barriers or enablers of 201 202 implementation in i-PARIHS and will be examined as part of the process evaluation. The inner 203 context spans the local and organisational settings. At a local level, inner context refers to the 204 immediate place of implementation - the RAC home - and encompasses factors such as the workplace culture, management and leadership support, workload, receptiveness, and 205 206 attitudes to change. The local context is embedded within the organisational context - the aged 207 care provider organisation - where factors relating to culture, leadership, support and resources are also important. Outer context relates to the wider aged care system, including policy 208 55 56 209 drivers, regulatory standards and frameworks, other initiatives that influence the care of 57

deteriorating residents, and more general health, social and economic issues that affect aged
 care. Initial mapping of contextual factors will be undertaken pre-implementation and tracked
 throughout the intervention phase of the study.

213 Facilitation

Facilitation in the i-PARIHS framework is positioned as the active ingredient of implementation, comprising facilitator roles and the use of enabling facilitation strategies. It is the facilitator's role to assess innovation, recipient and contextual factors that present barriers to or enablers of implementation and plan appropriate facilitation strategies to address these. The main facilitator role in EDDIE+ is the clinical facilitator appointed from within the RAC home to support implementation, with funding provided for backfill support. The clinical facilitator receives additional support from the EDDIE+ project team including the nurse educator and the project implementation facilitator. This is based on a model of internal-external facilitation (16). The nurse educator is responsible for developing and delivering the training on clinical deterioration and the diagnostic equipment to RAC staff, whilst the implementation facilitator will undertake the baseline context assessment and support the clinical facilitators to develop facilitation skills. As part of the process evaluation, it will be important to collect data about the different facilitator roles, the strategies used to facilitate implementation and how well these worked. 

- 38 228 Process evaluation elements
- 41 229 Fidelity

Fidelity will be evaluated in relation to the delivery of EDDIE+ as intended, namely: attendance at mandatory EDDIE+ training by nurses and personal care workers (expressed as a percentage of total staff employed who attended training), number of EDDIE+ sessions delivered/attended, use of the new equipment, and recruitment and retention of clinical facilitators. These data will be extracted from EDDIE+ check in forms completed by the nominated clinical facilitator at each site and the communication and tracking data collected from the project team, including education attendance records [see Supplementary file]. Additional data sources will be used to 

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2 3	237	determine any critical time junctures such as COVID-19 lockdowns, infection outbreaks and
4 5	238	other events that may have impacted the implementation of EDDIE+.
6	250	other events that may have impacted the implementation of EDDIE+.
7 8	239	Acceptability
9 10 11	240	Data will be collected on the acceptability of EDDIE+ from the perspective of four stakeholder
11 12	241	groups: RAC staff including Registered Nurses, Enrolled Nurses and Personal Care Workers,
13 14	242	family members or nominated advocates of residents, clinical facilitators, and local and external
15 16	243	stakeholders [see Tables 2 & 3]. Semi-structured interviews will be conducted with these
17 18	244	different groups to ascertain their views about EDDIE+. Family members and nominated
19	245	advocates will be asked about their awareness and experiences of EDDIE+ and how it impacted
20 21	246	the resident's care. RAC staff and other stakeholders will be interviewed about EDDIE+ and how
22 23	247	it was implemented to determine what they found most and least helpful about EDDIE+ and
24 25	248	whether they thought the intervention was transferable to other RAC homes [see
26 27 28 29 30 31 32	249	Supplementary files S1 and S2 for interview guides]. Additionally, a three-question traffic light
	250	survey will be distributed to family members and nominated advocates to determine if their
	251	experience with EDDIE+ was positive, negative, or neutral, if EDDIE+ impacted the care of their
	252	loved one in a good way, and their views on whether EDDIE+ should be introduced into other
33 34	253	RAC homes [see Supplementary file S3].
35 36	254	Mechanisms of impact
37 38	234	
39	255	As illustrated in the logic model in Figure 1, the EDDIE+ intervention is expected to produce
40 41	256	improvements in resident, staff, and system level outcomes through mechanisms including
42 43	257	enhanced staff knowledge and skills, increased staff confidence and sense of empowerment,
44 45	258	and greater confidence of family members and external care providers in the ability of RAC
46	259	home staff to provide appropriate clinical care for residents. These mechanisms will be
47 48	260	explored through several data sources. RAC staff will be requested to complete a self-efficacy
49 50	261	survey pre and post EDDIE+ implementation using a validated self-efficacy questionnaire (17) to
51 52	262	evaluate reported changes in staff confidence and capability [Supplementary file S4].
53 54	263	Questionnaire data will be supplemented with data from semi-structured interviews conducted
55 56	264	with RAC staff, clinical facilitators, managers, and external care providers, such as general
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265 practitioners, to assess mechanisms relating to confidence, staff empowerment and skills and
 266 knowledge development [Supplementary files S1 and S2].

#### 267 Understanding barriers and enablers

Consistent with the i-PARIHS framework, barriers and enablers to implementation will be explored in relation to the EDDIE+ intervention (acceptability and feasibility), recipient characteristics (RAC staff 'want to' and 'can do' factors) and the inner and outer context. During semi-structured interviews, RAC staff and wider stakeholders will be asked to provide specific examples of barriers and enablers of EDDIE+, what worked well (or less well) in their own RAC home and what would need to be considered for future implementation in other facilities. Supplementary information related to barriers and enablers will be extracted from the baseline context mapping, communication and activity tracking spreadsheets and check in forms completed by clinical facilitators and the nurse educator and project implementation facilitator. 

#### <sup>28</sup> 29 278 <u>S</u>

#### 8 Setting and participant recruitment for process evaluation

Twelve Bolton Clarke Residential Aged Care Facilities in Queensland, Australia have been recruited to participate in the EDDIE+ study. The stepped wedge design involved 4 phases (preparation, baseline/usual care exposure, intervention introduction and intervention exposure) that took place from March 2021 to May 2022. The process evaluation will be conducted from May to September 2022 with data from all participating homes. This will include recruitment of RAC staff, clinical facilitators, family members of residents (where applicable), and local and external stakeholders including GPs, home managers and allied health managers [see Table 2].

#### 47 287 <u>Quantitative Data</u>

Quantitative data will be extracted from baseline context mapping, communication, activity tracking and check in sheets, and resident family awareness questionnaires [see Table 2]. These data will include the hours of EDDIE+ training, days of intervention exposure, home structure (bed number, staff, occupancy), local services, and communication mechanisms. The evaluation of these data will inform intervention fidelity. 

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293 Pre and post intervention staff-efficacy surveys will be collected using a validated questionnaire 294 (17). The questionnaire comprises three sections. Section one provides information about the 295 staff member's demographics, their role at the facility, years worked at the facility, years 296 worked in aged care and their qualifications. Section two is a 5-point Likert scale with 10 297 statements related to job self-efficacy. The statements include job related confidence and ability, having the required skills to perform the job well and how they compare themselves to 298 299 others in the field. Section three is a 5-point Likert scale with 7 statements related to team selfefficacy. Section three has questions related to team members' skills, abilities, and 300 effectiveness in relation to completing their own tasks and functioning as a team. 301

#### 302 <u>Qualitative Data</u>

Qualitative data will be primarily collected from a series of semi-structured interviews with 303 304 staff, family members and advocates of residents, EDDIE+ clinical facilitators, the nurse 305 educator, project implementation facilitator and external stakeholders. Interviewees will be recruited by email and direct correspondence. Staff at participating RAC sites will be invited to 306 participate in an interview by the project implementation facilitator during one of the end of 307 308 intervention site visits. Relevant family members and stakeholders from the participating RAC 309 homes will be identified by the EDDIE+ facilitator and BC investigators and details forwarded to the QUT project team. The QUT project team will then make contact through email 310 311 correspondence. Once written consent is obtained, interviewee details will be passed on 312 through email to investigators leading the process evaluation (EB and GH) who will coordinate a mutual time for the interview. 313

Participation will be voluntary and informed consent will be obtained prior to the conduct of
the interview. Additional qualitative data will be extracted from communication tracking field
notes, baseline context assessments and check in forms where relevant. These data will address
multiple aims of the process evaluation such as the acceptability of EDDIE+, contextual barriers
and enablers, and the mechanisms of action (Table 2).

319 Staff, Local and External Stakeholder interviews

At intervention completion the RAC staff, including those in managerial positions, and external stakeholders such as GPs and allied health providers, will be invited to participate in semi-structured interviews. Interviews will be up to 30 minutes in length and completed via telephone or Microsoft Teams. Topics to be covered during the interview include feasibility of implementation, adaptation and tailoring of EDDIE+, what worked and did not work, and factors to consider for sustainability and future scale up of EDDIE+ in other RAC homes [see Supplementary file]. Additionally, an open-ended interview will be conducted with the nurse educator and project implementation facilitator after the completion of the trial to ascertain their reflections and experience of the EDDIE+ intervention and implementation process. Family and nominated advocate interviews At intervention completion, family members and nominated advocates of residents, including those who have and those who have not experienced clinical deterioration, will be invited to participate in a short interview either via telephone or using Microsoft Teams. Interviews with family members and advocates are anticipated to take around 15 minutes dependent upon interviewee responses and knowledge of the program. Questions will explore their awareness and experience of EDDIE+. All interviewees who have signed the consent form and completed an interview will be allocated a unique identifier to maintain confidentiality. No identifiable information will be reported in the findings from these interviews. Interviews will take place up to four months post-trial with a maximum of 30 interviews per stakeholder group across the 12 sites. Data Analysis Quantitative Data Descriptive statistics related to the process evaluation (counts, mean, standard deviations) will be analysed in Microsoft Excel to determine the communication level and engagement from each site based on the quantity of emails, meetings, and phone calls. Job-related and team-related self-efficacy data from nursing and personal care workers will be subject to descriptive 

and inferential analysis using SPSS to assess whether EDDIE+ improved staff's perceived self-

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efficacy post-intervention. The baseline self-efficacy survey will be completed immediately prior
to the participant's (RN, EN, PCW) first EDDIE+ training session while post intervention selfefficacy surveys will be provided to staff between the final two weeks of the intervention
exposure and up to two weeks post trial.

351 Internal consistency of job-related and team-related self-efficacy will be assessed separately using Cronbach's Alpha. Differences between mean baseline and post intervention scores on 352 the self-efficacy measures will be assessed using t-tests, to determine if there is a statistically 353 significant (p < .05) change in job-related self-efficacy and team-related self-efficacy. Linear 354 regression will be used to determine the contribution of staff-related factors including role, 355 356 experience, age, gender, and location, to changes in job-related and team-related self-efficacy scores. Missing outcome data from staff lost to follow-up will be treated as missing completely 357 358 at random (MCAR) and handled using complete case analysis.

#### 359 Qualitative Data

360 Semi-structured Interviews will be digitally recorded with consent from the interviewee and transcribed using Microsoft software. Once transcribed and checked for accuracy, interview 361 transcripts will be mapped against the i-PARIHS constructs of innovation, recipients, context, 362 and facilitation using NVivo qualitative data software. Additionally, qualitative data will be 363 364 extracted from the baseline context mapping as well as communication, activity tracking and 365 check in forms where appropriate and mapped to the i-PARIHS framework. Data that do not align with the i-PARIHS framework will be analysed using a descriptive qualitative approach 366 367 (18). Transcripts will be read by two members of the project team with qualitative research experience and content analysis will be used to code data, group codes into categories and 368 369 identify major themes (19). The analysis will be complete once agreement between researchers 370 is attained and no new themes emerge.

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<sup>1</sup> 371 Integrating results of data analysis

372 Process evaluation data analysis will be undertaken independently of the analysis of the
 373 effectiveness data from the trial. Once the trial results are available, combined analysis will be

3 4	374	undertaken to determine the extent to which the process evaluation helps explain the main
5 6	375	trial findings.
7 8 9	376	Patient and public involvement
9 10 11	377	There is no planned resident or public involvement in the design of the process evaluation due
12	378	to the Covid-19 pandemic and restricted access to residential aged care settings. Whilst
13 14	379	recognising this as a potential limitation to the study, family members and nominated
15 16	380	advocates of residents will be invited to participate in interviews and surveys as part of the
17 18 19	381	process evaluation.
20 21	382	Ethics and dissemination
22 23	383	Ethical approval for this study has been granted by the Bolton Clarke Human Research Ethics
24	384	Committee (approval number: 170031) with administrative ethical approval granted by the
25 26	385	Queensland University of Technology University Human Research Ethics Committee
27 28	386	[2000000618]. Full ethical approval includes a waiver of consent for access to residents'
29 30	387	demographic, clinical and health services de-identified data. A separate health services data
31 32	388	linkage based on RAC home addresses will be sought through a Public Health Act (PHA)
33 34	389	application. Group or individual interviews will require written consent prior to
35	390	commencement. Protocol amendments will be submitted as variations to the approving ethics
36 37	391	committees at time of identification. Additionally, the project manager will notify committees
38 39	392	in the circumstance of protocol deviations and adverse events in accordance with local
40 41 42	393	procedures.
43	394	Study findings will be disseminated through traditional academic channels, such as journal
44 45	395	publications and conference presentations, alongside more interactive strategies, including
46 47	396	engagement with a stakeholder network established to embed knowledge translation within
48 49 50	397	the research.
51 52	398	Discussion
53 54	399	Early detection and management of deterioration in residents of aged care homes could result
55 56 57	400	in a decrease of avoidable and unnecessary hospital transfers. The original EDDIE program was
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considered feasible, well received, and reduced total hospital bed days by 41% (6, 7). However, these promising results were inferred using a relatively small sample size and a pre-post design that did not control for external trends. Following the success of EDDIE in a single site, a modified version of the pilot (EDDIE+) was developed. A stepped wedge randomised controlled trial involving 12 RAC homes will evaluate the effectiveness and cost-consequences of EDDIE+ with the aim of confirming preliminary findings and strengthening the evidence base for wider implementation. The embedded process evaluation will explore whether the scaled-up intervention was delivered and implemented as originally proposed, if EDDIE+ was acceptable from the perspective of various stakeholders, the mechanisms of impact through which EDDIE+ improved outcomes (or not), and contextual barriers and enablers that may have influenced implementation. A mixed method, theory-informed approach will provide an in-depth evaluation of the EDDIE+ program and valuable insights into determinants of implementation success across multiple sites. This could help to identify key factors to consider in the future development and implementation of hospital avoidance programs such as EDDIE+. 

#### 415 Limitations

416 Direct resident involvement in the evaluation of EDDIE+ would strengthen the process
 417 evaluation, however, this is not achievable during a pandemic that has led to strict visitor
 418 lockdowns in RAC. As an alternative strategy, data to reflect residents' experiences will be
 419 collected from family members and nominated advocates.

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Another potential limitation is that EDDIE+ is being implemented and evaluated with a single aged care provider in Queensland which could compromise transferability to other aged care settings and providers. However, the RAC facilities involved in EDDIE+ represent a range of metropolitan and rural settings and different socioeconomic populations across Queensland. Furthermore, the original EDDIE intervention was undertaken with a different aged care provider allowing for some comparison. Applying the i-PARIHS framework to collect and analyse data at an individual facility level will enable us to identify the detailed relationships between contextual factors, implementation processes and outcomes, which could inform future scaleup of EDDIE+. Future studies and process evaluations could further explore the generalisability 

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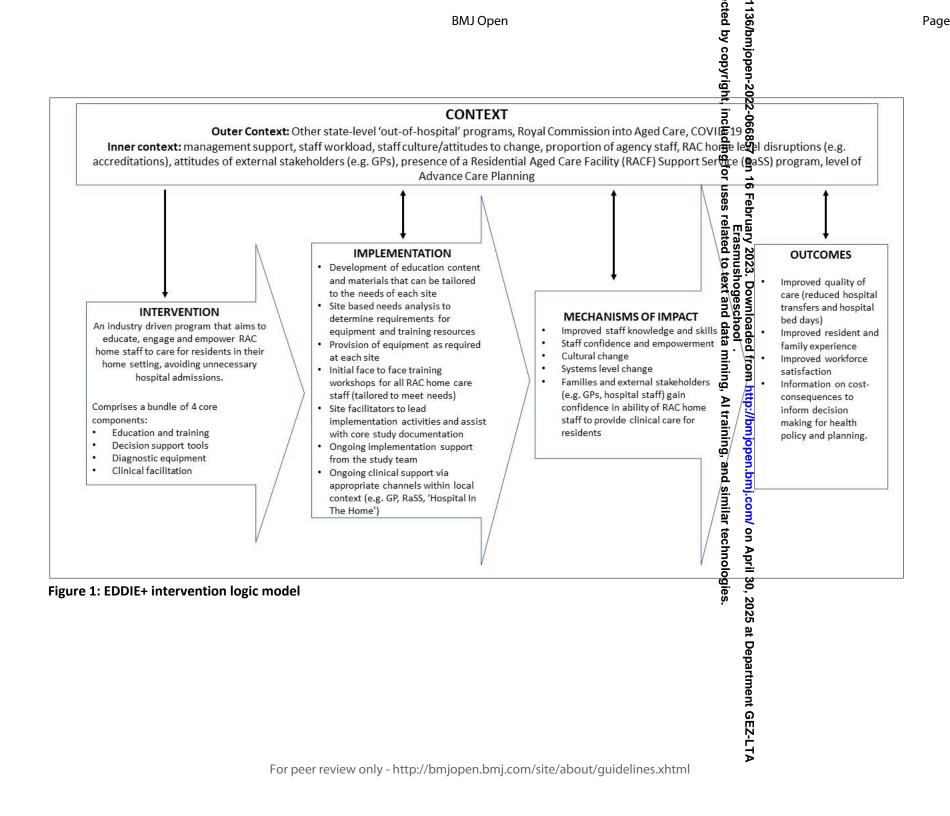
3 4	429	and applicability to other aged care facilities and directly involve residents in the feedback and
5 6	430	evaluation of such programs.
7 8	431	Supplementary information
8 9 10	432	Supplementary file – example data collection tools
11 12	433	Contributors
13 14	434	HC, NG, XL, GH, TD, LC, CM, FO conceived of the EDDIE+ study. GH, EB and MA have led the
15	435	development of the process evaluation. EB and GH drafted the manuscript with input from all
16 17	436	contributing authors. All authors critically revised the manuscript and approved the final
18 19 20	437	version.
20 21 22	438	Competing interests
23 24	439	None declared.
25 26	440	Funding
27 28	441	This project is funded by a National Health and Medical Research Council Medical Research
29 30	442	Future Fund grant (GNT1177501) and led by Queensland University of Technology. The funding
31 32	443	body did not have a role in the study design and subsequent protocol paper, nor are the
33 34	444	funders involved with ongoing data collection, management, analysis, and interpretation.
35 36	445	Acknowledgements
37 38	446	A collaborative research agreement is established between QUT and partnering institutions. We
39	447	thank the following partnering institutions: Flinders University, Central Queensland University,
40 41	448	Bolton Clarke, University of the Sunshine Coast, Metro North Hospital and Health Service and
42 43 44	449	University of Newcastle.
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EDDIE+ Supplementary file - examples of data collection tools

- **S1:** Family member interview guide
- S2: Stakeholder interview guide
- <text> S3: Family member or nominated advocate questionnaire
- S4: Staff self-efficacy survey (RN, EN, PCW)

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#### **S1:** Family member interview guide







## Family member interview example topic guide

The following guide is intended to be used to conduct post implementation reviews of EDDIE+.

#### **Objective:**

Identify family or nominated advocate awareness and experience of the EDDIE+ program.

#### Participants:

Interviews will be held with family members or nominated advocate of residents.

Notes – might not be one episode of care – could be multiple within the intervention period.

#### Introduction

EDDIE+ is a research project that has been introduced at *RAC home name*. The purpose of this research project is to implement and evaluate a RAC home-driven hospital avoidance program that aims to upskill, empower and provide support for nursing and care staff to detect deterioration in elderly residents early, so that they can provide care in place (at *RAC home name*), avoid residents being transferred unnecessarily to hospital, and reduce hospital length of stay if patients are admitted.

#### Questions

- How did you find your experience with this program?
- What has changed in your life because of using this program?
- What would you tell a friend/family member about the program?

# EDDIE Researching Early Detection of Deterioration in Elderly residents

## RAC stakeholder interview example topic guide

The following guide is intended to be used to conduct post implementation reviews of EDDIE+.

#### **Objective:**

Identify factors that supported and barriers that impeded the implementation and success of the project, including factors that may be important for scale-up or adoption in other RAC homes.

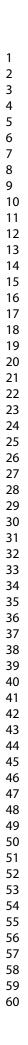
#### **Participants:**

Interviews will be held with the following key groups as applicable:

- Nurses and carers
- Other RAC home stakeholders

The number and mix of groups will be dependent on the RAC home.

Key topic	Prompt questions
How was the intervention tailored and implemented?	<ol> <li>Can you describe how the intervention was implemented?</li> <li>Was the intervention implemented according to the implementation plan?</li> <li>Who were the key stakeholders to get on board with the intervention?</li> <li>To what extent were the needs and preferences of clients considered when deciding to implement the intervention?</li> </ol>
What about the intervention worked?	<ol> <li>What did you like about the program?</li> <li>What has been most helpful to you?</li> <li>What were implementation facilitators?</li> </ol>
What about the intervention didn't	1. What didn't you like about the program?
worked?	2. What has been least helpful to you?
What factors will be important for scale-up	1. How do you think this would work in other RAC homes?
and/or sustainability?	2. What is important for this to work in other RAC homes?
Is EDDIE+ generalisable to other RAC home settings?	1. What would need to be considered?



**S3:** Family member or nominated advocate guestionnaire







Researching Early Detection of Deterioration In Elderly residents

# Family member or nominated advocate questionnaire

This survey asks your opinions about the EDDIE+ program at Bolton Clarke and how you feel it has affected thecare your family member has received. There are no right or wrong answers to these questions.

Please circle the face that most reflects how you feels about the following statements.

1. How did you find your experience with the EDDIE+ program?







2. The EDDIE+ program impacted the care my loved one received in a good way.









## S4: Staff self-efficacy survey (RN, EN, PCW)







# Researching Early Detection of Deterioration In Elderly residents

# Nurse and carer questionnaire

This survey will ask some general questions about you, as well as some questions about your role atBolton Clarke. There are no right or wrong answers to these questions. All answers will remain confidential. Only the EDDIE+ team at the Queensland University of Technology (QUT) will see your answers.

It will take about 10 minutes to complete.

Please do NOT complete this survey if you are under 18 years of age.

We would like to ask you similar questions at the end of the EDDIE+ trial. To help us match your responses please make yourself a code. The code is unique to you and we cannot identify you in any way from this code.

Write the first 3 letters of your mother's surname?(e.g. Davis will be DAV)Write the numbers of your birth month(e.g. February is 02)

	ABOUT YOU
irst, p	lease tell us a bit about yourself:
1.	Ageyears
2.	What best describes your gender?
	Female
	Male
	Other (please specify)
	Prefer not to say
3.	What best describes your work role at Bolton Clark?
	Registered nurse
	Enrolled nurse
	Personal care worker
	Other (please specify)
4.	How long have you cared for residents at Bolton Clarke? years
5.	How long have you cared for residents in a Residential Aged Care home?years
6.	What qualifications have you completed? (tick all that apply)
	□ None
	Registered nurse
	Enrolled Nurse
	$\Box$ Certificate III in Aged Care/Community Care, Disability or Individual Support
	CHCCS305C – Assist clients with medication
	First Aid/CPR certificate
	Other certificate, not sure of name
	Other (please specify)

# Job related self-efficacy

Please circle how much you agree or disagree with the following statements.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. I have confidence in my ability to do my job.	1	2	3	4	5
2. There are some tasks required by my job that I cannot do well.	1	2	3	4	5
3. When my performance is poor, it is due to my lack of ability.	1	2	3	4	5
4. I doubt my ability to do my job.	1	2	3	4	5
5. I have all the skills needed to perform my job very well.	1	2	3	4	5
6. Most people in my line of work can do this job better than I can.	1	2	3	4	5
7. I am an expert at my job.	1	2	3	4	5
8. My future in this job is limited because of my lack of skills.	1	2	3	4	5
9. I am very proud of my job skills and abilities.	1	2	3	4	5
10. I feel threatened when others watch me work.	1	2	3	4	5

# Group related self-efficacy

Please circle how much you agree or disagree with the following statements.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. The group I work with has above average ability.	1	2	3	4	5
2. This group is poor compared to other groups doing similar work.	1	2	3	4	5
3. This group is not able to perform as well as it should.	1	2	3	4	5
4. The members of this group have excellent job skills.	1	2	3	4	5
5. Some members of this group should be excluded due to lack of ability.	1	2	3	4	5
6. This group is not very effective.	1	2	3	4	5
7. Some members in this group cannot do their tasks well.	1	2	3	4	5

Thank you for completing this survey. Please return to the nurse educator or place it in the box provided.

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